16.2.6 Individual Efficacy Response Data

Listing 16.2.6.1a
Overall Survival

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [3]	Date of Death	Duration of Overall Survival (Months) [4]	If Censored, Reason	Date of Last Telephone Contact
101-0001/59/M/A2	26JUL2011	20FEB2012			7+	Voluntary Withdrawal	20FEB2012
101-0005/77/M/W2	08AUG2011	17APR2013	3	17APR2013	20.6		17APR2013
101-0006/62/M/W2	12AUG2011	17APR2012	3	17APR2012	8.3		17APR2012
101-0007/77/M/A1	16AUG2011	11MAY2013	3	11MAY2013	21.2		16MAY2013
101-0008/83/M/BL	22AUG2011	11AUG2012	3	11AUG2012	11.9		11AUG2012
101-0009/82/M/A1	14SEP2011	05SEP2012	3	05SEP2012	11.9		05SEP2012
101-0011/75/F/W2	14NOV2011	03JAN2012	3	16DEC2011	1.1		03JAN2012
101-0012/68/M/W2	29NOV2011	20AUG2012	3	02AUG2012	8.3		20AUG2012
101-0013/66/F/A5	10JAN2012	17JUL2014	3	14JUL2014	30.6		17JUL2014

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Use the date of death for the 487th subject as the cutoff date(24Mar2015), if the subject died after the cutoff date, they will be event in the sensitivity analysis. Censored records are indicated with ‘+’. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.

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Overall Survival

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101-0016/61/M/A4	10JAN2012				41.8+	Follow-up visit	16JUN2015
101-0018/51/M/A1	21FEB2012	31MAR2012	3	31MAR2012	1.3		12FEB2013
101-0019/68/M/W2	28FEB2012	14MAY2013	5	20MAR2014	25.1		20MAR2014
101-0021/74/M/W2	20MAR2012	10JUN2013	3	10JUN2013	14.9		17JUL2013
101-0022/55/M/BL	20MAR2012	04JUN2012	3	31MAY2012	2.4		04JUN2012
101-0023/70/M/W2	30MAR2012	18DEC2012	5	18DEC2012	8.8		18DEC2012
101-0024/35/F/A4	01MAY2012	07NOV2013	3	05NOV2013	18.5		07NOV2013
101-0025/57/F/W2	20APR2012	03AUG2012	3	03AUG2012	3.5		03AUG2012
101-0026/82/M/W2	15MAY2012	17MAY2013	3	16MAY2013	12.2		17MAY2013

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Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [3]	Date of Death	Duration of Overall Survival (Months) [4]	If Censored, Reason	Date of Last Telephone Contact
101-0028/60/M/W2	15JUN2012	02APR2013	3	02APR2013	9.7		25APR2013
101-0029/70/M/A1	18JUN2012	02AUG2013	3	02AUG2013	13.7		02AUG2013
101-0030/51/M/W2	05JUL2012	27NOV2012	3	20DEC2012	5.6		20DEC2012
101-0032/84/M/W2	01AUG2012	12SEP2013	5	06JUL2013	11.3		12SEP2013
101-0033/66/F/W2	03AUG2012				35.2+	Follow-up visit	25JUN2015
101-0036/68/M/A4	23OCT2012	05FEB2013	3	05FEB2013	3.5		05FEB2013
101-0037/57/M/A1	07DEC2012	06APR2015			28.4+	Lost to Follow-up	01DEC2014
101-0038/56/M/W2	05FEB2013	01FEB2014	3	01FEB2014	12.1		01FEB2014

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101-0039/77/F/W2	05APR2013				27.1+	Follow-up visit	26JUN2015
101-0040/60/M/W2	27JUN2013	04NOV2013	3	03NOV2013	4.3		04NOV2013
101-0041/54/M/W2	30JUL2013	25NOV2014	3	24NOV2014	16.1		25NOV2014
101-0042/64/M/W2	05AUG2013	12OCT2014	3	12OCT2014	14.5		12OCT2014
101-0044/78/M/W2	17OCT2013	24OCT2014	5	24OCT2014	12.4		24OCT2014
101-0045/74/F/W2	21OCT2013	03JUN2014	5	26APR2014	6.3		03JUN2014
101-0046/70/M/OTH	22OCT2013	04JUN2014	3	28MAR2014	5.3		04JUN2014
101-0047/52/M/W2	22OCT2013	11MAR2015	3	26FEB2015	16.4		01DEC2014
101-0048/66/F/W2	22OCT2013				20.4+	Follow-up visit	25JUN2015

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101-0049/71/M/A8	28OCT2013				20.2+	Follow-up visit	24JUN2015
101-0050/59/M/W2	29OCT2013	15JAN2014	3	15JAN2014	2.6		
102-0001/53/M/BL	25APR2012	07SEP2012	3	09NOV2012	6.6		07SEP2012
102-0003/63/M/BL	12SEP2012	07JAN2013	3	25JAN2013	4.5		07FEB2013
102-0008/64/M/BL	08JAN2014	05FEB2014	5	10FEB2014	1.1		
102-0009/58/M/W2	29OCT2014	19FEB2015	3	04FEB2015	3.3		19FEB2015
103-0001/56/M/W2	11MAY2012	23OCT2012	3	23OCT2012	5.5		23OCT2012
103-0003/66/M/W2	15FEB2013	26OCT2013	3	26OCT2013	8.5		26OCT2013
103-0004/40/F/A1	17APR2014	01SEP2014	3	01SEP2014	4.6		01SEP2014

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104-0003/56/F/W2	19JUL2012	29OCT2012	3	19OCT2012	3.1		29OCT2012
104-0004/74/M/W2	23OCT2012	12JUN2013	3	24MAY2013	7.1		12JUN2013
104-0008/55/M/PI	03SEP2013	14OCT2014	3	11SEP2014	12.5		14OCT2014
104-0010/71/F/A8	08JAN2014				17.1+	Follow-up visit	03JUN2015
104-0012/78/F/A2	02OCT2014	25MAR2015	3	25MAR2015	5.8+	Deaths after the date of the 487th event	25MAR2015
106-0001/42/F/W2	28FEB2012	02JUL2012	3	05OCT2012	7.4		
107-0002/71/M/W2	23AUG2012	23DEC2013	3	23DEC2013	16.3		23DEC2013

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107-0003/73/M/BL	22FEB2013	07MAY2013	3	07MAY2013	2.5		
107-0004/63/M/W2	01MAR2013				28.4+	Follow-up visit	29JUN2015
107-0006/60/M/W2	14MAY2013	07APR2014	3	04APR2014	10.9		07APR2014
108-0001/60/F/W2	20MAR2012	19JUN2012	3	19JUN2012	3.1		19JUN2012
108-0002/78/M/BL	31MAY2012	03APR2013	3	03APR2013	10.3		03APR2013
108-0004/61/M/W2	18APR2013	07JUL2014	3	22JUL2014	15.4		04AUG2014
108-0005/68/M/W2	08MAY2013	19OCT2013	99: Basilar artery pseudoaneurysm	19OCT2013	5.5		19OCT2013
108-0008/77/M/W2	09OCT2014				8+	Follow-up visit	04JUN2015

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109-0003/68/M/W2	03MAY2013	08AUG2013	3	09AUG2013	3.3		17SEP2013
109-0004/57/M/W2	19JUL2013	14MAR2014	3	22FEB2014	7.3		14MAR2014
109-0006/62/M/PI	22AUG2013	16SEP2014	3	25AUG2014	12.3		16SEP2014
109-0007/55/M/W2	05DEC2013	16SEP2014	3	10AUG2014	8.3		16SEP2014
109-0008/70/F/W2	22MAY2014				12.7+	Follow-up visit	05JUN2015
109-0009/57/M/W2	09JUL2014	10JUN2015	3	25MAY2015	10.7+	Deaths after the date of the 487th event	10JUN2015
109-0010/65/M/W2	09JUL2014				11.5+	Follow-up visit	18JUN2015

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109-0011/64/M/A4	24SEP2014				8.7+	Follow-up visit	12JUN2015
109-0013/64/F/W2	05NOV2014	12MAY2015	3	10MAY2015	6.2+	Deaths after the date of the 487th event	
110-0003/63/M/OTH	09JUL2012	07DEC2013	3	01DEC2013	17.0		07DEC2013
110-0004/53/M/A4	25OCT2012	03DEC2013	3	23NOV2013	13.2		03DEC2013
110-0005/77/M/W2	15MAR2013				27.3+	Follow-up visit	11JUN2015
110-0007/62/M/A4	17MAY2013	26FEB2014	3	26FEB2014	9.5		07MAR2014
110-0008/63/F/BL	09JUL2013	03MAR2014	3	10FEB2014	7.2		03MAR2014

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110-0011/77/M/A1	22JAN2015				4.6+	Follow-up visit	09JUN2015
111-0001/37/M/A4	12JUL2012	08JUL2014	3	06JUL2014	24.2		08JUL2014
111-0004/64/M/W2	23MAY2013	18OCT2013	3	29AUG2013	3.3		21OCT2013
111-0006/59/M/W2	03OCT2013	12MAY2014	2	12MAY2014	7.4		
111-0007/55/M/W2	06FEB2014				16.4+	Follow-up visit	12JUN2015
112-0006/58/M/W2	26MAR2013	29AUG2013	3	29AUG2013	5.2		07AUG2013
112-0009/50/M/A8	19JUN2013	06DEC2013	3	12DEC2013	5.9		01NOV2013
112-0011/56/M/A4	10JAN2014	23JUN2014	3	28JUN2014	5.7		06JUN2014
112-0012/71/M/W2	23MAY2014	07FEB2015	3	07FEB2015	8.7		02FEB2015

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[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Use the date of death for the 487th subject as the cutoff date(24Mar2015), if the subject died after the cutoff date, they will be event in the sensitivity analysis. Censored records are indicated with ‘+’. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.

Listing 16.2.6.1a
Overall Survival

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [3]	Date of Death	Duration of Overall Survival (Months) [4]	If Censored, Reason	Date of Last Telephone Contact
112-0013/28/F/W2	23MAY2014	29AUG2014	3	29OCT2014	5.3		
112-0014/79/M/A8	06JUN2014	24OCT2014	3	24OCT2014	4.7		13OCT2014
112-0015/66/M/A8	24OCT2014	02JAN2015	3	02JAN2015	2.4		
113-0001/61/M/W2	24AUG2012	18NOV2013	5	20JAN2014	17.2		26AUG2013
113-0002/64/F/W2	12OCT2012	22APR2014	3	11APR2014	18.2		22APR2014
113-0005/58/M/W2	22JAN2014	20MAR2014	3	05APR2014	2.5		30APR2014
113-0008/78/M/A8	13FEB2014				16.3+	Follow-up visit	16JUN2015
113-0010/59/M/W2	28APR2014	04JUN2014	3	22JUN2014	1.9		07JUL2014
113-0013/56/M/W2	04NOV2014				7.3+	Follow-up visit	10JUN2015

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Use the date of death for the 487th subject as the cutoff date(24Mar2015), if the subject died after the cutoff date, they will be event in the sensitivity analysis. Censored records are indicated with ‘+’. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.

Listing 16.2.6.1a
Overall Survival

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [3]	Date of Death	Duration of Overall Survival (Months) [4]	If Censored, Reason	Date of Last Telephone Contact
113-0016/72/M/A8	03FEB2015				4.5+	Follow-up visit	17JUN2015
114-0003/59/M/W2	29NOV2012	07OCT2013	3	07OCT2013	10.4		16SEP2013
114-0005/73/M/W2	05DEC2013	09APR2015			16.4+	Voluntary Withdrawal	09APR2015
114-0007/60/F/W2	18NOV2014				8.2+	Ongoing	
115-0001/59/F/A4	27NOV2012				30.6+	Follow-up visit	02JUN2015
115-0002/45/F/W2	27NOV2012	19FEB2013	3	18FEB2013	2.8		19FEB2013
115-0003/63/M/W2	17JAN2013	20AUG2013	3	17AUG2013	7.1		20AUG2013
115-0008/51/M/A8	19JUN2013	22JUL2013	3	17JUL2013	1.0		

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[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Use the date of death for the 487th subject as the cutoff date(24Mar2015), if the subject died after the cutoff date, they will be event in the sensitivity analysis. Censored records are indicated with ‘+’. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.

Listing 16.2.6.1a
Overall Survival

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [3]	Date of Death	Duration of Overall Survival (Months) [4]	If Censored, Reason	Date of Last Telephone Contact
115-0009/85/M/W2	12DEC2013	03SEP2014	3	01SEP2014	8.8		03SEP2014
115-0011/56/M/W2	05JUN2014	01DEC2014	3	27NOV2014	5.9		01DEC2014
115-0014/72/M/W2	10FEB2015	11MAY2015	3	10MAY2015	3+	Deaths after the date of the 487th event	11MAY2015
116-0002/67/F/W2	18MAR2013	14DEC2013	3	14DEC2013	9.1		
116-0003/67/M/BL	28MAR2013	29MAY2013	3	29MAY2013	2.1		
117-0001/69/M/W2	02APR2013	12NOV2014	5	08NOV2014	19.5		12NOV2014
118-0001/67/F/A8	09AUG2013	29NOV2014	3	29NOV2014	15.9		17NOV2014
119-0001/80/M/A8	21JAN2014	14FEB2014	5	AUG2014	0.8		29AUG2014

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
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Listing 16.2.6.1a
Overall Survival

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [3]	Date of Death	Duration of Overall Survival (Months) [4]	If Censored, Reason	Date of Last Telephone Contact
121-0001/62/M/W2	14FEB2014	02DEC2014			9.7+	Voluntary Withdrawal	02DEC2014
121-0004/64/F/W2	02JAN2015	15APR2015	3	06MAR2015	2.1		15APR2015
201-0001/68/F/W2	25JAN2012	08OCT2012	99: Cardiac arrest	24SEP2012	8.1		08OCT2012
201-0005/73/M/W2	19JUL2012	21JAN2013	99: Cardiac arrest	14JAN2013	6.0		21JAN2013
201-0008/79/M/W2	16MAY2013	21OCT2013	3	15OCT2013	5.1		21OCT2013
201-0011/73/M/W2	04JUL2013				23.9+	Follow-up visit	19JUN2015
201-0012/79/M/W2	24JUL2013				23.2+	Follow-up visit	19JUN2015
201-0013/67/F/W2	24JUL2013	20MAY2014	99: Cardiac arrest	19MAY2014	10.0		20MAY2014

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Use the date of death for the 487th subject as the cutoff date(24Mar2015), if the subject died after the cutoff date, they will be event in the sensitivity analysis. Censored records are indicated with ‘+’. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.

Listing 16.2.6.1a
Overall Survival

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [3]	Date of Death	Duration of Overall Survival (Months) [4]	If Censored, Reason	Date of Last Telephone Contact
201-0016/72/M/W2	14NOV2013	19MAY2015	99: Cardiocirculatory arrest	30APR2015	17.8+	Deaths after the date of the 487th event	19MAY2015
201-0017/82/M/W2	28NOV2013	26MAR2015	99: Cardiac arrest	05MAR2015	15.4		26MAR2015
201-0018/78/F/W2	06DEC2013	27JAN2014	99: Acute renal failure	21JAN2014	1.6		27JAN2014
201-0019/68/M/W2	19DEC2013				18.3+	Follow-up visit	19JUN2015
201-0020/67/M/W2	23JAN2014				17.2+	Follow-up visit	22JUN2015
201-0021/54/M/W2	13FEB2014	02JUL2014	99: Block of diuresis	10JUN2014	3.9		02JUL2014

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[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
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Listing 16.2.6.1a
Overall Survival

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [3]	Date of Death	Duration of Overall Survival (Months) [4]	If Censored, Reason	Date of Last Telephone Contact
201-0024/74/M/W2	29JAN2015	13APR2015	99: Respiratory failure	11APR2015	2.4+	Deaths after the date of the 487th event	
201-0025/75/M/W2	29JAN2015				4.7+	Follow-up visit	19JUN2015
203-0001/61/F/W2	06MAR2012	30APR2012	3	06JUN2012	3.1		
203-0002/72/M/W2	06MAR2012	19APR2012	3	19APR2012	1.5		
203-0005/53/M/W2	05APR2012	23DEC2014	3	26JUN2013	14.9		03JUL2013
203-0013/68/M/W2	30DEC2013	30APR2014	3	17MAR2014	2.6		30APR2014
203-0015/85/M/W2	30JAN2014	19SEP2014	3	01JUN2014	4.1		19SEP2014

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
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Listing 16.2.6.1a
Overall Survival

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [3]	Date of Death	Duration of Overall Survival (Months) [4]	If Censored, Reason	Date of Last Telephone Contact
203-0017/58/M/W2	03MAR2014	29AUG2014	3	29AUG2014	6.0		29AUG2014
203-0018/58/F/W2	04APR2014	22SEP2014	3	24JUL2014	3.7		22SEP2014
205-0001/77/M/W2	24FEB2012	26NOV2014	3	06NOV2014	32.9		26NOV2014
205-0004/77/F/W2	20MAR2012	24JUN2012	3	24JUN2012	3.2		
205-0008/76/M/W2	27APR2012	30JUL2012	3	30JUL2012	3.2		01AUG2012
205-0012/73/F/W2	06DEC2012	08JAN2013	2	08JAN2013	1.1		
205-0015/71/M/W2	19JUN2013	11SEP2014	5	22JUN2014	12.3		11SEP2014
205-0016/70/M/W2	25JUN2013				25.3+	Ongoing	
205-0017/71/M/W2	08AUG2013	18AUG2014	3	18AUG2014	12.5		18AUG2014
205-0020/82/M/W2	11OCT2013	24JUN2015	5	18MAY2014	7.3		24JUN2015

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Use the date of death for the 487th subject as the cutoff date(24Mar2015), if the subject died after the cutoff date, they will be event in the sensitivity analysis. Censored records are indicated with ‘+’. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.

Listing 16.2.6.1a
Overall Survival

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [3]	Date of Death	Duration of Overall Survival (Months) [4]	If Censored, Reason	Date of Last Telephone Contact
205-0022/67/M/W2	05NOV2013	28NOV2013	2	22NOV2013	0.6		28NOV2013
205-0024/80/M/W2	03DEC2013	20AUG2014	99: Bleeding in hypertensive gastropathy	16AUG2014	8.6		20AUG2014
205-0025/63/F/W2	29NOV2013	21MAR2014	99: Pleural effusion	21MAR2014	3.8		11MAR2014
207-0001/81/F/W2	19MAR2012	21DEC2012	3	23OCT2012	7.3		21DEC2012
207-0005/74/M/W2	12JUN2012	04JUL2012			0.8+	Voluntary Withdrawal	
207-0006/73/M/W2	18JUN2012	19SEP2012	3	03OCT2012	3.6		14NOV2012
207-0008/66/M/W2	09JUL2012	13AUG2012	3	28AUG2012	1.7		
207-0011/78/M/W2	21JAN2013	26FEB2013	3	06MAR2013	1.5		26FEB2013

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
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Listing 16.2.6.1a
Overall Survival

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [3]	Date of Death	Duration of Overall Survival (Months) [4]	If Censored, Reason	Date of Last Telephone Contact
207-0015/77/M/W2	13AUG2013	16OCT2014	3	02OCT2014	13.9		16OCT2014
207-0020/77/M/W2	18JUN2014	29SEP2014	3	17SEP2014	3.1		
207-0021/74/M/W2	19JUN2014	10APR2015	3	30MAR2015	9.5+	Deaths after the date of the 487th event	10APR2015
207-0022/74/M/W2	10JUL2014				11.7+	Follow-up visit	25JUN2015
208-0001/59/M/W2	20SEP2012				34.5+	Ongoing	
208-0002/82/F/W2	20SEP2012	08MAR2013	3	08MAR2013	5.7		05MAR2013
208-0006/69/F/W2	28AUG2013	30AUG2014	3	20JUL2014	10.9		30AUG2014

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
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Listing 16.2.6.1a
Overall Survival

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [3]	Date of Death	Duration of Overall Survival (Months) [4]	If Censored, Reason	Date of Last Telephone Contact
208-0007/53/M/W2	07JUL2014				11.1+	Follow-up visit	04JUN2015
209-0001/66/M/W2	15NOV2012	18APR2013	3	04MAY2013	5.7		18APR2013
209-0004/74/M/W2	09APR2013	15OCT2013	3	26OCT2013	6.7		15OCT2013
209-0008/66/M/W2	11JUL2013	25OCT2013	3	01NOV2013	3.8		
209-0012/63/M/W2	03DEC2013	06AUG2014	3	04AUG2014	8.2		06AUG2014
209-0013/52/M/W2	23DEC2013				18.1+	Follow-up visit	17JUN2015
210-0001/67/M/W2	30AUG2013	07MAY2014	3	30APR2014	8.1		07MAY2014

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Use the date of death for the 487th subject as the cutoff date(24Mar2015), if the subject died after the cutoff date, they will be event in the sensitivity analysis. Censored records are indicated with '+'. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.

Listing 16.2.6.1a
Overall Survival

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [3]	Date of Death	Duration of Overall Survival (Months) [4]	If Censored, Reason	Date of Last Telephone Contact
210-0002/80/M/W2	09OCT2013	27MAY2015	3	20MAY2015	19.6+	Deaths after the date of the 487th event	15MAY2015
210-0007/73/M/W2	07JUL2014				12.7+	Ongoing	
210-0009/49/F/W2	10NOV2014				7.4+	Follow-up visit	18JUN2015
210-0011/73/M/W2	17NOV2014	06MAR2015	3	04MAR2015	3.6		06MAR2015
210-0012/47/F/W2	16DEC2014				6.2+	Follow-up visit	18JUN2015
210-0014/71/F/W2	26JAN2015				4.8+	Follow-up visit	18JUN2015

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Use the date of death for the 487th subject as the cutoff date(24Mar2015), if the subject died after the cutoff date, they will be event in the sensitivity analysis. Censored records are indicated with ‘+’. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.

Listing 16.2.6.1a
Overall Survival

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [3]	Date of Death	Duration of Overall Survival (Months) [4]	If Censored, Reason	Date of Last Telephone Contact
251-0001/55/F/W2	24JUL2012	06DEC2012	3	26DEC2012	5.2		
252-0002/76/M/W2	28AUG2012	17DEC2012	3	26MAY2013	9.1		17DEC2012
252-0003/68/M/W2	28DEC2012	22AUG2013	3	24AUG2013	8.0		22AUG2013
252-0007/77/M/W2	25FEB2014	04APR2014	3	03MAY2014	2.3		
252-0011/81/M/BL	24NOV2014				8+	Ongoing	
253-0002/63/M/W2	09MAR2012	08JUN2012	3	09AUG2012	5.1		
253-0010/76/M/W2	07JUN2013	06MAY2014	3	30MAY2014	11.9		06MAY2014
254-0001/69/M/W2	17MAY2012	04DEC2012	3	04DEC2012	6.7		05DEC2012
257-0001/47/M/A4	04APR2012	10SEP2012	3	10SEP2012	5.3		14AUG2012
257-0002/56/M/W2	18APR2012	22DEC2012	3	22DEC2012	8.3		22DEC2012

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Use the date of death for the 487th subject as the cutoff date(24Mar2015), if the subject died after the cutoff date, they will be event in the sensitivity analysis. Censored records are indicated with '+'. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.

Listing 16.2.6.1a
Overall Survival

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [3]	Date of Death	Duration of Overall Survival (Months) [4]	If Censored, Reason	Date of Last Telephone Contact
257-0007/80/M/W2	21FEB2013	20JAN2014	3	20JAN2014	11.1		
257-0008/80/F/W2	26MAR2013	06JUN2014	3	06JUN2014	14.6		04MAR2014
257-0010/42/M/BL	23MAY2013				24+	Follow-up visit	13MAY2015
257-0012/76/M/W2	13MAY2013	25JUN2013	99: 1A.Sepsis, 1B.HCC, 2.ALD. death certificate indicates all to be applicable.	25JUN2013	1.5		
257-0015/69/F/BL	14APR2014	25MAY2014	3	25MAY2014	1.4		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Use the date of death for the 487th subject as the cutoff date(24Mar2015), if the subject died after the cutoff date, they will be event in the sensitivity analysis. Censored records are indicated with '+'. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.

Listing 16.2.6.1a
Overall Survival

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [3]	Date of Death	Duration of Overall Survival (Months) [4]	If Censored, Reason	Date of Last Telephone Contact
257-0017/74/M/A8	02MAY2014	10JUL2015	3	10JUL2015	14.5+	Deaths after the date of the 487th event	29JUN2015
257-0018/53/M/A6	28APR2014	31MAY2014	3	31MAY2014	1.1		
257-0022/60/M/W2	01DEC2014	29MAY2015	3	29MAY2015	6+	Deaths after the date of the 487th event	19MAY2015
257-0024/75/M/W2	22DEC2014	31MAR2015	3	31MAR2015	3.3+	Deaths after the date of the 487th event	

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Use the date of death for the 487th subject as the cutoff date(24Mar2015), if the subject died after the cutoff date, they will be event in the sensitivity analysis. Censored records are indicated with '+'. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.

Listing 16.2.6.1a
Overall Survival

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [3]	Date of Death	Duration of Overall Survival (Months) [4]	If Censored, Reason	Date of Last Telephone Contact
257-0025/69/M/BL	22DEC2014	30APR2015	3	30APR2015	4.3+	Deaths after the date of the 487th event	
257-0026/65/M/W2	19JAN2015				5.4+	Follow-up visit	30JUN2015
257-0027/52/M/A6	19JAN2015	02MAR2015	99: Spontaneous intracerebral haemorrhage into metastatic brain tumour	02MAR2015	1.4		
258-0005/64/M/OTH	09AUG2013	02MAY2014	3	16MAY2014	9.4		02MAY2014
258-0007/74/M/W2	09OCT2013	14NOV2013	3	23NOV2013	1.5		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Use the date of death for the 487th subject as the cutoff date(24Mar2015), if the subject died after the cutoff date, they will be event in the sensitivity analysis. Censored records are indicated with ‘+’. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.

Listing 16.2.6.1a
Overall Survival

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [3]	Date of Death	Duration of Overall Survival (Months) [4]	If Censored, Reason	Date of Last Telephone Contact
258-0008/70/M/W2	18NOV2013	03MAR2014	3	26MAR2014	4.3		03MAR2014
258-0009/64/M/W2	19MAY2014	16MAR2015	3	30APR2015	11.6+	Deaths after the date of the 487th event	16MAR2015
258-0010/53/M/W2	02JUN2014				12.2+	Follow-up visit	03JUN2015
258-0012/66/F/W2	15JUL2014	18MAR2015	3	09APR2015	9+	Deaths after the date of the 487th event	15APR2015
258-0015/65/M/W2	02DEC2014				6.9+	Follow-up visit	26JUN2015

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
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Listing 16.2.6.1a
Overall Survival

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [3]	Date of Death	Duration of Overall Survival (Months) [4]	If Censored, Reason	Date of Last Telephone Contact
259-0001/68/F/W2	03JUN2013				24.9+	Follow-up visit	18JUN2015
259-0002/54/F/W2	09SEP2013	06JUL2014	3	06JUL2014	10.0		30JUN2014
260-0003/81/M/A7	05NOV2014				8.7+	Ongoing	
301-0005/61/M/A2	24MAY2012	14DEC2012	3	24NOV2012	6.2		14DEC2012
301-0007/55/F/A2	04JAN2013	28MAR2013	2	26MAR2013	2.7		
301-0009/55/M/A2	11JAN2013	11MAY2013	3	01MAY2013	3.7		11MAY2013
302-0002/32/F/A2	07NOV2011	15DEC2011	3	15DEC2011	1.3		
302-0004/57/M/A2	10JAN2012	21MAR2012	3	21MAR2012	2.4		
302-0007/76/M/A2	14FEB2012	25MAR2013	3	23MAR2013	13.5		25MAR2013

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
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[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Use the date of death for the 487th subject as the cutoff date(24Mar2015), if the subject died after the cutoff date, they will be event in the sensitivity analysis. Censored records are indicated with ‘+’. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.

Listing 16.2.6.1a
Overall Survival

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [3]	Date of Death	Duration of Overall Survival (Months) [4]	If Censored, Reason	Date of Last Telephone Contact
302-0008/37/M/A2	28FEB2012	07SEP2012	3	07SEP2012	6.4		07SEP2012
302-0010/45/M/A2	17APR2012	08DEC2012	3	08DEC2012	7.9		08DEC2012
302-0011/52/M/A2	24APR2012	06JUN2012	3	06JUN2012	1.5		06JUN2012
302-0015/60/M/A2	16APR2013	10MAR2014	3	10MAR2014	11.0		10MAR2014
302-0016/60/M/A2	16APR2013	28JAN2014	3	28JAN2014	9.6		28JAN2014
302-0019/52/M/A2	14MAY2013	20MAY2014	3	20MAY2014	12.4		28MAY2014
302-0022/65/M/A2	09JUL2013	05OCT2013	3	05OCT2013	3.0		
302-0023/68/M/A2	10SEP2013	07SEP2014	3	07SEP2014	12.1		07SEP2014

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
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Listing 16.2.6.1a
Overall Survival

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [3]	Date of Death	Duration of Overall Survival (Months) [4]	If Censored, Reason	Date of Last Telephone Contact
302-0024/66/F/A2	24SEP2013	09APR2015	3	09APR2015	18.8+	Deaths after the date of the 487th event	09APR2015
302-0025/40/M/A2	22OCT2013	06JUL2014	3	06JUL2014	8.6		06JUL2014
302-0026/49/M/A2	12NOV2013				19.5+	Follow-up visit	18JUN2015
303-0001/50/M/A2	03FEB2012	18FEB2013	3	18FEB2013	12.7		18FEB2013
303-0003/47/M/A2	28NOV2012	25APR2013	3	20APR2013	4.8		25APR2013
303-0004/18/M/A2	10DEC2012	14MAY2013	3	10MAY2013	5.1		14MAY2013
303-0006/64/M/A2	10APR2013	25JUL2013	3	25JUL2013	3.6		25JUL2013

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Listing 16.2.6.1a
Overall Survival

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [3]	Date of Death	Duration of Overall Survival (Months) [4]	If Censored, Reason	Date of Last Telephone Contact
303-0007/50/M/A2	24JUL2013	25OCT2013	3	25OCT2013	3.1		
304-0001/54/M/A2	05NOV2012	04MAR2013	3	08FEB2013	3.2		04MAR2013
304-0005/58/M/A2	05JUN2013	05JUL2013	3	05JUL2013	1.0		
305-0002/57/M/A2	14FEB2012	23DEC2013	3	23DEC2013	22.6		23DEC2013
305-0003/50/M/A2	15FEB2012	07AUG2013	3	07AUG2013	18.0		07AUG2013
305-0005/48/M/A2	21FEB2012	30JUN2015	3	09MAY2012	2.6		30JUN2015
305-0006/65/M/A2	08MAR2012	22OCT2012	1	22OCT2012	7.6		22OCT2012
305-0009/45/F/A2	11APR2012	01AUG2014	3	15JUL2014	27.5		01AUG2014
305-0010/64/F/A2	18APR2012	16SEP2013	3	30AUG2013	16.7		16SEP2013
305-0011/68/M/A2	27APR2012	14DEC2012	3	26NOV2012	7.1		14DEC2012

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Use the date of death for the 487th subject as the cutoff date(24Mar2015), if the subject died after the cutoff date, they will be event in the sensitivity analysis. Censored records are indicated with ‘+’. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.

Listing 16.2.6.1a
Overall Survival

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [3]	Date of Death	Duration of Overall Survival (Months) [4]	If Censored, Reason	Date of Last Telephone Contact
305-0012/62/F/A2	04MAY2012				38.4+	Follow-up visit	29JUN2015
305-0014/61/F/A2	10JUL2012	09MAR2013	3	09MAR2013	8.1		09MAR2013
305-0019/35/M/A2	11SEP2012	16NOV2012	2	13NOV2012	2.1		16NOV2012
305-0023/54/M/A2	02JAN2013	24SEP2013	3	03SEP2013	8.2		24SEP2013
305-0025/77/F/A2	22JAN2013	02AUG2013	3	02AUG2013	6.4		05AUG2013
305-0026/45/M/A2	26FEB2013	20DEC2013	2	20DEC2013	9.9		20DEC2013
305-0028/73/F/A2	15MAR2013	16JUN2013	3	16JUN2013	3.1		
305-0030/61/M/A2	02APR2013	26JUN2014	5	26JUN2014	15.0		26JUN2014
305-0031/29/M/A2	02APR2013	13MAY2013	3	13MAY2013	1.4		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Use the date of death for the 487th subject as the cutoff date(24Mar2015), if the subject died after the cutoff date, they will be event in the sensitivity analysis. Censored records are indicated with '+'. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.

Listing 16.2.6.1a
Overall Survival

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [3]	Date of Death	Duration of Overall Survival (Months) [4]	If Censored, Reason	Date of Last Telephone Contact
305-0034/53/M/A2	03JUL2013	24AUG2013	3	24AUG2013	1.8		
305-0036/38/M/A2	05SEP2013	22MAY2014			8.7+	Lost to Follow-up	22MAY2014
305-0037/50/M/A2	24OCT2013	30JUL2014	3	24JUN2014	8.1		30JUL2014
305-0039/36/M/A2	28NOV2013	26DEC2013	3	26DEC2013	1.0		
305-0040/61/M/A2	15NOV2013	27JUN2014	5	26JUN2014	7.5		27JUN2014
305-0043/70/M/A2	01JUL2014				11.7+	Follow-up visit	17JUN2015
305-0044/67/M/A2	08JUL2014				11.7+	Follow-up visit	22JUN2015
305-0045/65/M/A2	17OCT2014	05DEC2014	3	05DEC2014	1.7		05DEC2014

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Use the date of death for the 487th subject as the cutoff date(24Mar2015), if the subject died after the cutoff date, they will be event in the sensitivity analysis. Censored records are indicated with '+'. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.

Listing 16.2.6.1a
Overall Survival

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [3]	Date of Death	Duration of Overall Survival (Months) [4]	If Censored, Reason	Date of Last Telephone Contact
305-0047/58/M/A2	25DEC2014	28JAN2015	3	28JAN2015	1.2		
305-0048/55/M/A2	24FEB2015				5+	Ongoing	
306-0001/56/M/A2	17FEB2012	18NOV2013	3	04NOV2013	20.9		18NOV2013
306-0002/73/M/A2	14FEB2012	10SEP2012	99: Left occipital lobar hemorrhage with intraventricular hemorrhage	21AUG2012	6.3		10SEP2012
306-0005/69/F/A2	24FEB2012	31JUL2012	3	29JUL2012	5.2		31JUL2012
306-0006/43/M/A2	20MAR2012	14MAY2012	3	14MAY2012	1.9		09JUN2015
306-0007/56/M/A2	05MAR2012	29NOV2012	3	28NOV2012	9.0		29NOV2012
306-0008/40/M/A2	12MAR2012	22JUN2012	3	12JUN2012	3.1		22JUN2012

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Use the date of death for the 487th subject as the cutoff date(24Mar2015), if the subject died after the cutoff date, they will be event in the sensitivity analysis. Censored records are indicated with '+'. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.

Listing 16.2.6.1a
Overall Survival

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [3]	Date of Death	Duration of Overall Survival (Months) [4]	If Censored, Reason	Date of Last Telephone Contact
306-0011/47/M/A2	15MAR2012	02JUN2012	3	02JUN2012	2.7		
306-0012/61/M/A2	02APR2012	11DEC2012	3	22NOV2012	7.8		11DEC2012
306-0014/47/M/A2	19APR2012	20JUN2012	3	20JUN2012	2.1		
306-0017/49/M/A2	12JUL2012	22NOV2012	3	16NOV2012	4.3		22NOV2012
306-0019/78/M/A2	22AUG2012	04DEC2012	3	04DEC2012	3.5		04DEC2012
306-0020/63/M/A2	04OCT2012	10JUN2013	3	07JUN2013	8.2		10JUN2013
306-0023/68/M/A2	27NOV2012	24JUL2013	3	28JUN2013	7.1		24JUL2013
306-0026/58/M/A2	04FEB2013				28.5+	Follow-up visit	09JUN2015
306-0027/67/M/A2	19FEB2013				28+	Follow-up visit	09JUN2015

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Use the date of death for the 487th subject as the cutoff date(24Mar2015), if the subject died after the cutoff date, they will be event in the sensitivity analysis. Censored records are indicated with ‘+’. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.

Listing 16.2.6.1a
Overall Survival

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [3]	Date of Death	Duration of Overall Survival (Months) [4]	If Censored, Reason	Date of Last Telephone Contact
306-0030/63/M/A2	23APR2013	06AUG2013	3	18JUL2013	2.9		06AUG2013
306-0031/40/M/A2	15MAY2013	27MAY2014	3	17MAY2014	12.3		27MAY2014
306-0034/65/M/A2	01JUL2013	09AUG2013	3	09AUG2013	1.3		
306-0035/48/M/A2	08JUL2013	16DEC2013	3	01DEC2013	4.9		16DEC2013
306-0036/73/M/A2	09JUL2013	30NOV2013	3	25NOV2013	4.7		30NOV2013
306-0038/66/M/A2	21AUG2013	20MAY2014	3	04MAY2014	8.6		20MAY2014
306-0039/62/M/A2	20AUG2013	31DEC2013	3	15DEC2013	3.9		31DEC2013
306-0040/44/F/A2	24SEP2013	14JUL2014	3	09JUL2014	9.6		14JUL2014
306-0041/62/M/A2	29OCT2013	13MAR2014	3	12MAR2014	4.5		
306-0043/56/M/A2	19MAY2014	30OCT2014	3	07OCT2014	4.7		30OCT2014

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
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Listing 16.2.6.1a
Overall Survival

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [3]	Date of Death	Duration of Overall Survival (Months) [4]	If Censored, Reason	Date of Last Telephone Contact
307-0002/61/M/A2	03NOV2011	16APR2012	3	16APR2012	5.5		17APR2012
307-0003/68/M/A2	10NOV2011	01MAR2013	3	09FEB2013	15.3		01MAR2013
307-0004/60/M/A2	10NOV2011	19MAR2012	3	18MAR2012	4.3		19MAR2012
307-0008/58/M/A2	20DEC2011	02OCT2012	3	01OCT2012	9.6		02OCT2012
307-0011/75/M/A2	07FEB2012	02APR2012	99: Sepsis	02APR2012	1.9		02APR2012
307-0014/61/M/A2	16FEB2012	04JUN2013	3	21MAY2013	15.4		04JUN2013
307-0018/70/M/A2	14JUN2012	14JAN2015	3	14JAN2015	31.5		14JAN2015
307-0020/68/F/A2	16AUG2012	12JUN2015	3	23MAR2013	7.3		11JUN2015
307-0022/60/M/A2	27NOV2012	13MAY2013	3	18APR2013	4.8		13MAY2013
307-0025/68/M/A2	18DEC2012	25SEP2013	3	25SEP2013	9.4		25SEP2013

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
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Listing 16.2.6.1a
Overall Survival

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [3]	Date of Death	Duration of Overall Survival (Months) [4]	If Censored, Reason	Date of Last Telephone Contact
307-0026/65/M/A2	27DEC2012	18DEC2013	3	09DEC2013	11.6		18DEC2013
307-0030/53/M/A2	06MAR2013	31MAY2013	3	31MAY2013	2.9		
307-0031/60/M/A2	15MAR2013	19DEC2013	3	19DEC2013	9.3		
307-0032/74/F/A2	11APR2013	13MAY2013	3	11MAY2013	1.0		
307-0037/61/M/A2	03OCT2013	02MAY2014	3	19APR2014	6.6		02MAY2014
307-0039/51/M/A2	05NOV2013	12JUN2015	3	16OCT2014	11.5		12JUN2015
307-0040/65/M/A2	27MAY2014	05AUG2014	3	04AUG2014	2.3		05AUG2014
307-0043/54/M/A2	25JUN2014	01NOV2014	99: Hepatic failure	01NOV2014	4.3		
307-0044/53/M/A2	27JUN2014	18JUN2015	3	11SEP2014	2.6		18JUN2015

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Use the date of death for the 487th subject as the cutoff date(24Mar2015), if the subject died after the cutoff date, they will be event in the sensitivity analysis. Censored records are indicated with '+'. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.

Listing 16.2.6.1a
Overall Survival

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [3]	Date of Death	Duration of Overall Survival (Months) [4]	If Censored, Reason	Date of Last Telephone Contact
307-0045/48/M/A2	07JUL2014				10.3+	Follow-up visit	12MAY2015
307-0046/46/M/A2	17JUL2014	13MAR2015	3	13MAR2015	8.0		13MAR2015
308-0003/54/M/A2	29JAN2013	10DEC2013	3	10DEC2013	10.5		10DEC2013
308-0005/69/F/A2	30APR2013	10SEP2013	3	10SEP2013	4.5		10SEP2013
309-0001/46/M/A2	12JUN2012	16APR2013	3	04APR2013	9.9		16APR2013
309-0002/56/M/A2	13JUN2012	16NOV2012	3	27OCT2012	4.6		16NOV2012
309-0003/52/F/A2	20JUN2012	26FEB2013	3	29JAN2013	7.5		26FEB2013
309-0004/55/M/A2	25JUN2012	19JUL2012	3	19JUL2012	0.8		19JUL2012
309-0008/38/M/A2	21FEB2013	03JAN2014	3	31DEC2013	10.5		03JAN2014

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
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Overall Survival

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [3]	Date of Death	Duration of Overall Survival (Months) [4]	If Censored, Reason	Date of Last Telephone Contact
309-0010/47/M/A2	25MAR2013				28.3+	Follow-up visit	21JUL2015
309-0011/59/M/A2	08APR2013	10JUL2013	3	02JUL2013	2.9		
309-0012/82/M/A2	23MAY2013	29JAN2014	3	31DEC2013	7.4		29JAN2014
309-0015/62/M/A2	24JUN2013	29MAY2014	3	20MAY2014	11.0		29MAY2014
309-0016/72/F/A2	05SEP2013	13FEB2014	3	14JAN2014	4.4		13FEB2014
309-0017/73/F/A2	02DEC2013	16JUL2014	3	26JUN2014	6.9		16JUL2014
309-0018/82/M/A2	03JUN2014	31OCT2014	3	28OCT2014	4.9		31OCT2014
309-0021/54/F/A2	17JUL2014	16DEC2014	3	28NOV2014	4.5		16DEC2014
309-0025/49/M/A2	25AUG2014	05SEP2014	3	04SEP2014	0.4		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Use the date of death for the 487th subject as the cutoff date(24Mar2015), if the subject died after the cutoff date, they will be event in the sensitivity analysis. Censored records are indicated with ‘+’. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.

Listing 16.2.6.1a
Overall Survival

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [3]	Date of Death	Duration of Overall Survival (Months) [4]	If Censored, Reason	Date of Last Telephone Contact
309-0026/41/M/A2	22SEP2014	26FEB2015	3	15FEB2015	4.9		26FEB2015
309-0028/62/M/A2	03NOV2014				8.2+	Follow-up visit	06JUL2015
309-0030/33/M/A2	15DEC2014	24FEB2015	3	20FEB2015	2.3		24FEB2015
309-0031/34/M/A2	25DEC2014	27APR2015	3	03APR2015	3.3+	Deaths after the date of the 487th event	27APR2015
309-0032/63/M/A2	08JAN2015	01APR2015	3	30MAR2015	2.7+	Deaths after the date of the 487th event	01APR2015

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Use the date of death for the 487th subject as the cutoff date(24Mar2015), if the subject died after the cutoff date, they will be event in the sensitivity analysis. Censored records are indicated with '+'. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.

Listing 16.2.6.1a
Overall Survival

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [3]	Date of Death	Duration of Overall Survival (Months) [4]	If Censored, Reason	Date of Last Telephone Contact
309-0033/78/F/A2	29JAN2015				5.8+	Ongoing	
310-0001/61/M/A2	19JUN2012	10JUN2013	3	01JUN2013	11.6		10JUN2013
310-0002/55/M/A2	12JUL2012	05NOV2012	3	13OCT2012	3.1		05NOV2012
310-0003/61/M/A2	06FEB2013	19MAY2014	3	29APR2014	14.9		19MAY2014
310-0008/49/M/A2	19JUN2013	30AUG2013	3	13AUG2013	1.9		30AUG2013
310-0012/73/M/A2	07NOV2013				19.1+	Follow-up visit	02JUN2015
310-0013/54/M/A2	03SEP2014	14MAY2015	3	29APR2015	8+	Deaths after the date of the 487th event	14MAY2015

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Use the date of death for the 487th subject as the cutoff date(24Mar2015), if the subject died after the cutoff date, they will be event in the sensitivity analysis. Censored records are indicated with ‘+’. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.

Listing 16.2.6.1a
Overall Survival

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [3]	Date of Death	Duration of Overall Survival (Months) [4]	If Censored, Reason	Date of Last Telephone Contact
311-0002/60/M/A2	14AUG2013	01NOV2013	3	20NOV2013	3.3		02JUL2015
311-0007/55/M/A2	18NOV2013	02DEC2014	3	13NOV2014	12.0		02DEC2014
311-0008/71/M/A2	21MAY2014	09JUL2014	3	DEC2014	1.7		02JUL2015
401-0003/36/M/A7	24JUN2013	30NOV2013	3	24NOV2013	5.1		29NOV2013
401-0005/58/M/A7	16OCT2013	20AUG2014	3	17MAY2014	7.1		20AUG2014
402-0003/75/M/A7	30APR2013	14NOV2013	3	08NOV2013	6.4		14NOV2013
402-0006/71/M/A7	02MAY2013	22NOV2013	3	20NOV2013	6.8		22NOV2013
402-0008/43/M/A7	21MAY2013	02AUG2013	3	22JUL2013	2.1		02AUG2013
402-0009/70/M/A7	16MAY2013	11AUG2013	3	11AUG2013	2.9		11AUG2013
402-0011/64/M/A7	23MAY2013	11OCT2013	3	04OCT2013	4.5		11OCT2013

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Use the date of death for the 487th subject as the cutoff date(24Mar2015), if the subject died after the cutoff date, they will be event in the sensitivity analysis. Censored records are indicated with ‘+’. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.

Listing 16.2.6.1a
Overall Survival

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [3]	Date of Death	Duration of Overall Survival (Months) [4]	If Censored, Reason	Date of Last Telephone Contact
402-0017/50/M/A7	11JUN2013	16AUG2013	3	09AUG2013	2.0		16AUG2013
402-0018/48/M/A7	24JUN2013	16DEC2013	3	08DEC2013	5.6		04DEC2013
402-0019/54/M/A7	01JUL2013	15NOV2013	3	06NOV2013	4.3		15NOV2013
402-0021/64/M/A7	13AUG2013				22.1+	Follow-up visit	05JUN2015
402-0024/57/M/A7	27AUG2013	03JAN2014	3	24DEC2013	4.0		03JAN2014
402-0025/58/M/A7	25SEP2013	21JAN2015	3	08JAN2015	15.7		21JAN2015
402-0027/52/M/A7	04OCT2013	28NOV2013	3	28NOV2013	1.9		28NOV2013
402-0028/60/M/A7	04OCT2013	18FEB2014	3	29JAN2014	3.9		18FEB2014
402-0031/65/M/A7	12NOV2013				19+	Follow-up visit	05JUN2015

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Use the date of death for the 487th subject as the cutoff date(24Mar2015), if the subject died after the cutoff date, they will be event in the sensitivity analysis. Censored records are indicated with '+'. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.

Listing 16.2.6.1a
Overall Survival

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [3]	Date of Death	Duration of Overall Survival (Months) [4]	If Censored, Reason	Date of Last Telephone Contact
402-0033/63/F/A7	06DEC2013	25APR2014	3	07APR2014	4.1		25APR2014
402-0035/44/M/A7	24DEC2013	25JUN2014	3	02MAY2014	4.3		26MAY2014
403-0001/55/M/A7	22MAY2013	30SEP2013	3	11SEP2013	3.8		30SEP2013
403-0002/52/M/A7	11JUN2013	14OCT2013	3	11OCT2013	4.1		14OCT2013
403-0005/50/F/A7	16JUL2013	06NOV2013	3	28OCT2013	3.5		06NOV2013
403-0006/66/M/A7	29JUL2013	03APR2014	5	24MAR2014	8.0		03APR2014
403-0007/65/M/MIX	21AUG2013	12DEC2013	3	05JAN2014	4.6		
404-0001/71/M/A7	22JUL2013	11SEP2013	99: Metabolic acidosis	11SEP2013	1.7		
404-0002/56/F/A7	22AUG2013	02JUL2014	3	01JUN2014	9.5		02JUL2014

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Use the date of death for the 487th subject as the cutoff date(24Mar2015), if the subject died after the cutoff date, they will be event in the sensitivity analysis. Censored records are indicated with ‘+’. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.

Listing 16.2.6.1a
Overall Survival

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [3]	Date of Death	Duration of Overall Survival (Months) [4]	If Censored, Reason	Date of Last Telephone Contact
405-0002/46/M/A7	16APR2013	04JUN2013	2	12MAY2013	0.9		
405-0004/38/M/A7	24APR2013	20MAY2014	3	21MAY2014	13.1		30MAY2014
405-0006/62/M/A7	29APR2013	20JUN2013	3	10JUN2013	1.4		
405-0007/53/M/A7	07MAY2013	19AUG2014	3	02AUG2014	15.1		19AUG2014
405-0009/50/M/A7	14MAY2013	23AUG2013	3	19AUG2013	3.3		21AUG2013
405-0010/39/M/A7	23MAY2013	21FEB2014			9.2+	Lost to Follow-up	21FEB2014
405-0011/63/M/A7	13MAY2013	01JUL2014	3	05JUN2014	13.0		01JUL2014
405-0013/45/M/A7	20MAY2013	17JAN2014			8.1+	Lost to Follow-up	17JAN2014
405-0014/35/M/A7	31MAY2013	12AUG2013	3	19JUL2013	1.7		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Use the date of death for the 487th subject as the cutoff date(24Mar2015), if the subject died after the cutoff date, they will be event in the sensitivity analysis. Censored records are indicated with '+'. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.

Listing 16.2.6.1a
Overall Survival

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [3]	Date of Death	Duration of Overall Survival (Months) [4]	If Censored, Reason	Date of Last Telephone Contact
405-0016/41/M/A7	27MAY2013	14JUL2013	3	14JUL2013	1.6		
405-0018/70/F/A7	12JUN2013	12AUG2013	3	13JUL2013	1.1		
405-0020/69/M/A7	19JUN2013	30OCT2014	3	14OCT2014	16.1		30OCT2014
405-0021/47/M/A7	19JUN2013	07OCT2014	3	05OCT2014	15.8		07OCT2014
405-0022/65/M/A7	04JUL2013	02APR2014	3	17MAR2014	8.6		02APR2014
405-0023/46/M/A7	17JUN2013	11DEC2013	3	10DEC2013	5.9		13DEC2013
405-0025/47/M/A7	26JUN2013	10DEC2013	3	10DEC2013	5.6		10DEC2013
405-0028/67/M/A7	24JUL2013	04JAN2014	3	07DEC2013	4.6		04JAN2014
405-0030/35/M/A7	31JUL2013	06NOV2013	3	06NOV2013	3.3		
405-0032/69/M/A7	23JUL2013	10MAR2015	3	13FEB2015	19.0		10MAR2015

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Use the date of death for the 487th subject as the cutoff date(24Mar2015), if the subject died after the cutoff date, they will be event in the sensitivity analysis. Censored records are indicated with ‘+’. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.

Listing 16.2.6.1a
Overall Survival

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [3]	Date of Death	Duration of Overall Survival (Months) [4]	If Censored, Reason	Date of Last Telephone Contact
405-0033/43/M/A7	08AUG2013	28APR2014	3	28APR2014	8.8		14MAY2014
405-0034/61/M/A7	08AUG2013	07OCT2014	3	07OCT2014	14.2		13OCT2014
405-0035/66/M/A7	19AUG2013				22+	Follow-up visit	08JUN2015
405-0039/73/M/A7	13SEP2013	02JUN2014	3	02JUN2014	8.8		18JUN2014
405-0040/65/M/A7	23SEP2013				20.7+	Follow-up visit	05JUN2015
405-0042/53/M/A7	04OCT2013	31DEC2013	3	26DEC2013	2.8		31DEC2013
405-0043/49/M/A7	26SEP2013	20DEC2013	3	20DEC2013	2.9		30DEC2013
405-0044/56/M/A7	25SEP2013	08DEC2014	3	05DEC2014	14.6		08DEC2014
501-0001/59/M/A1	13NOV2013	24JUN2014	3	26MAY2014	6.5		24JUN2014

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Use the date of death for the 487th subject as the cutoff date(24Mar2015), if the subject died after the cutoff date, they will be event in the sensitivity analysis. Censored records are indicated with ‘+’. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.

Listing 16.2.6.1a
Overall Survival

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [3]	Date of Death	Duration of Overall Survival (Months) [4]	If Censored, Reason	Date of Last Telephone Contact
501-0002/36/F/A1	02DEC2013	19JAN2015	3	16JAN2015	13.7		19JAN2015
501-0005/80/M/A1	23JAN2014				18.2+	Ongoing	
501-0006/60/M/A1	13FEB2014	29NOV2014	3	18NOV2014	9.3		29NOV2014
501-0007/43/M/A1	03MAR2014	11JUL2014	3	27JUN2014	3.9		11JUL2014
501-0008/76/F/A1	15APR2014	25MAY2015	3	23MAY2015	13.5+	Deaths after the date of the 487th event	25MAY2015
501-0009/62/M/A1	18JUL2014				11.2+	Follow-up visit	19JUN2015

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Use the date of death for the 487th subject as the cutoff date(24Mar2015), if the subject died after the cutoff date, they will be event in the sensitivity analysis. Censored records are indicated with '+'. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.

Listing 16.2.6.1a
Overall Survival

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [3]	Date of Death	Duration of Overall Survival (Months) [4]	If Censored, Reason	Date of Last Telephone Contact
501-0010/65/M/A1	10SEP2014	02APR2015	3	26MAR2015	6.6+	Deaths after the date of the 487th event	02APR2015
502-0002/65/M/A1	08JAN2014	20JAN2014	99: Respiratory failure	19JAN2014	0.4		
503-0001/32/M/A1	09DEC2013	20MAR2014	3	14FEB2014	2.3		20MAR2014
503-0004/49/M/A1	11MAR2014	18APR2014	3	05APR2014	0.9		
503-0006/54/M/A1	06AUG2014				11+	Follow-up visit	02JUL2015
503-0007/57/M/A1	28OCT2014				8.3+	Follow-up visit	02JUL2015

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Use the date of death for the 487th subject as the cutoff date(24Mar2015), if the subject died after the cutoff date, they will be event in the sensitivity analysis. Censored records are indicated with ‘+’. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.

Listing 16.2.6.1a
Overall Survival

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [3]	Date of Death	Duration of Overall Survival (Months) [4]	If Censored, Reason	Date of Last Telephone Contact
503-0008/50/M/A1	30OCT2014	18MAY2015	3	30APR2015	6.1+	Deaths after the date of the 487th event	18MAY2015
503-0009/57/M/A1	19NOV2014	29NOV2014	3	29NOV2014	0.4		
504-0001/47/M/A1	17FEB2014	10AUG2014	3	27JUL2014	5.4		10AUG2014
504-0007/32/M/A1	11OCT2014	11NOV2014	3	31OCT2014	0.7		
505-0001/70/M/A1	12AUG2014	01FEB2015	3	24JAN2015	5.5		01FEB2015
506-0002/54/M/A1	12MAY2014				13.9+	Follow-up visit	02JUL2015

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Use the date of death for the 487th subject as the cutoff date(24Mar2015), if the subject died after the cutoff date, they will be event in the sensitivity analysis. Censored records are indicated with '+'. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.

Listing 16.2.6.1a
Overall Survival

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [3]	Date of Death	Duration of Overall Survival (Months) [4]	If Censored, Reason	Date of Last Telephone Contact
506-0003/66/M/A1	10SEP2014	29APR2015	5	04APR2015	6.9+	Deaths after the date of the 487th event	29APR2015
506-0004/49/M/A1	27OCT2014	15FEB2015	3	15FEB2015	3.7		15FEB2015
508-0001/36/M/A1	08JAN2014	15AUG2014			7.3+	Lost to Follow-up	15AUG2014
508-0003/49/F/A1	17MAR2014	15APR2014	3	15APR2014	1.0		
509-0001/45/M/A1	30APR2014	29AUG2014	3	06AUG2014	3.3		29AUG2014
509-0002/51/M/A1	26MAY2014	27AUG2014			3.1+	Lost to Follow-up	
510-0002/50/M/A1	23MAY2014	25AUG2014	3	13AUG2014	2.8		25AUG2014

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Use the date of death for the 487th subject as the cutoff date(24Mar2015), if the subject died after the cutoff date, they will be event in the sensitivity analysis. Censored records are indicated with ‘+’. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.

Listing 16.2.6.1a
Overall Survival

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [3]	Date of Death	Duration of Overall Survival (Months) [4]	If Censored, Reason	Date of Last Telephone Contact
510-0004/72/M/A1	01AUG2014				11.1+	Follow-up visit	30JUN2015
511-0001/35/M/A1	21JAN2014	30AUG2014	3	25AUG2014	7.2		30AUG2014
511-0002/49/M/A1	11MAR2014				16+	Follow-up visit	02JUL2015
512-0001/59/M/A1	04MAR2014	04SEP2014	3	04SEP2014	6.2		04SEP2014
513-0001/28/M/A1	09APR2014	22JUL2014	99: Oral cavity internal hemorrhage	21JUN2014	2.5		22JUL2014
513-0004/46/M/A1	18JUN2014	07AUG2014	2	26JUL2014	1.3		07AUG2014
513-0005/61/M/A1	31OCT2014	20MAR2015	3	01MAR2015	4.1		20MAR2015
515-0001/64/M/A1	20FEB2014	01AUG2014	3	17JUL2014	4.9		01AUG2014

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Use the date of death for the 487th subject as the cutoff date(24Mar2015), if the subject died after the cutoff date, they will be event in the sensitivity analysis. Censored records are indicated with ‘+’. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.

Listing 16.2.6.1a
Overall Survival

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [3]	Date of Death	Duration of Overall Survival (Months) [4]	If Censored, Reason	Date of Last Telephone Contact
515-0003/69/M/A1	13MAY2014	08APR2015	3	05APR2015	10.9+	Deaths after the date of the 487th event	08APR2015
515-0004/52/M/A1	27MAY2014	25SEP2014	3	19SEP2014	3.9		
515-0006/47/M/A1	05AUG2014				11+	Follow-up visit	29JUN2015
515-0007/39/M/A1	17SEP2014	09DEC2014	3	22NOV2014	2.2		09DEC2014
515-0008/60/M/A1	27NOV2014	04JUN2015	3	12MAY2015	5.6+	Deaths after the date of the 487th event	04JUN2015

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Use the date of death for the 487th subject as the cutoff date(24Mar2015), if the subject died after the cutoff date, they will be event in the sensitivity analysis. Censored records are indicated with '+'. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.

Listing 16.2.6.1a
Overall Survival

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [3]	Date of Death	Duration of Overall Survival (Months) [4]	If Censored, Reason	Date of Last Telephone Contact
516-0001/45/M/A1	07AUG2014				10.9+	Follow-up visit	30JUN2015
517-0001/42/M/A1	23DEC2013	19MAR2014	3	02MAR2014	2.3		19MAR2014
517-0002/43/M/A1	26MAR2014				15.4+	Follow-up visit	01JUL2015
517-0005/46/M/MIX	04JUN2014	08AUG2014	3	28JUL2014	1.8		08AUG2014
517-0006/67/F/A1	20AUG2014				10.5+	Follow-up visit	01JUL2015
517-0007/66/M/A1	20AUG2014	10DEC2014	3	15NOV2014	2.9		10DEC2014

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
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Listing 16.2.6.1a
Overall Survival

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [3]	Date of Death	Duration of Overall Survival (Months) [4]	If Censored, Reason	Date of Last Telephone Contact
517-0008/59/M/A1	22AUG2014	21JAN2015	3	18JAN2015	5.0		21JAN2015
517-0009/23/M/A1	17SEP2014	09JUN2015	3	31MAY2015	8.6+	Deaths after the date of the 487th event	09JUN2015

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Use the date of death for the 487th subject as the cutoff date(24Mar2015), if the subject died after the cutoff date, they will be event in the sensitivity analysis. Censored records are indicated with ‘+’. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.

Listing 16.2.6.1a
Overall Survival

Treatment Group: Placebo

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [2]	Date of Death	Duration of Overall Survival (Months) [3]	If Censored, Reason [4]	Date of Last Telephone Contact
101-0002/70/M/OTH	29JUL2011	07NOV2011	3	04JUN2012	10.4		04JUL2012
101-0004/78/F/A2	05AUG2011				47.7+	Follow-up visit	06JUL2015
101-0010/43/M/BL	14SEP2011	20SEP2011	3	27OCT2011	1.5		20SEP2012
101-0014/61/M/W2	06JAN2012	26OCT2012	3	26OCT2012	9.8		05NOV2013
101-0015/65/M/A4	06JAN2012	03JAN2013	3	03JAN2013	12.1		03JAN2013
101-0017/60/M/W2	21FEB2012	19JAN2013	3	19JAN2013	11.1		19JAN2013
101-0020/86/M/W2	12MAR2012	30DEC2012	3	30DEC2012	9.8		30DEC2012
101-0027/72/M/W2	22MAY2012	11AUG2012	3	11AUG2012	2.7		16AUG2012
101-0031/69/F/W2	17JUL2012	22OCT2012	3	15NOV2012	4.1		15NOV2012

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Use the date of death for the 487th subject as the cutoff date(24Mar2015), if the subject died after the cutoff date, they will be event in the sensitivity analysis. Censored records are indicated with ‘+’. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.

Listing 16.2.6.1a
Overall Survival

Treatment Group: Placebo

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [2]	Date of Death	Duration of Overall Survival (Months) [3]	If Censored, Reason [4]	Date of Last Telephone Contact
101-0034/44/M/OTH	11SEP2012	04DEC2013	3	04DEC2013	15.0		04DEC2013
101-0035/37/M/A6	14SEP2012	27JAN2013	3	25JAN2013	4.5		27JAN2013
101-0043/69/M/W1	22OCT2013	26MAY2014	3	26MAY2014	7.2		26MAY2014
101-0051/70/F/W2	27JAN2014	23MAY2014	5	23MAY2014	3.9		23MAY2014
102-0006/66/M/BL	11DEC2013	07OCT2014	5	11OCT2014	10.2		07OCT2014
102-0007/61/M/W2	02JAN2014	09MAY2014	3	19MAY2014	4.6		
103-0002/74/M/W2	12DEC2012	09FEB2015	3	09FEB2015	26.3		10FEB2015
103-0006/57/M/W2	19NOV2014				7+	Follow-up visit	16JUN2015
104-0002/80/M/W2	07MAY2012	29JUL2013	3	27JUL2013	14.9		29JUL2013

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
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Listing 16.2.6.1a
Overall Survival

Treatment Group: Placebo

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [2]	Date of Death	Duration of Overall Survival (Months) [3]	If Censored, Reason [4]	Date of Last Telephone Contact
104-0007/89/M/A1	07AUG2013				23.8+	Ongoing	
105-0003/57/M/W2	05NOV2013	16JUN2015			19.6+	Study completed	16JUN2015
105-0006/60/F/BL	29DEC2014				6.9+	Ongoing	
108-0003/85/M/W2	19NOV2012	30NOV2013	3	30NOV2013	12.6		30NOV2013
109-0002/63/M/W2	22MAR2013				27+	Follow-up visit	10JUN2015
109-0005/64/F/W2	30JUL2013	08OCT2013	99: Kidney and heart failure	08OCT2013	2.4		
109-0012/21/F/W2	25SEP2014				8.6+	Follow-up visit	10JUN2015

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
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[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Use the date of death for the 487th subject as the cutoff date(24Mar2015), if the subject died after the cutoff date, they will be event in the sensitivity analysis. Censored records are indicated with ‘+’. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.

Listing 16.2.6.1a
Overall Survival

Treatment Group: Placebo

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [2]	Date of Death	Duration of Overall Survival (Months) [3]	If Censored, Reason [4]	Date of Last Telephone Contact
109-0014/50/F/W2	26JAN2015	03APR2015	5	11APR2015	2.5+	Deaths after the date of the 487th event	
111-0003/37/M/A1	08JAN2013	20MAR2013	3	19MAR2013	2.4		
112-0010/56/F/W2	06DEC2013	25APR2014	1	26APR2014	4.7		26APR2014
113-0007/74/M/W2	30JAN2014	21JUL2014	3	27JUL2014	6.0		29JUL2014
113-0015/58/F/BL	26NOV2014				7.1+	Follow-up visit	25JUN2015
114-0001/25/F/OTH	02AUG2012	12NOV2012	3	05DEC2012	4.2		12NOV2012
114-0004/54/F/A1	06FEB2013	09JUN2014	3	09JUN2014	16.3		09JUN2014

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Use the date of death for the 487th subject as the cutoff date(24Mar2015), if the subject died after the cutoff date, they will be event in the sensitivity analysis. Censored records are indicated with ‘+’. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.

Listing 16.2.6.1a
Overall Survival

Treatment Group: Placebo

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [2]	Date of Death	Duration of Overall Survival (Months) [3]	If Censored, Reason [4]	Date of Last Telephone Contact
115-0005/60/M/W2	15MAR2013	07JUN2013	3	16MAY2013	2.1		
115-0006/62/M/W2	11APR2013	31JUL2013	3	31JUL2013	3.7		31JUL2013
115-0007/57/M/W2	19APR2013	25JUN2013	3	23JUN2013	2.2		25JUN2013
115-0010/54/M/A4	14APR2014	21OCT2014	3	21OCT2014	6.4		21OCT2014
121-0003/65/M/BL	01JUL2014	13MAY2015	3	12JAN2015	6.5		13MAY2015
201-0002/76/M/W2	15MAR2012	07OCT2013	3	02OCT2013	18.9		07OCT2013
201-0006/71/M/W2	12JUL2012	11NOV2013	2	10NOV2013	16.2		11NOV2013
201-0007/71/M/W2	26JUL2012	30JUL2014	3	14JUL2014	24.0		30JUL2014
201-0009/65/M/W2	20JUN2013				25.4+	Ongoing	
201-0010/81/F/W2	27JUN2013	27JAN2014	3	26JAN2014	7.1		27JAN2014

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Use the date of death for the 487th subject as the cutoff date(24Mar2015), if the subject died after the cutoff date, they will be event in the sensitivity analysis. Censored records are indicated with '+'. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.

Listing 16.2.6.1a
Overall Survival

Treatment Group: Placebo

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [2]	Date of Death	Duration of Overall Survival (Months) [3]	If Censored, Reason [4]	Date of Last Telephone Contact
201-0014/73/M/W2	17JUL2013	14APR2014	99: Cardiac arrest	18MAR2014	8.2		14APR2014
201-0015/49/M/W2	08AUG2013	30OCT2014	99: Renal failure	28OCT2014	14.9		30OCT2014
201-0022/80/F/W2	09MAY2014				13.6+	Follow-up visit	19JUN2015
203-0004/81/M/W2	30MAR2012	09MAY2013	2	09MAY2013	13.5		09MAY2013
203-0006/76/M/W2	11APR2012	07JUL2012	3	07JUL2012	2.9		
203-0007/59/M/W2	04JUN2012	19OCT2012	3	02OCT2012	4.0		
203-0009/73/M/W2	13SEP2012	07JAN2015	3	07JAN2015	28.2		07JAN2015
203-0010/74/M/W2	26SEP2012				33.1+	Follow-up visit	15JUN2015
203-0014/73/M/W2	23JAN2014	29OCT2014	3	13OCT2014	8.8		29OCT2014

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Use the date of death for the 487th subject as the cutoff date(24Mar2015), if the subject died after the cutoff date, they will be event in the sensitivity analysis. Censored records are indicated with ‘+’. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.

Listing 16.2.6.1a
Overall Survival

Treatment Group: Placebo

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [2]	Date of Death	Duration of Overall Survival (Months) [3]	If Censored, Reason [4]	Date of Last Telephone Contact
203-0016/57/M/W2	04FEB2014	08OCT2014	3	22SEP2014	7.7		08OCT2014
203-0019/68/M/W2	22MAY2014	16SEP2014	3	18AUG2014	3.0		16SEP2014
204-0003/64/M/W2	08JUL2013	20JAN2014	1	08JAN2014	6.2		20JAN2014
204-0004/76/F/W2	15SEP2013	23JUL2014	3	25JUN2014	9.5		23JUL2014
205-0002/71/M/W2	24FEB2012	06JUL2012	3	14JUN2012	3.7		06JUL2012
205-0003/79/M/W2	27MAR2012	17OCT2013	3	18DEC2013	21.1		17OCT2013
205-0005/71/M/W2	20MAR2012	13NOV2012	3	09NOV2012	7.8		06NOV2012
205-0014/70/M/W2	18JUN2013	02OCT2013	3	02NOV2013	4.6		02OCT2013
205-0023/72/M/W2	08NOV2013	25JUN2015	5	10JUN2014	7.2		25JUN2015

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
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[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Use the date of death for the 487th subject as the cutoff date(24Mar2015), if the subject died after the cutoff date, they will be event in the sensitivity analysis. Censored records are indicated with ‘+’. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.

Listing 16.2.6.1a
Overall Survival

Treatment Group: Placebo

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [2]	Date of Death	Duration of Overall Survival (Months) [3]	If Censored, Reason [4]	Date of Last Telephone Contact
205-0026/61/F/W2	09FEB2015				4.2+	Follow-up visit	15JUN2015
205-0028/73/F/W2	27JAN2015	15FEB2015	3	15FEB2015	0.7		
207-0002/71/M/W2	21MAR2012	02OCT2012	3	02OCT2012	6.5		03OCT2012
207-0007/72/M/W2	02JUL2012	04JAN2013	3	04JAN2013	6.2		04JAN2013
207-0012/67/M/W2	21MAR2013	19MAY2014	3	12APR2014	12.9		19MAY2014
207-0016/82/F/W2	10OCT2013	19DEC2014	5	04OCT2014	12.0		14OCT2014
207-0017/81/F/W2	22NOV2013	09APR2014	3	07MAR2014	3.5		
207-0019/55/M/W2	03JUN2014	01AUG2014	3	25JUL2014	1.8		
209-0006/68/M/W2	02MAY2013	17JUL2014	3	16JUL2014	14.7		17JUL2014

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Use the date of death for the 487th subject as the cutoff date(24Mar2015), if the subject died after the cutoff date, they will be event in the sensitivity analysis. Censored records are indicated with '+'. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.

Listing 16.2.6.1a
Overall Survival

Treatment Group: Placebo

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [2]	Date of Death	Duration of Overall Survival (Months) [3]	If Censored, Reason [4]	Date of Last Telephone Contact
209-0011/69/M/W2	03DEC2013				18.7+	Follow-up visit	15JUN2015
209-0014/80/M/W2	17MAR2014				15.3+	Follow-up visit	17JUN2015
210-0003/74/M/W2	04NOV2013	22JUL2014	3	18JUL2014	8.6		22JUL2014
210-0004/71/M/W2	08JAN2014	25AUG2014	3	22AUG2014	7.6		25AUG2014
210-0005/53/M/W2	20FEB2014	15JAN2015	3	23DEC2014	10.2		15JAN2015
210-0006/45/M/W2	23JUN2014	26NOV2014	3	26NOV2014	5.2		28NOV2014
251-0002/69/M/W2	07AUG2013	20NOV2013	5	20NOV2013	3.5		13NOV2013
251-0003/68/M/W2	05NOV2013	22OCT2014	3	26NOV2014	12.9		07JAN2015
252-0001/65/M/A3	08MAY2012	15OCT2012	3	23DEC2012	7.7		15OCT2012

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Use the date of death for the 487th subject as the cutoff date(24Mar2015), if the subject died after the cutoff date, they will be event in the sensitivity analysis. Censored records are indicated with ‘+’. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.

Listing 16.2.6.1a
Overall Survival

Treatment Group: Placebo

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [2]	Date of Death	Duration of Overall Survival (Months) [3]	If Censored, Reason [4]	Date of Last Telephone Contact
252-0004/50/M/A1	28MAY2013	01SEP2013	3	06SEP2013	3.4		12SEP2013
252-0006/64/M/W2	01OCT2013	24APR2015	3	23APR2015	19+	Deaths after the date of the 487th event	24APR2015
252-0008/76/M/W2	27MAY2014	14JAN2015	3	07MAR2015	9.5		14JAN2015
252-0010/56/F/W2	04NOV2014	19MAR2015	3	31MAR2015	4.9+	Deaths after the date of the 487th event	19MAR2015
253-0003/75/M/W2	15JUN2012	26JUN2013	3	30SEP2013	15.8		26JUN2013
253-0004/79/M/W2	07SEP2012	26FEB2013	3	16MAR2013	6.4		26FEB2013

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
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Listing 16.2.6.1a
Overall Survival

Treatment Group: Placebo

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [2]	Date of Death	Duration of Overall Survival (Months) [3]	If Censored, Reason [4]	Date of Last Telephone Contact
253-0005/74/F/W2	02NOV2012	08JAN2013	3	08MAR2013	4.2		08JAN2013
253-0006/63/M/A3	28DEC2012	01SEP2014	3	09SEP2014	20.7		01SEP2014
253-0011/67/M/W2	06OCT2014				9.7+	Ongoing	
253-0012/67/M/W2	08DEC2014	20JAN2015	3	20JAN2015	1.5		
257-0005/66/M/W2	03JAN2013	22MAY2013	3	19MAY2013	4.6		
257-0013/63/M/W2	30MAY2013	07AUG2013	3	07AUG2013	2.3		
257-0020/72/M/A1	27OCT2014	22DEC2014	3	21JAN2015	2.9		
258-0002/69/F/W2	11APR2013	14AUG2014	5	21JUL2014	15.6		14AUG2014
258-0003/67/F/W2	15MAY2013				25.5+	Follow-up visit	17JUN2015

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
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[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Use the date of death for the 487th subject as the cutoff date(24Mar2015), if the subject died after the cutoff date, they will be event in the sensitivity analysis. Censored records are indicated with '+'. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.

Listing 16.2.6.1a
Overall Survival

Treatment Group: Placebo

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [2]	Date of Death	Duration of Overall Survival (Months) [3]	If Censored, Reason [4]	Date of Last Telephone Contact
258-0004/66/M/W2	21MAY2013	21JUN2013	3	23JUN2013	1.1		
258-0006/69/M/W2	15OCT2013	12DEC2013	3	07DEC2013	1.8		
258-0013/59/M/W2	11NOV2014	09APR2015	3	21MAR2015	4.4		09APR2015
259-0003/73/M/W2	11JUN2014	06MAY2015	3	10JUL2015	13.2+	Deaths after the date of the 487th event	
259-0004/52/M/W2	21JUL2014	08SEP2014	3	31DEC2014	5.5		
260-0002/66/M/W2	02OCT2013	14JUL2014	1	24JUL2014	9.9		27AUG2014
301-0001/47/F/A2	01NOV2011	13MAY2013	3	18APR2013	17.8		13MAY2013
301-0003/61/F/A2	01MAR2012	19SEP2012	3	28AUG2012	6.0		19SEP2012

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Use the date of death for the 487th subject as the cutoff date(24Mar2015), if the subject died after the cutoff date, they will be event in the sensitivity analysis. Censored records are indicated with ‘+’. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.

Listing 16.2.6.1a
Overall Survival

Treatment Group: Placebo

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [2]	Date of Death	Duration of Overall Survival (Months) [3]	If Censored, Reason [4]	Date of Last Telephone Contact
301-0008/53/M/A2	04JAN2013	10JUN2013	3	22MAY2013	4.6		10JUN2013
302-0006/49/M/A2	10JAN2012	27MAR2012	3	24MAR2012	2.5		27MAR2012
302-0009/73/M/A2	17APR2012	10JUL2012	3	04JUL2012	2.6		10JUL2012
302-0012/62/M/A2	24APR2012	11OCT2012	3	11OCT2012	5.7		11OCT2012
302-0013/62/M/A2	26MAR2013	17DEC2013	3	14DEC2013	8.8		17DEC2013
302-0020/52/M/A2	21MAY2013	26NOV2013	3	26NOV2013	6.3		26NOV2013
302-0021/75/F/A2	11JUN2013	14FEB2014	3	14FEB2014	8.3		14FEB2014
304-0003/56/F/A2	14MAR2013				27.8+	Follow-up visit	24JUN2015
304-0004/69/M/A2	03JUN2013	07OCT2013	3	25SEP2013	3.8		07OCT2013

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
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Overall Survival

Treatment Group: Placebo

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [2]	Date of Death	Duration of Overall Survival (Months) [3]	If Censored, Reason [4]	Date of Last Telephone Contact
304-0007/72/M/A2	13NOV2013	20OCT2014	99: Terminal statge hepatic encephalopathy	28SEP2014	10.7		20OCT2014
305-0004/79/M/A2	24FEB2012	03JUL2012	3	03JUL2012	4.4		03JUL2012
305-0007/67/M/A2	09MAR2012	08NOV2013	3	08NOV2013	20.3		08NOV2013
305-0015/84/M/A2	06JUL2012	28NOV2012	3	28NOV2012	4.9		24DEC2012
305-0016/78/M/A2	10JUL2012	12NOV2012	3	12NOV2012	4.2		12NOV2012
305-0021/83/F/A2	22NOV2012	28APR2013	3	23MAR2013	4.1		28APR2013
305-0024/69/M/A2	15JAN2013	08AUG2013	3	08AUG2013	6.9		08AUG2013
305-0033/37/F/A2	02JUL2013	22JUL2014	3	19JUL2014	12.8		22JUL2014
305-0035/60/M/A2	28AUG2013	29SEP2014	3	29SEP2014	13.3		29SEP2014

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Use the date of death for the 487th subject as the cutoff date(24Mar2015), if the subject died after the cutoff date, they will be event in the sensitivity analysis. Censored records are indicated with ‘+’. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.

Listing 16.2.6.1a
Overall Survival

Treatment Group: Placebo

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [2]	Date of Death	Duration of Overall Survival (Months) [3]	If Censored, Reason [4]	Date of Last Telephone Contact
305-0046/60/M/A2	07NOV2014				7.4+	Follow-up visit	16JUN2015
306-0004/46/M/A2	21FEB2012	07APR2012	3	07APR2012	1.6		07APR2012
306-0010/69/M/A2	21MAR2012	10APR2013	3	30MAR2013	12.5		10APR2013
306-0013/42/M/A2	16APR2012	18JUN2012	3	18JUN2012	2.1		
306-0015/73/M/A2	17MAY2012	27MAY2013	3	14MAY2013	12.1		23JUL2013
306-0016/58/M/A2	25JUN2012	14OCT2013	3	21SEP2013	15.1		14OCT2013
306-0022/56/M/A2	13NOV2012	04FEB2014	3	03FEB2014	14.9		04FEB2014
306-0028/53/M/A2	28MAR2013	16JAN2014	3	23DEC2013	9.0		16JAN2014

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Use the date of death for the 487th subject as the cutoff date(24Mar2015), if the subject died after the cutoff date, they will be event in the sensitivity analysis. Censored records are indicated with ‘+’. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.

Listing 16.2.6.1a
Overall Survival

Treatment Group: Placebo

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [2]	Date of Death	Duration of Overall Survival (Months) [3]	If Censored, Reason [4]	Date of Last Telephone Contact
306-0045/60/F/A1	20JUN2014	30JUN2015	3	12JUN2015	11.9+	Deaths after the date of the 487th event	30JUN2015
307-0006/72/M/A2	29NOV2011	23DEC2011	3	23DEC2011	0.8		
307-0009/53/M/A2	03JAN2012	12JUN2015	3	29MAR2012	2.9		12JUN2015
307-0012/42/M/A2	07FEB2012	10APR2012	5	10APR2012	2.1		10APR2012
307-0015/75/M/A2	25APR2012	28MAR2013	3	05MAR2013	10.5		28MAR2013
307-0021/68/M/A2	21AUG2012	21FEB2013	3	10FEB2013	5.8		21FEB2013
307-0028/69/F/A2	14JAN2013	01JUL2013	3	15JUN2013	5.1		01JUL2013
307-0034/48/M/A2	13AUG2013	20FEB2014	3	04FEB2014	5.9		20FEB2014

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Use the date of death for the 487th subject as the cutoff date(24Mar2015), if the subject died after the cutoff date, they will be event in the sensitivity analysis. Censored records are indicated with '+'. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.

Listing 16.2.6.1a
Overall Survival

Treatment Group: Placebo

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [2]	Date of Death	Duration of Overall Survival (Months) [3]	If Censored, Reason [4]	Date of Last Telephone Contact
307-0036/76/M/A2	02OCT2013	08JUL2014	3	30JUN2014	9.1		08JUL2014
307-0042/55/M/A2	19JUN2014				11+	Follow-up visit	14MAY2015
308-0002/36/F/A2	31DEC2012	18FEB2014	3	16FEB2014	13.8		18FEB2014
308-0004/52/M/A2	05FEB2013	30APR2015	3	07APR2015	26.4+	Deaths after the date of the 487th event	30APR2015
308-0006/64/M/A2	14MAY2013	28NOV2014	3	14NOV2014	18.3		28NOV2014
308-0008/47/M/A2	23JUL2013	26DEC2013	3	26DEC2013	5.2		26DEC2013
308-0009/61/M/A2	19JUL2013	12SEP2013	99: Sepsis	12SEP2013	1.9		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Use the date of death for the 487th subject as the cutoff date(24Mar2015), if the subject died after the cutoff date, they will be event in the sensitivity analysis. Censored records are indicated with ‘+’. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.

Listing 16.2.6.1a
Overall Survival

Treatment Group: Placebo

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [2]	Date of Death	Duration of Overall Survival (Months) [3]	If Censored, Reason [4]	Date of Last Telephone Contact
309-0006/56/M/A2	26NOV2012	11JUN2015	3	24MAY2015	30.3+	Deaths after the date of the 487th event	11JUN2015
309-0007/58/M/A2	17DEC2012	25JUN2013	3	12JUN2013	5.9		25JUN2013
309-0013/45/M/A2	20JUN2013	24NOV2014	3	17NOV2014	17.2		24NOV2014
309-0014/39/M/A2	20JUN2013	29JAN2014	3	18JAN2014	7.1		29JAN2014
309-0019/68/M/A2	24JUN2014				13.1+	Ongoing	
309-0027/49/M/A2	03NOV2014	17JUN2015	3	12JUN2015	7.4+	Deaths after the date of the 487th event	17JUN2015

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Use the date of death for the 487th subject as the cutoff date(24Mar2015), if the subject died after the cutoff date, they will be event in the sensitivity analysis. Censored records are indicated with '+'. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.

Listing 16.2.6.1a
Overall Survival

Treatment Group: Placebo

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [2]	Date of Death	Duration of Overall Survival (Months) [3]	If Censored, Reason [4]	Date of Last Telephone Contact
309-0029/50/M/A2	01DEC2014	11MAY2015	3	09APR2015	4.3+	Deaths after the date of the 487th event	11MAY2015
310-0004/50/F/A2	06FEB2013	19AUG2013	5	AUG2013	6.5		19AUG2013
310-0005/59/M/A2	27MAR2013	30DEC2013	3	07DEC2013	8.5		30DEC2013
310-0006/50/F/A2	01MAY2013	13OCT2014	3	05OCT2014	17.4		13OCT2014
310-0007/74/M/A2	13JUN2013				24.7+	Follow-up visit	23JUN2015
310-0009/46/M/A2	07AUG2013	24JAN2014	3	10JAN2014	5.2		24JAN2014
310-0010/34/F/A2	26AUG2013	25DEC2013	3	11DEC2013	3.6		25DEC2013

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Use the date of death for the 487th subject as the cutoff date(24Mar2015), if the subject died after the cutoff date, they will be event in the sensitivity analysis. Censored records are indicated with '+'. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.

Listing 16.2.6.1a
Overall Survival

Treatment Group: Placebo

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [2]	Date of Death	Duration of Overall Survival (Months) [3]	If Censored, Reason [4]	Date of Last Telephone Contact
310-0011/52/M/A2	24OCT2013				20.3+	Follow-up visit	23JUN2015
310-0014/64/M/A2	24SEP2014	25JUN2015	3	16JUN2015	8.9+	Deaths after the date of the 487th event	25JUN2015
311-0003/44/M/A2	25SEP2013	03DEC2014	3	22NOV2014	14.1		03DEC2014
311-0004/68/M/A2	30SEP2013	21OCT2013	3	16NOV2013	1.6		
311-0005/58/M/A2	21OCT2013	14AUG2014	3	03AUG2014	9.6		14AUG2014
311-0006/73/F/A2	07NOV2013	19MAR2014	3	16MAR2014	4.3		19MAR2014
311-0009/51/F/A2	15JUL2014				11.3+	Follow-up visit	18JUN2015

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
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Listing 16.2.6.1a
Overall Survival

Treatment Group: Placebo

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [2]	Date of Death	Duration of Overall Survival (Months) [3]	If Censored, Reason [4]	Date of Last Telephone Contact
311-0010/47/M/A2	02SEP2014				10.8+	Ongoing	
311-0011/46/M/A2	30OCT2014				7.7+	Follow-up visit	18JUN2015
311-0012/55/M/A2	29JAN2015				5.8+	Ongoing	
401-0001/70/M/A7	04JUN2013	18AUG2013	3	18AUG2013	2.5		18AUG2013
401-0002/56/M/A7	19JUN2013	07MAY2015	5	21FEB2014	8.3		07MAY2015
402-0001/35/M/A7	22APR2013	24JUN2013	3	03AUG2013	3.5		07FEB2014
402-0002/58/M/A7	23APR2013	10JUN2014	3	08MAY2014	12.7		10JUN2014
402-0005/70/M/A7	09MAY2013	16OCT2013	3	02OCT2013	4.9		16OCT2013
402-0010/50/M/A7	20MAY2013	25JUL2013	3	13JUL2013	1.8		25JUL2013

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
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[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Use the date of death for the 487th subject as the cutoff date(24Mar2015), if the subject died after the cutoff date, they will be event in the sensitivity analysis. Censored records are indicated with ‘+’. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.

Listing 16.2.6.1a
Overall Survival

Treatment Group: Placebo

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [2]	Date of Death	Duration of Overall Survival (Months) [3]	If Censored, Reason [4]	Date of Last Telephone Contact
402-0022/60/F/A7	19AUG2013	03MAR2014	3	03MAR2014	6.6		25MAR2014
402-0023/57/M/A7	02SEP2013	17JAN2014	3	29DEC2013	4.0		17JAN2014
402-0029/49/M/A7	11NOV2013	04JAN2014	3	04JAN2014	1.8		07JAN2014
402-0032/49/F/A7	06DEC2013	01JUL2014	3	19JUN2014	6.5		01JUL2014
402-0034/43/F/A7	19DEC2013				18.3+	Follow-up visit	19JUN2015
403-0004/37/M/A7	11JUL2013	07MAY2015	3	01MAY2015	22+	Deaths after the date of the 487th event	07MAY2015
404-0003/53/M/A7	10SEP2013	07NOV2013	3	20OCT2013	1.4		07NOV2013

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[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Use the date of death for the 487th subject as the cutoff date(24Mar2015), if the subject died after the cutoff date, they will be event in the sensitivity analysis. Censored records are indicated with ‘+’. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.

Listing 16.2.6.1a
Overall Survival

Treatment Group: Placebo

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [2]	Date of Death	Duration of Overall Survival (Months) [3]	If Censored, Reason [4]	Date of Last Telephone Contact
404-0004/62/F/A7	15OCT2013	25DEC2013	3	25DEC2013	2.4		
405-0001/55/M/A7	22APR2013	02APR2014	3	15MAR2014	10.9		02APR2014
405-0005/35/M/A6	24APR2013	20MAY2015	3	01MAY2015	24.6+	Deaths after the date of the 487th event	20MAY2015
405-0012/72/M/A7	15MAY2013	25DEC2013	3	02DEC2013	6.7		26DEC2013
405-0019/62/M/A7	26JUN2013	11AUG2013	3	11AUG2013	1.6		
405-0024/69/M/A7	03JUL2013	05AUG2013	3	05AUG2013	1.1		
405-0026/67/M/A7	08JUL2013	24FEB2014	3	13FEB2014	7.4		24FEB2014
405-0036/70/M/A7	19AUG2013	15JAN2014	3	15JAN2014	5.0		17FEB2014

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
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Overall Survival

Treatment Group: Placebo

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [2]	Date of Death	Duration of Overall Survival (Months) [3]	If Censored, Reason [4]	Date of Last Telephone Contact
405-0041/57/M/A7	13SEP2013				21+	Follow-up visit	03JUN2015
501-0003/22/M/A1	11DEC2013	28JUL2014	3	01JUL2014	6.8		28JUL2014
501-0004/26/M/A1	18DEC2013	08AUG2014	3	31JUL2014	7.5		08AUG2014
501-0011/61/M/A1	25SEP2014	12JAN2015	3	07JAN2015	3.5		12JAN2015
502-0001/70/M/A1	13DEC2013	16JAN2014	2	14JAN2014	1.1		
502-0003/48/M/A1	14JAN2014	05AUG2014	2	10JUL2014	5.9		05AUG2014
503-0002/71/F/A1	20FEB2014	18MAY2015	3	20APR2015	14.2+	Deaths after the date of the 487th event	18MAY2015

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Use the date of death for the 487th subject as the cutoff date(24Mar2015), if the subject died after the cutoff date, they will be event in the sensitivity analysis. Censored records are indicated with ‘+’. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.

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Overall Survival

Treatment Group: Placebo

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [2]	Date of Death	Duration of Overall Survival (Months) [3]	If Censored, Reason [4]	Date of Last Telephone Contact
503-0003/47/F/A1	07MAR2014	15JUL2014	5	JUN2014	3.4		15JUL2014
503-0005/72/M/A1	25MAR2014				15.5+	Follow-up visit	02JUL2015
504-0003/53/M/A1	13MAR2014	09JUN2014	3	16MAY2014	2.2		09JUN2014
504-0005/41/F/A1	03SEP2014	11NOV2014	3	08NOV2014	2.2		
504-0006/51/M/A1	04SEP2014	27MAR2015	3	13MAR2015	6.4		27MAR2015
506-0001/43/M/A1	15APR2014	30JUL2014	3	29JUL2014	3.5		30JUL2014
506-0005/24/M/A1	22DEC2014	26JAN2015	3	20JAN2015	1.0		26JAN2015
507-0001/51/M/A1	24JUL2014				11.5+	Follow-up visit	02JUL2015

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Use the date of death for the 487th subject as the cutoff date(24Mar2015), if the subject died after the cutoff date, they will be event in the sensitivity analysis. Censored records are indicated with ‘+’. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.

Listing 16.2.6.1a
Overall Survival

Treatment Group: Placebo

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [2]	Date of Death	Duration of Overall Survival (Months) [3]	If Censored, Reason [4]	Date of Last Telephone Contact
507-0002/44/M/A1	29JUL2014	10NOV2014	99: Respiratory and circulatory failure	10NOV2014	3.5		10NOV2014
508-0002/64/M/A1	19FEB2014	16APR2014	3	15APR2014	1.9		
508-0004/58/M/A1	27AUG2014	30SEP2014			1.2+	Lost to Follow-up	
509-0003/39/M/A1	24JUL2014	12JAN2015	3	01JAN2015	5.4		12JAN2015
510-0001/67/M/A1	26FEB2014				16.3+	Follow-up visit	30JUN2015
510-0003/43/M/A1	05JUN2014	27NOV2014	5	20NOV2014	5.6		27NOV2014
513-0003/46/M/A1	30APR2014	15JUN2014	5	12JUN2014	1.5		15JUL2014
515-0005/45/M/A1	23JUN2014	10OCT2014	3	04OCT2014	3.5		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Use the date of death for the 487th subject as the cutoff date(24Mar2015), if the subject died after the cutoff date, they will be event in the sensitivity analysis. Censored records are indicated with ‘+’. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.

Listing 16.2.6.1a
Overall Survival

Treatment Group: Placebo

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [2]	Date of Death	Duration of Overall Survival (Months) [3]	If Censored, Reason [4]	Date of Last Telephone Contact
517-0003/45/M/A1	14MAY2014	18MAR2015			10.3+	Lost to Follow-up	29JAN2015
517-0010/67/M/A1	12NOV2014	08APR2015	3	24MAR2015	4.4		08APR2015

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Use the date of death for the 487th subject as the cutoff date(24Mar2015), if the subject died after the cutoff date, they will be event in the sensitivity analysis. Censored records are indicated with ‘+’. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.

Listing 16.2.6.1b
Overall Survival– Sensitivity Analysis

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [2]	Date of Death	Duration of Overall Survival (Months) [3]	If Censored, Reason	Date of Last Telephone Contact
101-0001/59/M/A2	26JUL2011	20FEB2012			7+	Voluntary Withdrawal	20FEB2012
101-0005/77/M/W2	08AUG2011	17APR2013	3	17APR2013	20.6		17APR2013
101-0006/62/M/W2	12AUG2011	17APR2012	3	17APR2012	8.3		17APR2012
101-0007/77/M/A1	16AUG2011	11MAY2013	3	11MAY2013	21.2		16MAY2013
101-0008/83/M/BL	22AUG2011	11AUG2012	3	11AUG2012	11.9		11AUG2012
101-0009/82/M/A1	14SEP2011	05SEP2012	3	05SEP2012	11.9		05SEP2012
101-0011/75/F/W2	14NOV2011	03JAN2012	3	16DEC2011	1.1		03JAN2012
101-0012/68/M/W2	29NOV2011	20AUG2012	3	02AUG2012	8.3		20AUG2012
101-0013/66/F/A5	10JAN2012	17JUL2014	3	14JUL2014	30.6		17JUL2014

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Censored records are indicated with '+'. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.
Cut-off date: 22JUL2015.

Listing 16.2.6.1b
Overall Survival– Sensitivity Analysis

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [2]	Date of Death	Duration of Overall Survival (Months) [3]	If Censored, Reason	Date of Last Telephone Contact
101-0016/61/M/A4	10JAN2012				41.8+	Follow-up visit	16JUN2015
101-0018/51/M/A1	21FEB2012	31MAR2012	3	31MAR2012	1.3		12FEB2013
101-0019/68/M/W2	28FEB2012	14MAY2013	5	20MAR2014	25.1		20MAR2014
101-0021/74/M/W2	20MAR2012	10JUN2013	3	10JUN2013	14.9		17JUL2013
101-0022/55/M/BL	20MAR2012	04JUN2012	3	31MAY2012	2.4		04JUN2012
101-0023/70/M/W2	30MAR2012	18DEC2012	5	18DEC2012	8.8		18DEC2012
101-0024/35/F/A4	01MAY2012	07NOV2013	3	05NOV2013	18.5		07NOV2013
101-0025/57/F/W2	20APR2012	03AUG2012	3	03AUG2012	3.5		03AUG2012
101-0026/82/M/W2	15MAY2012	17MAY2013	3	16MAY2013	12.2		17MAY2013

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Censored records are indicated with '+'. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.
Cut-off date: 22JUL2015.

Listing 16.2.6.1b
Overall Survival– Sensitivity Analysis

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [2]	Date of Death	Duration of Overall Survival (Months) [3]	If Censored, Reason	Date of Last Telephone Contact
101-0028/60/M/W2	15JUN2012	02APR2013	3	02APR2013	9.7		25APR2013
101-0029/70/M/A1	18JUN2012	02AUG2013	3	02AUG2013	13.7		02AUG2013
101-0030/51/M/W2	05JUL2012	27NOV2012	3	20DEC2012	5.6		20DEC2012
101-0032/84/M/W2	01AUG2012	12SEP2013	5	06JUL2013	11.3		12SEP2013
101-0033/66/F/W2	03AUG2012				35.2+	Follow-up visit	25JUN2015
101-0036/68/M/A4	23OCT2012	05FEB2013	3	05FEB2013	3.5		05FEB2013
101-0037/57/M/A1	07DEC2012	06APR2015			28.4+	Lost to Follow-up	01DEC2014
101-0038/56/M/W2	05FEB2013	01FEB2014	3	01FEB2014	12.1		01FEB2014

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Censored records are indicated with '+'. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.
Cut-off date: 22JUL2015.

Listing 16.2.6.1b
Overall Survival– Sensitivity Analysis

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [2]	Date of Death	Duration of Overall Survival (Months) [3]	If Censored, Reason	Date of Last Telephone Contact
101-0039/77/F/W2	05APR2013				27.1+	Follow-up visit	26JUN2015
101-0040/60/M/W2	27JUN2013	04NOV2013	3	03NOV2013	4.3		04NOV2013
101-0041/54/M/W2	30JUL2013	25NOV2014	3	24NOV2014	16.1		25NOV2014
101-0042/64/M/W2	05AUG2013	12OCT2014	3	12OCT2014	14.5		12OCT2014
101-0044/78/M/W2	17OCT2013	24OCT2014	5	24OCT2014	12.4		24OCT2014
101-0045/74/F/W2	21OCT2013	03JUN2014	5	26APR2014	6.3		03JUN2014
101-0046/70/M/OTH	22OCT2013	04JUN2014	3	28MAR2014	5.3		04JUN2014
101-0047/52/M/W2	22OCT2013	11MAR2015	3	26FEB2015	16.4		01DEC2014
101-0048/66/F/W2	22OCT2013				20.4+	Follow-up visit	25JUN2015

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Censored records are indicated with '+'. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.
Cut-off date: 22JUL2015.

Listing 16.2.6.1b
Overall Survival– Sensitivity Analysis

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [2]	Date of Death	Duration of Overall Survival (Months) [3]	If Censored, Reason	Date of Last Telephone Contact
101-0049/71/M/A8	28OCT2013				20.2+	Follow-up visit	24JUN2015
101-0050/59/M/W2	29OCT2013	15JAN2014	3	15JAN2014	2.6		
102-0001/53/M/BL	25APR2012	07SEP2012	3	09NOV2012	6.6		07SEP2012
102-0003/63/M/BL	12SEP2012	07JAN2013	3	25JAN2013	4.5		07FEB2013
102-0008/64/M/BL	08JAN2014	05FEB2014	5	10FEB2014	1.1		
102-0009/58/M/W2	29OCT2014	19FEB2015	3	04FEB2015	3.3		19FEB2015
103-0001/56/M/W2	11MAY2012	23OCT2012	3	23OCT2012	5.5		23OCT2012
103-0003/66/M/W2	15FEB2013	26OCT2013	3	26OCT2013	8.5		26OCT2013
103-0004/40/F/A1	17APR2014	01SEP2014	3	01SEP2014	4.6		01SEP2014

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Censored records are indicated with '+'. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.
Cut-off date: 22JUL2015.

Listing 16.2.6.1b
Overall Survival– Sensitivity Analysis

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [2]	Date of Death	Duration of Overall Survival (Months) [3]	If Censored, Reason	Date of Last Telephone Contact
104-0003/56/F/W2	19JUL2012	29OCT2012	3	19OCT2012	3.1		29OCT2012
104-0004/74/M/W2	23OCT2012	12JUN2013	3	24MAY2013	7.1		12JUN2013
104-0008/55/M/PI	03SEP2013	14OCT2014	3	11SEP2014	12.5		14OCT2014
104-0010/71/F/A8	08JAN2014				17.1+	Follow-up visit	03JUN2015
104-0012/78/F/A2	02OCT2014	25MAR2015	3	25MAR2015	5.8		25MAR2015
106-0001/42/F/W2	28FEB2012	02JUL2012	3	05OCT2012	7.4		
107-0002/71/M/W2	23AUG2012	23DEC2013	3	23DEC2013	16.3		23DEC2013
107-0003/73/M/BL	22FEB2013	07MAY2013	3	07MAY2013	2.5		
107-0004/63/M/W2	01MAR2013				28.4+	Follow-up visit	29JUN2015

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Censored records are indicated with '+'. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.
Cut-off date: 22JUL2015.

Listing 16.2.6.1b
Overall Survival– Sensitivity Analysis

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [2]	Date of Death	Duration of Overall Survival (Months) [3]	If Censored, Reason	Date of Last Telephone Contact
107-0006/60/M/W2	14MAY2013	07APR2014	3	04APR2014	10.9		07APR2014
108-0001/60/F/W2	20MAR2012	19JUN2012	3	19JUN2012	3.1		19JUN2012
108-0002/78/M/BL	31MAY2012	03APR2013	3	03APR2013	10.3		03APR2013
108-0004/61/M/W2	18APR2013	07JUL2014	3	22JUL2014	15.4		04AUG2014
108-0005/68/M/W2	08MAY2013	19OCT2013	99: Basilar artery pseudoaneurysm	19OCT2013	5.5		19OCT2013
108-0008/77/M/W2	09OCT2014				8+	Follow-up visit	04JUN2015
109-0003/68/M/W2	03MAY2013	08AUG2013	3	09AUG2013	3.3		17SEP2013
109-0004/57/M/W2	19JUL2013	14MAR2014	3	22FEB2014	7.3		14MAR2014
109-0006/62/M/PI	22AUG2013	16SEP2014	3	25AUG2014	12.3		16SEP2014

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Censored records are indicated with '+'. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.
Cut-off date: 22JUL2015.

Listing 16.2.6.1b
Overall Survival– Sensitivity Analysis

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [2]	Date of Death	Duration of Overall Survival (Months) [3]	If Censored, Reason	Date of Last Telephone Contact
109-0007/55/M/W2	05DEC2013	16SEP2014	3	10AUG2014	8.3		16SEP2014
109-0008/70/F/W2	22MAY2014				12.7+	Follow-up visit	05JUN2015
109-0009/57/M/W2	09JUL2014	10JUN2015	3	25MAY2015	10.7		10JUN2015
109-0010/65/M/W2	09JUL2014				11.5+	Follow-up visit	18JUN2015
109-0011/64/M/A4	24SEP2014				8.7+	Follow-up visit	12JUN2015
109-0013/64/F/W2	05NOV2014	12MAY2015	3	10MAY2015	6.2		
110-0003/63/M/OTH	09JUL2012	07DEC2013	3	01DEC2013	17.0		07DEC2013
110-0004/53/M/A4	25OCT2012	03DEC2013	3	23NOV2013	13.2		03DEC2013

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Censored records are indicated with '+'. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.
Cut-off date: 22JUL2015.

Listing 16.2.6.1b
Overall Survival– Sensitivity Analysis

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [2]	Date of Death	Duration of Overall Survival (Months) [3]	If Censored, Reason	Date of Last Telephone Contact
110-0005/77/M/W2	15MAR2013				27.3+	Follow-up visit	11JUN2015
110-0007/62/M/A4	17MAY2013	26FEB2014	3	26FEB2014	9.5		07MAR2014
110-0008/63/F/BL	09JUL2013	03MAR2014	3	10FEB2014	7.2		03MAR2014
110-0011/77/M/A1	22JAN2015				4.6+	Follow-up visit	09JUN2015
111-0001/37/M/A4	12JUL2012	08JUL2014	3	06JUL2014	24.2		08JUL2014
111-0004/64/M/W2	23MAY2013	18OCT2013	3	29AUG2013	3.3		21OCT2013
111-0006/59/M/W2	03OCT2013	12MAY2014	2	12MAY2014	7.4		
111-0007/55/M/W2	06FEB2014				16.4+	Follow-up visit	12JUN2015

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Censored records are indicated with '+'. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.
Cut-off date: 22JUL2015.

Listing 16.2.6.1b
Overall Survival– Sensitivity Analysis

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [2]	Date of Death	Duration of Overall Survival (Months) [3]	If Censored, Reason	Date of Last Telephone Contact
112-0006/58/M/W2	26MAR2013	29AUG2013	3	29AUG2013	5.2		07AUG2013
112-0009/50/M/A8	19JUN2013	06DEC2013	3	12DEC2013	5.9		01NOV2013
112-0011/56/M/A4	10JAN2014	23JUN2014	3	28JUN2014	5.7		06JUN2014
112-0012/71/M/W2	23MAY2014	07FEB2015	3	07FEB2015	8.7		02FEB2015
112-0013/28/F/W2	23MAY2014	29AUG2014	3	29OCT2014	5.3		
112-0014/79/M/A8	06JUN2014	24OCT2014	3	24OCT2014	4.7		13OCT2014
112-0015/66/M/A8	24OCT2014	02JAN2015	3	02JAN2015	2.4		
113-0001/61/M/W2	24AUG2012	18NOV2013	5	20JAN2014	17.2		26AUG2013
113-0002/64/F/W2	12OCT2012	22APR2014	3	11APR2014	18.2		22APR2014
113-0005/58/M/W2	22JAN2014	20MAR2014	3	05APR2014	2.5		30APR2014

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Censored records are indicated with '+'. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.
Cut-off date: 22JUL2015.

Listing 16.2.6.1b
Overall Survival– Sensitivity Analysis

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [2]	Date of Death	Duration of Overall Survival (Months) [3]	If Censored, Reason	Date of Last Telephone Contact
113-0008/78/M/A8	13FEB2014				16.3+	Follow-up visit	16JUN2015
113-0010/59/M/W2	28APR2014	04JUN2014	3	22JUN2014	1.9		07JUL2014
113-0013/56/M/W2	04NOV2014				7.3+	Follow-up visit	10JUN2015
113-0016/72/M/A8	03FEB2015				4.5+	Follow-up visit	17JUN2015
114-0003/59/M/W2	29NOV2012	07OCT2013	3	07OCT2013	10.4		16SEP2013
114-0005/73/M/W2	05DEC2013	09APR2015			16.4+	Voluntary Withdrawal	09APR2015
114-0007/60/F/W2	18NOV2014				8.2+	Ongoing	

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Censored records are indicated with '+'. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.
Cut-off date: 22JUL2015.

Listing 16.2.6.1b
Overall Survival– Sensitivity Analysis

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [2]	Date of Death	Duration of Overall Survival (Months) [3]	If Censored, Reason	Date of Last Telephone Contact
115-0001/59/F/A4	27NOV2012				30.6+	Follow-up visit	02JUN2015
115-0002/45/F/W2	27NOV2012	19FEB2013	3	18FEB2013	2.8		19FEB2013
115-0003/63/M/W2	17JAN2013	20AUG2013	3	17AUG2013	7.1		20AUG2013
115-0008/51/M/A8	19JUN2013	22JUL2013	3	17JUL2013	1.0		
115-0009/85/M/W2	12DEC2013	03SEP2014	3	01SEP2014	8.8		03SEP2014
115-0011/56/M/W2	05JUN2014	01DEC2014	3	27NOV2014	5.9		01DEC2014
115-0014/72/M/W2	10FEB2015	11MAY2015	3	10MAY2015	3.0		11MAY2015
116-0002/67/F/W2	18MAR2013	14DEC2013	3	14DEC2013	9.1		
116-0003/67/M/BL	28MAR2013	29MAY2013	3	29MAY2013	2.1		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Censored records are indicated with '+'. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.
Cut-off date: 22JUL2015.

Listing 16.2.6.1b
Overall Survival– Sensitivity Analysis

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [2]	Date of Death	Duration of Overall Survival (Months) [3]	If Censored, Reason	Date of Last Telephone Contact
117-0001/69/M/W2	02APR2013	12NOV2014	5	08NOV2014	19.5		12NOV2014
118-0001/67/F/A8	09AUG2013	29NOV2014	3	29NOV2014	15.9		17NOV2014
119-0001/80/M/A8	21JAN2014	14FEB2014	5		0.8		29AUG2014
121-0001/62/M/W2	14FEB2014	02DEC2014			9.7+	Voluntary Withdrawal	02DEC2014
121-0004/64/F/W2	02JAN2015	15APR2015	3	06MAR2015	2.1		15APR2015
201-0001/68/F/W2	25JAN2012	08OCT2012	99: Cardiac arrest	24SEP2012	8.1		08OCT2012
201-0005/73/M/W2	19JUL2012	21JAN2013	99: Cardiac arrest	14JAN2013	6.0		21JAN2013
201-0008/79/M/W2	16MAY2013	21OCT2013	3	15OCT2013	5.1		21OCT2013
201-0011/73/M/W2	04JUL2013				23.9+	Follow-up visit	19JUN2015

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Censored records are indicated with '+'. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.
Cut-off date: 22JUL2015.

Listing 16.2.6.1b
Overall Survival– Sensitivity Analysis

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [2]	Date of Death	Duration of Overall Survival (Months) [3]	If Censored, Reason	Date of Last Telephone Contact
201-0012/79/M/W2	24JUL2013				23.2+	Follow-up visit	19JUN2015
201-0013/67/F/W2	24JUL2013	20MAY2014	99: Cardiac arrest	19MAY2014	10.0		20MAY2014
201-0016/72/M/W2	14NOV2013	19MAY2015	99: Cardiocirculatory arrest	30APR2015	17.8		19MAY2015
201-0017/82/M/W2	28NOV2013	26MAR2015	99: Cardiac arrest	05MAR2015	15.4		26MAR2015
201-0018/78/F/W2	06DEC2013	27JAN2014	99: Acute renal failure	21JAN2014	1.6		27JAN2014
201-0019/68/M/W2	19DEC2013				18.3+	Follow-up visit	19JUN2015

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Censored records are indicated with '+'. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.
Cut-off date: 22JUL2015.

Listing 16.2.6.1b
Overall Survival– Sensitivity Analysis

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [2]	Date of Death	Duration of Overall Survival (Months) [3]	If Censored, Reason	Date of Last Telephone Contact
201-0020/67/M/W2	23JAN2014				17.2+	Follow-up visit	22JUN2015
201-0021/54/M/W2	13FEB2014	02JUL2014	99: Block of diuresis	10JUN2014	3.9		02JUL2014
201-0024/74/M/W2	29JAN2015	13APR2015	99: Respiratory failure	11APR2015	2.4		
201-0025/75/M/W2	29JAN2015				4.7+	Follow-up visit	19JUN2015
203-0001/61/F/W2	06MAR2012	30APR2012	3	06JUN2012	3.1		
203-0002/72/M/W2	06MAR2012	19APR2012	3	19APR2012	1.5		
203-0005/53/M/W2	05APR2012	23DEC2014	3	26JUN2013	14.9		03JUL2013
203-0013/68/M/W2	30DEC2013	30APR2014	3	17MAR2014	2.6		30APR2014

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Censored records are indicated with '+'. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.
Cut-off date: 22JUL2015.

Listing 16.2.6.1b
Overall Survival– Sensitivity Analysis

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [2]	Date of Death	Duration of Overall Survival (Months) [3]	If Censored, Reason	Date of Last Telephone Contact
203-0015/85/M/W2	30JAN2014	19SEP2014	3	01JUN2014	4.1		19SEP2014
203-0017/58/M/W2	03MAR2014	29AUG2014	3	29AUG2014	6.0		29AUG2014
203-0018/58/F/W2	04APR2014	22SEP2014	3	24JUL2014	3.7		22SEP2014
205-0001/77/M/W2	24FEB2012	26NOV2014	3	06NOV2014	32.9		26NOV2014
205-0004/77/F/W2	20MAR2012	24JUN2012	3	24JUN2012	3.2		
205-0008/76/M/W2	27APR2012	30JUL2012	3	30JUL2012	3.2		01AUG2012
205-0012/73/F/W2	06DEC2012	08JAN2013	2	08JAN2013	1.1		
205-0015/71/M/W2	19JUN2013	11SEP2014	5	22JUN2014	12.3		11SEP2014
205-0016/70/M/W2	25JUN2013				25.3+	Ongoing	
205-0017/71/M/W2	08AUG2013	18AUG2014	3	18AUG2014	12.5		18AUG2014

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Censored records are indicated with '+'. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.
Cut-off date: 22JUL2015.

Listing 16.2.6.1b
Overall Survival– Sensitivity Analysis

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [2]	Date of Death	Duration of Overall Survival (Months) [3]	If Censored, Reason	Date of Last Telephone Contact
205-0020/82/M/W2	11OCT2013	24JUN2015	5	18MAY2014	7.3		24JUN2015
205-0022/67/M/W2	05NOV2013	28NOV2013	2	22NOV2013	0.6		28NOV2013
205-0024/80/M/W2	03DEC2013	20AUG2014	99: Bleeding in hypertensive gastropathy	16AUG2014	8.6		20AUG2014
205-0025/63/F/W2	29NOV2013	21MAR2014	99: Pleural effusion	21MAR2014	3.8		11MAR2014
207-0001/81/F/W2	19MAR2012	21DEC2012	3	23OCT2012	7.3		21DEC2012
207-0005/74/M/W2	12JUN2012	04JUL2012			0.8+	Voluntary Withdrawal	
207-0006/73/M/W2	18JUN2012	19SEP2012	3	03OCT2012	3.6		14NOV2012
207-0008/66/M/W2	09JUL2012	13AUG2012	3	28AUG2012	1.7		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Censored records are indicated with '+'. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.
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Listing 16.2.6.1b
Overall Survival– Sensitivity Analysis

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [2]	Date of Death	Duration of Overall Survival (Months) [3]	If Censored, Reason	Date of Last Telephone Contact
207-0011/78/M/W2	21JAN2013	26FEB2013	3	06MAR2013	1.5		26FEB2013
207-0015/77/M/W2	13AUG2013	16OCT2014	3	02OCT2014	13.9		16OCT2014
207-0020/77/M/W2	18JUN2014	29SEP2014	3	17SEP2014	3.1		
207-0021/74/M/W2	19JUN2014	10APR2015	3	30MAR2015	9.5		10APR2015
207-0022/74/M/W2	10JUL2014				11.7+	Follow-up visit	25JUN2015
208-0001/59/M/W2	20SEP2012				34.5+	Ongoing	
208-0002/82/F/W2	20SEP2012	08MAR2013	3	08MAR2013	5.7		05MAR2013
208-0006/69/F/W2	28AUG2013	30AUG2014	3	20JUL2014	10.9		30AUG2014
208-0007/53/M/W2	07JUL2014				11.1+	Follow-up visit	04JUN2015

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Censored records are indicated with '+'. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.
Cut-off date: 22JUL2015.

Listing 16.2.6.1b
Overall Survival– Sensitivity Analysis

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [2]	Date of Death	Duration of Overall Survival (Months) [3]	If Censored, Reason	Date of Last Telephone Contact
209-0001/66/M/W2	15NOV2012	18APR2013	3	04MAY2013	5.7		18APR2013
209-0004/74/M/W2	09APR2013	15OCT2013	3	26OCT2013	6.7		15OCT2013
209-0008/66/M/W2	11JUL2013	25OCT2013	3	01NOV2013	3.8		
209-0012/63/M/W2	03DEC2013	06AUG2014	3	04AUG2014	8.2		06AUG2014
209-0013/52/M/W2	23DEC2013				18.1+	Follow-up visit	17JUN2015
210-0001/67/M/W2	30AUG2013	07MAY2014	3	30APR2014	8.1		07MAY2014
210-0002/80/M/W2	09OCT2013	27MAY2015	3	20MAY2015	19.6		15MAY2015
210-0007/73/M/W2	07JUL2014				12.7+	Ongoing	
210-0009/49/F/W2	10NOV2014				7.4+	Follow-up visit	18JUN2015

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Censored records are indicated with '+'. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.
Cut-off date: 22JUL2015.

Listing 16.2.6.1b
Overall Survival– Sensitivity Analysis

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [2]	Date of Death	Duration of Overall Survival (Months) [3]	If Censored, Reason	Date of Last Telephone Contact
210-0011/73/M/W2	17NOV2014	06MAR2015	3	04MAR2015	3.6		06MAR2015
210-0012/47/F/W2	16DEC2014				6.2+	Follow-up visit	18JUN2015
210-0014/71/F/W2	26JAN2015				4.8+	Follow-up visit	18JUN2015
251-0001/55/F/W2	24JUL2012	06DEC2012	3	26DEC2012	5.2		
252-0002/76/M/W2	28AUG2012	17DEC2012	3	26MAY2013	9.1		17DEC2012
252-0003/68/M/W2	28DEC2012	22AUG2013	3	24AUG2013	8.0		22AUG2013
252-0007/77/M/W2	25FEB2014	04APR2014	3	03MAY2014	2.3		
252-0011/81/M/BL	24NOV2014				8+	Ongoing	
253-0002/63/M/W2	09MAR2012	08JUN2012	3	09AUG2012	5.1		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
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[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Censored records are indicated with '+'. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.
Cut-off date: 22JUL2015.

Listing 16.2.6.1b
Overall Survival– Sensitivity Analysis

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [2]	Date of Death	Duration of Overall Survival (Months) [3]	If Censored, Reason	Date of Last Telephone Contact
253-0010/76/M/W2	07JUN2013	06MAY2014	3	30MAY2014	11.9		06MAY2014
254-0001/69/M/W2	17MAY2012	04DEC2012	3	04DEC2012	6.7		05DEC2012
257-0001/47/M/A4	04APR2012	10SEP2012	3	10SEP2012	5.3		14AUG2012
257-0002/56/M/W2	18APR2012	22DEC2012	3	22DEC2012	8.3		22DEC2012
257-0007/80/M/W2	21FEB2013	20JAN2014	3	20JAN2014	11.1		
257-0008/80/F/W2	26MAR2013	06JUN2014	3	06JUN2014	14.6		04MAR2014
257-0010/42/M/BL	23MAY2013				24+	Follow-up visit	13MAY2015

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Censored records are indicated with '+'. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.
Cut-off date: 22JUL2015.

Listing 16.2.6.1b
Overall Survival– Sensitivity Analysis

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [2]	Date of Death	Duration of Overall Survival (Months) [3]	If Censored, Reason	Date of Last Telephone Contact
257-0012/76/M/W2	13MAY2013	25JUN2013	99: 1A.Sepsis, 1B.HCC, 2.ALD. death certificate indicates all to be applicable.	25JUN2013	1.5		
257-0015/69/F/BL	14APR2014	25MAY2014	3	25MAY2014	1.4		
257-0017/74/M/A8	02MAY2014	10JUL2015	3	10JUL2015	14.5		29JUN2015
257-0018/53/M/A6	28APR2014	31MAY2014	3	31MAY2014	1.1		
257-0022/60/M/W2	01DEC2014	29MAY2015	3	29MAY2015	6.0		19MAY2015
257-0024/75/M/W2	22DEC2014	31MAR2015	3	31MAR2015	3.3		
257-0025/69/M/BL	22DEC2014	30APR2015	3	30APR2015	4.3		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Censored records are indicated with '+'. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.
Cut-off date: 22JUL2015.

Listing 16.2.6.1b
Overall Survival– Sensitivity Analysis

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [2]	Date of Death	Duration of Overall Survival (Months) [3]	If Censored, Reason	Date of Last Telephone Contact
257-0026/65/M/W2	19JAN2015				5.4+	Follow-up visit	30JUN2015
257-0027/52/M/A6	19JAN2015	02MAR2015	99: Spontaneous intracerebral haemorrhage into metastatic brain tumour	02MAR2015	1.4		
258-0005/64/M/OTH	09AUG2013	02MAY2014	3	16MAY2014	9.4		02MAY2014
258-0007/74/M/W2	09OCT2013	14NOV2013	3	23NOV2013	1.5		
258-0008/70/M/W2	18NOV2013	03MAR2014	3	26MAR2014	4.3		03MAR2014
258-0009/64/M/W2	19MAY2014	16MAR2015	3	30APR2015	11.6		16MAR2015

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[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Censored records are indicated with '+'. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.
Cut-off date: 22JUL2015.

Listing 16.2.6.1b
Overall Survival– Sensitivity Analysis

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [2]	Date of Death	Duration of Overall Survival (Months) [3]	If Censored, Reason	Date of Last Telephone Contact
258-0010/53/M/W2	02JUN2014				12.2+	Follow-up visit	03JUN2015
258-0012/66/F/W2	15JUL2014	18MAR2015	3	09APR2015	9.0		15APR2015
258-0015/65/M/W2	02DEC2014				6.9+	Follow-up visit	26JUN2015
259-0001/68/F/W2	03JUN2013				24.9+	Follow-up visit	18JUN2015
259-0002/54/F/W2	09SEP2013	06JUL2014	3	06JUL2014	10.0		30JUN2014
260-0003/81/M/A7	05NOV2014				8.7+	Ongoing	
301-0005/61/M/A2	24MAY2012	14DEC2012	3	24NOV2012	6.2		14DEC2012
301-0007/55/F/A2	04JAN2013	28MAR2013	2	26MAR2013	2.7		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Censored records are indicated with '+'. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.
Cut-off date: 22JUL2015.

Listing 16.2.6.1b
Overall Survival– Sensitivity Analysis

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [2]	Date of Death	Duration of Overall Survival (Months) [3]	If Censored, Reason	Date of Last Telephone Contact
301-0009/55/M/A2	11JAN2013	11MAY2013	3	01MAY2013	3.7		11MAY2013
302-0002/32/F/A2	07NOV2011	15DEC2011	3	15DEC2011	1.3		
302-0004/57/M/A2	10JAN2012	21MAR2012	3	21MAR2012	2.4		
302-0007/76/M/A2	14FEB2012	25MAR2013	3	23MAR2013	13.5		25MAR2013
302-0008/37/M/A2	28FEB2012	07SEP2012	3	07SEP2012	6.4		07SEP2012
302-0010/45/M/A2	17APR2012	08DEC2012	3	08DEC2012	7.9		08DEC2012
302-0011/52/M/A2	24APR2012	06JUN2012	3	06JUN2012	1.5		06JUN2012
302-0015/60/M/A2	16APR2013	10MAR2014	3	10MAR2014	11.0		10MAR2014
302-0016/60/M/A2	16APR2013	28JAN2014	3	28JAN2014	9.6		28JAN2014
302-0019/52/M/A2	14MAY2013	20MAY2014	3	20MAY2014	12.4		28MAY2014

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
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[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Censored records are indicated with '+'. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.
Cut-off date: 22JUL2015.

Listing 16.2.6.1b
Overall Survival– Sensitivity Analysis

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [2]	Date of Death	Duration of Overall Survival (Months) [3]	If Censored, Reason	Date of Last Telephone Contact
302-0022/65/M/A2	09JUL2013	05OCT2013	3	05OCT2013	3.0		
302-0023/68/M/A2	10SEP2013	07SEP2014	3	07SEP2014	12.1		07SEP2014
302-0024/66/F/A2	24SEP2013	09APR2015	3	09APR2015	18.8		09APR2015
302-0025/40/M/A2	22OCT2013	06JUL2014	3	06JUL2014	8.6		06JUL2014
302-0026/49/M/A2	12NOV2013				19.5+	Follow-up visit	18JUN2015
303-0001/50/M/A2	03FEB2012	18FEB2013	3	18FEB2013	12.7		18FEB2013
303-0003/47/M/A2	28NOV2012	25APR2013	3	20APR2013	4.8		25APR2013
303-0004/18/M/A2	10DEC2012	14MAY2013	3	10MAY2013	5.1		14MAY2013
303-0006/64/M/A2	10APR2013	25JUL2013	3	25JUL2013	3.6		25JUL2013

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
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[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Censored records are indicated with '+'. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.
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Listing 16.2.6.1b
Overall Survival– Sensitivity Analysis

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [2]	Date of Death	Duration of Overall Survival (Months) [3]	If Censored, Reason	Date of Last Telephone Contact
303-0007/50/M/A2	24JUL2013	25OCT2013	3	25OCT2013	3.1		
304-0001/54/M/A2	05NOV2012	04MAR2013	3	08FEB2013	3.2		04MAR2013
304-0005/58/M/A2	05JUN2013	05JUL2013	3	05JUL2013	1.0		
305-0002/57/M/A2	14FEB2012	23DEC2013	3	23DEC2013	22.6		23DEC2013
305-0003/50/M/A2	15FEB2012	07AUG2013	3	07AUG2013	18.0		07AUG2013
305-0005/48/M/A2	21FEB2012	30JUN2015	3	09MAY2012	2.6		30JUN2015
305-0006/65/M/A2	08MAR2012	22OCT2012	1	22OCT2012	7.6		22OCT2012
305-0009/45/F/A2	11APR2012	01AUG2014	3	15JUL2014	27.5		01AUG2014
305-0010/64/F/A2	18APR2012	16SEP2013	3	30AUG2013	16.7		16SEP2013
305-0011/68/M/A2	27APR2012	14DEC2012	3	26NOV2012	7.1		14DEC2012

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Censored records are indicated with '+'. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.
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Listing 16.2.6.1b
Overall Survival– Sensitivity Analysis

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [2]	Date of Death	Duration of Overall Survival (Months) [3]	If Censored, Reason	Date of Last Telephone Contact
305-0012/62/F/A2	04MAY2012				38.4+	Follow-up visit	29JUN2015
305-0014/61/F/A2	10JUL2012	09MAR2013	3	09MAR2013	8.1		09MAR2013
305-0019/35/M/A2	11SEP2012	16NOV2012	2	13NOV2012	2.1		16NOV2012
305-0023/54/M/A2	02JAN2013	24SEP2013	3	03SEP2013	8.2		24SEP2013
305-0025/77/F/A2	22JAN2013	02AUG2013	3	02AUG2013	6.4		05AUG2013
305-0026/45/M/A2	26FEB2013	20DEC2013	2	20DEC2013	9.9		20DEC2013
305-0028/73/F/A2	15MAR2013	16JUN2013	3	16JUN2013	3.1		
305-0030/61/M/A2	02APR2013	26JUN2014	5	26JUN2014	15.0		26JUN2014
305-0031/29/M/A2	02APR2013	13MAY2013	3	13MAY2013	1.4		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Censored records are indicated with '+'. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.
Cut-off date: 22JUL2015.

Listing 16.2.6.1b
Overall Survival– Sensitivity Analysis

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [2]	Date of Death	Duration of Overall Survival (Months) [3]	If Censored, Reason	Date of Last Telephone Contact
305-0034/53/M/A2	03JUL2013	24AUG2013	3	24AUG2013	1.8		
305-0036/38/M/A2	05SEP2013	22MAY2014			8.7+	Lost to Follow-up	22MAY2014
305-0037/50/M/A2	24OCT2013	30JUL2014	3	24JUN2014	8.1		30JUL2014
305-0039/36/M/A2	28NOV2013	26DEC2013	3	26DEC2013	1.0		
305-0040/61/M/A2	15NOV2013	27JUN2014	5	26JUN2014	7.5		27JUN2014
305-0043/70/M/A2	01JUL2014				11.7+	Follow-up visit	17JUN2015
305-0044/67/M/A2	08JUL2014				11.7+	Follow-up visit	22JUN2015
305-0045/65/M/A2	17OCT2014	05DEC2014	3	05DEC2014	1.7		05DEC2014

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Censored records are indicated with '+'. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.
Cut-off date: 22JUL2015.

Listing 16.2.6.1b
Overall Survival– Sensitivity Analysis

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [2]	Date of Death	Duration of Overall Survival (Months) [3]	If Censored, Reason	Date of Last Telephone Contact
305-0047/58/M/A2	25DEC2014	28JAN2015	3	28JAN2015	1.2		
305-0048/55/M/A2	24FEB2015				5+	Ongoing	
306-0001/56/M/A2	17FEB2012	18NOV2013	3	04NOV2013	20.9		18NOV2013
306-0002/73/M/A2	14FEB2012	10SEP2012	99: Left occipital lobar hemorrhage with intraventricular hemorrhage	21AUG2012	6.3		10SEP2012
306-0005/69/F/A2	24FEB2012	31JUL2012	3	29JUL2012	5.2		31JUL2012
306-0006/43/M/A2	20MAR2012	14MAY2012	3	14MAY2012	1.9		09JUN2015
306-0007/56/M/A2	05MAR2012	29NOV2012	3	28NOV2012	9.0		29NOV2012
306-0008/40/M/A2	12MAR2012	22JUN2012	3	12JUN2012	3.1		22JUN2012

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Censored records are indicated with '+'. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.
Cut-off date: 22JUL2015.

Listing 16.2.6.1b
Overall Survival– Sensitivity Analysis

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [2]	Date of Death	Duration of Overall Survival (Months) [3]	If Censored, Reason	Date of Last Telephone Contact
306-0011/47/M/A2	15MAR2012	02JUN2012	3	02JUN2012	2.7		
306-0012/61/M/A2	02APR2012	11DEC2012	3	22NOV2012	7.8		11DEC2012
306-0014/47/M/A2	19APR2012	20JUN2012	3	20JUN2012	2.1		
306-0017/49/M/A2	12JUL2012	22NOV2012	3	16NOV2012	4.3		22NOV2012
306-0019/78/M/A2	22AUG2012	04DEC2012	3	04DEC2012	3.5		04DEC2012
306-0020/63/M/A2	04OCT2012	10JUN2013	3	07JUN2013	8.2		10JUN2013
306-0023/68/M/A2	27NOV2012	24JUL2013	3	28JUN2013	7.1		24JUL2013
306-0026/58/M/A2	04FEB2013				28.5+	Follow-up visit	09JUN2015
306-0027/67/M/A2	19FEB2013				28+	Follow-up visit	09JUN2015

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Censored records are indicated with '+'. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.
Cut-off date: 22JUL2015.

Listing 16.2.6.1b
Overall Survival– Sensitivity Analysis

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [2]	Date of Death	Duration of Overall Survival (Months) [3]	If Censored, Reason	Date of Last Telephone Contact
306-0030/63/M/A2	23APR2013	06AUG2013	3	18JUL2013	2.9		06AUG2013
306-0031/40/M/A2	15MAY2013	27MAY2014	3	17MAY2014	12.3		27MAY2014
306-0034/65/M/A2	01JUL2013	09AUG2013	3	09AUG2013	1.3		
306-0035/48/M/A2	08JUL2013	16DEC2013	3	01DEC2013	4.9		16DEC2013
306-0036/73/M/A2	09JUL2013	30NOV2013	3	25NOV2013	4.7		30NOV2013
306-0038/66/M/A2	21AUG2013	20MAY2014	3	04MAY2014	8.6		20MAY2014
306-0039/62/M/A2	20AUG2013	31DEC2013	3	15DEC2013	3.9		31DEC2013
306-0040/44/F/A2	24SEP2013	14JUL2014	3	09JUL2014	9.6		14JUL2014
306-0041/62/M/A2	29OCT2013	13MAR2014	3	12MAR2014	4.5		
306-0043/56/M/A2	19MAY2014	30OCT2014	3	07OCT2014	4.7		30OCT2014

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Censored records are indicated with '+'. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.
Cut-off date: 22JUL2015.

Listing 16.2.6.1b
Overall Survival– Sensitivity Analysis

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [2]	Date of Death	Duration of Overall Survival (Months) [3]	If Censored, Reason	Date of Last Telephone Contact
307-0002/61/M/A2	03NOV2011	16APR2012	3	16APR2012	5.5		17APR2012
307-0003/68/M/A2	10NOV2011	01MAR2013	3	09FEB2013	15.3		01MAR2013
307-0004/60/M/A2	10NOV2011	19MAR2012	3	18MAR2012	4.3		19MAR2012
307-0008/58/M/A2	20DEC2011	02OCT2012	3	01OCT2012	9.6		02OCT2012
307-0011/75/M/A2	07FEB2012	02APR2012	99: Sepsis	02APR2012	1.9		02APR2012
307-0014/61/M/A2	16FEB2012	04JUN2013	3	21MAY2013	15.4		04JUN2013
307-0018/70/M/A2	14JUN2012	14JAN2015	3	14JAN2015	31.5		14JAN2015
307-0020/68/F/A2	16AUG2012	12JUN2015	3	23MAR2013	7.3		11JUN2015
307-0022/60/M/A2	27NOV2012	13MAY2013	3	18APR2013	4.8		13MAY2013
307-0025/68/M/A2	18DEC2012	25SEP2013	3	25SEP2013	9.4		25SEP2013

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Censored records are indicated with '+'. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.
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Listing 16.2.6.1b
Overall Survival– Sensitivity Analysis

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [2]	Date of Death	Duration of Overall Survival (Months) [3]	If Censored, Reason	Date of Last Telephone Contact
307-0026/65/M/A2	27DEC2012	18DEC2013	3	09DEC2013	11.6		18DEC2013
307-0030/53/M/A2	06MAR2013	31MAY2013	3	31MAY2013	2.9		
307-0031/60/M/A2	15MAR2013	19DEC2013	3	19DEC2013	9.3		
307-0032/74/F/A2	11APR2013	13MAY2013	3	11MAY2013	1.0		
307-0037/61/M/A2	03OCT2013	02MAY2014	3	19APR2014	6.6		02MAY2014
307-0039/51/M/A2	05NOV2013	12JUN2015	3	16OCT2014	11.5		12JUN2015
307-0040/65/M/A2	27MAY2014	05AUG2014	3	04AUG2014	2.3		05AUG2014
307-0043/54/M/A2	25JUN2014	01NOV2014	99: Hepatic failure	01NOV2014	4.3		
307-0044/53/M/A2	27JUN2014	18JUN2015	3	11SEP2014	2.6		18JUN2015

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Censored records are indicated with '+'. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.
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Listing 16.2.6.1b
Overall Survival– Sensitivity Analysis

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [2]	Date of Death	Duration of Overall Survival (Months) [3]	If Censored, Reason	Date of Last Telephone Contact
307-0045/48/M/A2	07JUL2014				10.3+	Follow-up visit	12MAY2015
307-0046/46/M/A2	17JUL2014	13MAR2015	3	13MAR2015	8.0		13MAR2015
308-0003/54/M/A2	29JAN2013	10DEC2013	3	10DEC2013	10.5		10DEC2013
308-0005/69/F/A2	30APR2013	10SEP2013	3	10SEP2013	4.5		10SEP2013
309-0001/46/M/A2	12JUN2012	16APR2013	3	04APR2013	9.9		16APR2013
309-0002/56/M/A2	13JUN2012	16NOV2012	3	27OCT2012	4.6		16NOV2012
309-0003/52/F/A2	20JUN2012	26FEB2013	3	29JAN2013	7.5		26FEB2013
309-0004/55/M/A2	25JUN2012	19JUL2012	3	19JUL2012	0.8		19JUL2012
309-0008/38/M/A2	21FEB2013	03JAN2014	3	31DEC2013	10.5		03JAN2014

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
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[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Censored records are indicated with '+'. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.
Cut-off date: 22JUL2015.

Listing 16.2.6.1b
Overall Survival– Sensitivity Analysis

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [2]	Date of Death	Duration of Overall Survival (Months) [3]	If Censored, Reason	Date of Last Telephone Contact
309-0010/47/M/A2	25MAR2013				28.3+	Follow-up visit	21JUL2015
309-0011/59/M/A2	08APR2013	10JUL2013	3	02JUL2013	2.9		
309-0012/82/M/A2	23MAY2013	29JAN2014	3	31DEC2013	7.4		29JAN2014
309-0015/62/M/A2	24JUN2013	29MAY2014	3	20MAY2014	11.0		29MAY2014
309-0016/72/F/A2	05SEP2013	13FEB2014	3	14JAN2014	4.4		13FEB2014
309-0017/73/F/A2	02DEC2013	16JUL2014	3	26JUN2014	6.9		16JUL2014
309-0018/82/M/A2	03JUN2014	31OCT2014	3	28OCT2014	4.9		31OCT2014
309-0021/54/F/A2	17JUL2014	16DEC2014	3	28NOV2014	4.5		16DEC2014
309-0025/49/M/A2	25AUG2014	05SEP2014	3	04SEP2014	0.4		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
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[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
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Listing 16.2.6.1b
Overall Survival– Sensitivity Analysis

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [2]	Date of Death	Duration of Overall Survival (Months) [3]	If Censored, Reason	Date of Last Telephone Contact
309-0026/41/M/A2	22SEP2014	26FEB2015	3	15FEB2015	4.9		26FEB2015
309-0028/62/M/A2	03NOV2014				8.2+	Follow-up visit	06JUL2015
309-0030/33/M/A2	15DEC2014	24FEB2015	3	20FEB2015	2.3		24FEB2015
309-0031/34/M/A2	25DEC2014	27APR2015	3	03APR2015	3.3		27APR2015
309-0032/63/M/A2	08JAN2015	01APR2015	3	30MAR2015	2.7		01APR2015
309-0033/78/F/A2	29JAN2015				5.8+	Ongoing	
310-0001/61/M/A2	19JUN2012	10JUN2013	3	01JUN2013	11.6		10JUN2013
310-0002/55/M/A2	12JUL2012	05NOV2012	3	13OCT2012	3.1		05NOV2012
310-0003/61/M/A2	06FEB2013	19MAY2014	3	29APR2014	14.9		19MAY2014

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
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Listing 16.2.6.1b
Overall Survival– Sensitivity Analysis

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [2]	Date of Death	Duration of Overall Survival (Months) [3]	If Censored, Reason	Date of Last Telephone Contact
310-0008/49/M/A2	19JUN2013	30AUG2013	3	13AUG2013	1.9		30AUG2013
310-0012/73/M/A2	07NOV2013				19.1+	Follow-up visit	02JUN2015
310-0013/54/M/A2	03SEP2014	14MAY2015	3	29APR2015	8.0		14MAY2015
311-0002/60/M/A2	14AUG2013	01NOV2013	3	20NOV2013	3.3		02JUL2015
311-0007/55/M/A2	18NOV2013	02DEC2014	3	13NOV2014	12.0		02DEC2014
311-0008/71/M/A2	21MAY2014	09JUL2014	3		1.7		02JUL2015
401-0003/36/M/A7	24JUN2013	30NOV2013	3	24NOV2013	5.1		29NOV2013
401-0005/58/M/A7	16OCT2013	20AUG2014	3	17MAY2014	7.1		20AUG2014
402-0003/75/M/A7	30APR2013	14NOV2013	3	08NOV2013	6.4		14NOV2013

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Censored records are indicated with '+'. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.
Cut-off date: 22JUL2015.

Listing 16.2.6.1b
Overall Survival– Sensitivity Analysis

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [2]	Date of Death	Duration of Overall Survival (Months) [3]	If Censored, Reason	Date of Last Telephone Contact
402-0006/71/M/A7	02MAY2013	22NOV2013	3	20NOV2013	6.8		22NOV2013
402-0008/43/M/A7	21MAY2013	02AUG2013	3	22JUL2013	2.1		02AUG2013
402-0009/70/M/A7	16MAY2013	11AUG2013	3	11AUG2013	2.9		11AUG2013
402-0011/64/M/A7	23MAY2013	11OCT2013	3	04OCT2013	4.5		11OCT2013
402-0017/50/M/A7	11JUN2013	16AUG2013	3	09AUG2013	2.0		16AUG2013
402-0018/48/M/A7	24JUN2013	16DEC2013	3	08DEC2013	5.6		04DEC2013
402-0019/54/M/A7	01JUL2013	15NOV2013	3	06NOV2013	4.3		15NOV2013
402-0021/64/M/A7	13AUG2013				22.1+	Follow-up visit	05JUN2015
402-0024/57/M/A7	27AUG2013	03JAN2014	3	24DEC2013	4.0		03JAN2014

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Censored records are indicated with '+'. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.
Cut-off date: 22JUL2015.

Listing 16.2.6.1b
Overall Survival– Sensitivity Analysis

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [2]	Date of Death	Duration of Overall Survival (Months) [3]	If Censored, Reason	Date of Last Telephone Contact
402-0025/58/M/A7	25SEP2013	21JAN2015	3	08JAN2015	15.7		21JAN2015
402-0027/52/M/A7	04OCT2013	28NOV2013	3	28NOV2013	1.9		28NOV2013
402-0028/60/M/A7	04OCT2013	18FEB2014	3	29JAN2014	3.9		18FEB2014
402-0031/65/M/A7	12NOV2013				19+	Follow-up visit	05JUN2015
402-0033/63/F/A7	06DEC2013	25APR2014	3	07APR2014	4.1		25APR2014
402-0035/44/M/A7	24DEC2013	25JUN2014	3	02MAY2014	4.3		26MAY2014
403-0001/55/M/A7	22MAY2013	30SEP2013	3	11SEP2013	3.8		30SEP2013
403-0002/52/M/A7	11JUN2013	14OCT2013	3	11OCT2013	4.1		14OCT2013
403-0005/50/F/A7	16JUL2013	06NOV2013	3	28OCT2013	3.5		06NOV2013

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[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Censored records are indicated with '+'. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.
Cut-off date: 22JUL2015.

Listing 16.2.6.1b
Overall Survival– Sensitivity Analysis

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [2]	Date of Death	Duration of Overall Survival (Months) [3]	If Censored, Reason	Date of Last Telephone Contact
403-0006/66/M/A7	29JUL2013	03APR2014	5	24MAR2014	8.0		03APR2014
403-0007/65/M/MIX	21AUG2013	12DEC2013	3	05JAN2014	4.6		
404-0001/71/M/A7	22JUL2013	11SEP2013	99: Metabolic acidosis	11SEP2013	1.7		
404-0002/56/F/A7	22AUG2013	02JUL2014	3	01JUN2014	9.5		02JUL2014
405-0002/46/M/A7	16APR2013	04JUN2013	2	12MAY2013	0.9		
405-0004/38/M/A7	24APR2013	20MAY2014	3	21MAY2014	13.1		30MAY2014
405-0006/62/M/A7	29APR2013	20JUN2013	3	10JUN2013	1.4		
405-0007/53/M/A7	07MAY2013	19AUG2014	3	02AUG2014	15.1		19AUG2014
405-0009/50/M/A7	14MAY2013	23AUG2013	3	19AUG2013	3.3		21AUG2013

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
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Cut-off date: 22JUL2015.

Listing 16.2.6.1b
Overall Survival– Sensitivity Analysis

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [2]	Date of Death	Duration of Overall Survival (Months) [3]	If Censored, Reason	Date of Last Telephone Contact
405-0010/39/M/A7	23MAY2013	21FEB2014			9.2+	Lost to Follow-up	21FEB2014
405-0011/63/M/A7	13MAY2013	01JUL2014	3	05JUN2014	13.0		01JUL2014
405-0013/45/M/A7	20MAY2013	17JAN2014			8.1+	Lost to Follow-up	17JAN2014
405-0014/35/M/A7	31MAY2013	12AUG2013	3	19JUL2013	1.7		
405-0016/41/M/A7	27MAY2013	14JUL2013	3	14JUL2013	1.6		
405-0018/70/F/A7	12JUN2013	12AUG2013	3	13JUL2013	1.1		
405-0020/69/M/A7	19JUN2013	30OCT2014	3	14OCT2014	16.1		30OCT2014
405-0021/47/M/A7	19JUN2013	07OCT2014	3	05OCT2014	15.8		07OCT2014
405-0022/65/M/A7	04JUL2013	02APR2014	3	17MAR2014	8.6		02APR2014

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Censored records are indicated with '+'. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.
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Listing 16.2.6.1b
Overall Survival– Sensitivity Analysis

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [2]	Date of Death	Duration of Overall Survival (Months) [3]	If Censored, Reason	Date of Last Telephone Contact
405-0023/46/M/A7	17JUN2013	11DEC2013	3	10DEC2013	5.9		13DEC2013
405-0025/47/M/A7	26JUN2013	10DEC2013	3	10DEC2013	5.6		10DEC2013
405-0028/67/M/A7	24JUL2013	04JAN2014	3	07DEC2013	4.6		04JAN2014
405-0030/35/M/A7	31JUL2013	06NOV2013	3	06NOV2013	3.3		
405-0032/69/M/A7	23JUL2013	10MAR2015	3	13FEB2015	19.0		10MAR2015
405-0033/43/M/A7	08AUG2013	28APR2014	3	28APR2014	8.8		14MAY2014
405-0034/61/M/A7	08AUG2013	07OCT2014	3	07OCT2014	14.2		13OCT2014
405-0035/66/M/A7	19AUG2013				22+	Follow-up visit	08JUN2015
405-0039/73/M/A7	13SEP2013	02JUN2014	3	02JUN2014	8.8		18JUN2014

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
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[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Censored records are indicated with '+'. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.
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Listing 16.2.6.1b
Overall Survival– Sensitivity Analysis

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [2]	Date of Death	Duration of Overall Survival (Months) [3]	If Censored, Reason	Date of Last Telephone Contact
405-0040/65/M/A7	23SEP2013				20.7+	Follow-up visit	05JUN2015
405-0042/53/M/A7	04OCT2013	31DEC2013	3	26DEC2013	2.8		31DEC2013
405-0043/49/M/A7	26SEP2013	20DEC2013	3	20DEC2013	2.9		30DEC2013
405-0044/56/M/A7	25SEP2013	08DEC2014	3	05DEC2014	14.6		08DEC2014
501-0001/59/M/A1	13NOV2013	24JUN2014	3	26MAY2014	6.5		24JUN2014
501-0002/36/F/A1	02DEC2013	19JAN2015	3	16JAN2015	13.7		19JAN2015
501-0005/80/M/A1	23JAN2014				18.2+	Ongoing	
501-0006/60/M/A1	13FEB2014	29NOV2014	3	18NOV2014	9.3		29NOV2014
501-0007/43/M/A1	03MAR2014	11JUL2014	3	27JUN2014	3.9		11JUL2014

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Censored records are indicated with '+'. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.
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Listing 16.2.6.1b
Overall Survival– Sensitivity Analysis

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [2]	Date of Death	Duration of Overall Survival (Months) [3]	If Censored, Reason	Date of Last Telephone Contact
501-0008/76/F/A1	15APR2014	25MAY2015	3	23MAY2015	13.5		25MAY2015
501-0009/62/M/A1	18JUL2014				11.2+	Follow-up visit	19JUN2015
501-0010/65/M/A1	10SEP2014	02APR2015	3	26MAR2015	6.6		02APR2015
502-0002/65/M/A1	08JAN2014	20JAN2014	99: Respiratory failure	19JAN2014	0.4		
503-0001/32/M/A1	09DEC2013	20MAR2014	3	14FEB2014	2.3		20MAR2014
503-0004/49/M/A1	11MAR2014	18APR2014	3	05APR2014	0.9		
503-0006/54/M/A1	06AUG2014				11+	Follow-up visit	02JUL2015

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Censored records are indicated with '+'. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.
Cut-off date: 22JUL2015.

Listing 16.2.6.1b
Overall Survival– Sensitivity Analysis

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [2]	Date of Death	Duration of Overall Survival (Months) [3]	If Censored, Reason	Date of Last Telephone Contact
503-0007/57/M/A1	28OCT2014				8.3+	Follow-up visit	02JUL2015
503-0008/50/M/A1	30OCT2014	18MAY2015	3	30APR2015	6.1		18MAY2015
503-0009/57/M/A1	19NOV2014	29NOV2014	3	29NOV2014	0.4		
504-0001/47/M/A1	17FEB2014	10AUG2014	3	27JUL2014	5.4		10AUG2014
504-0007/32/M/A1	11OCT2014	11NOV2014	3	31OCT2014	0.7		
505-0001/70/M/A1	12AUG2014	01FEB2015	3	24JAN2015	5.5		01FEB2015
506-0002/54/M/A1	12MAY2014				13.9+	Follow-up visit	02JUL2015
506-0003/66/M/A1	10SEP2014	29APR2015	5	04APR2015	6.9		29APR2015
506-0004/49/M/A1	27OCT2014	15FEB2015	3	15FEB2015	3.7		15FEB2015

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Censored records are indicated with '+'. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.
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Listing 16.2.6.1b
Overall Survival– Sensitivity Analysis

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [2]	Date of Death	Duration of Overall Survival (Months) [3]	If Censored, Reason	Date of Last Telephone Contact
508-0001/36/M/A1	08JAN2014	15AUG2014			7.3+	Lost to Follow-up	15AUG2014
508-0003/49/F/A1	17MAR2014	15APR2014	3	15APR2014	1.0		
509-0001/45/M/A1	30APR2014	29AUG2014	3	06AUG2014	3.3		29AUG2014
509-0002/51/M/A1	26MAY2014	27AUG2014			3.1+	Lost to Follow-up	
510-0002/50/M/A1	23MAY2014	25AUG2014	3	13AUG2014	2.8		25AUG2014
510-0004/72/M/A1	01AUG2014				11.1+	Follow-up visit	30JUN2015
511-0001/35/M/A1	21JAN2014	30AUG2014	3	25AUG2014	7.2		30AUG2014

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Censored records are indicated with '+'. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.
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Listing 16.2.6.1b
Overall Survival– Sensitivity Analysis

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [2]	Date of Death	Duration of Overall Survival (Months) [3]	If Censored, Reason	Date of Last Telephone Contact
511-0002/49/M/A1	11MAR2014				16+	Follow-up visit	02JUL2015
512-0001/59/M/A1	04MAR2014	04SEP2014	3	04SEP2014	6.2		04SEP2014
513-0001/28/M/A1	09APR2014	22JUL2014	99: Oral cavity internal hemorrhage	21JUN2014	2.5		22JUL2014
513-0004/46/M/A1	18JUN2014	07AUG2014	2	26JUL2014	1.3		07AUG2014
513-0005/61/M/A1	31OCT2014	20MAR2015	3	01MAR2015	4.1		20MAR2015
515-0001/64/M/A1	20FEB2014	01AUG2014	3	17JUL2014	4.9		01AUG2014
515-0003/69/M/A1	13MAY2014	08APR2015	3	05APR2015	10.9		08APR2015
515-0004/52/M/A1	27MAY2014	25SEP2014	3	19SEP2014	3.9		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Censored records are indicated with '+'. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.
Cut-off date: 22JUL2015.

Listing 16.2.6.1b
Overall Survival– Sensitivity Analysis

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [2]	Date of Death	Duration of Overall Survival (Months) [3]	If Censored, Reason	Date of Last Telephone Contact
515-0006/47/M/A1	05AUG2014				11+	Follow-up visit	29JUN2015
515-0007/39/M/A1	17SEP2014	09DEC2014	3	22NOV2014	2.2		09DEC2014
515-0008/60/M/A1	27NOV2014	04JUN2015	3	12MAY2015	5.6		04JUN2015
516-0001/45/M/A1	07AUG2014				10.9+	Follow-up visit	30JUN2015
517-0001/42/M/A1	23DEC2013	19MAR2014	3	02MAR2014	2.3		19MAR2014
517-0002/43/M/A1	26MAR2014				15.4+	Follow-up visit	01JUL2015
517-0005/46/M/MIX	04JUN2014	08AUG2014	3	28JUL2014	1.8		08AUG2014

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Censored records are indicated with '+'. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.
Cut-off date: 22JUL2015.

Listing 16.2.6.1b
Overall Survival– Sensitivity Analysis

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [2]	Date of Death	Duration of Overall Survival (Months) [3]	If Censored, Reason	Date of Last Telephone Contact
517-0006/67/F/A1	20AUG2014				10.5+	Follow-up visit	01JUL2015
517-0007/66/M/A1	20AUG2014	10DEC2014	3	15NOV2014	2.9		10DEC2014
517-0008/59/M/A1	22AUG2014	21JAN2015	3	18JAN2015	5.0		21JAN2015
517-0009/23/M/A1	17SEP2014	09JUN2015	3	31MAY2015	8.6		09JUN2015

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Censored records are indicated with '+'. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.
Cut-off date: 22JUL2015.

Listing 16.2.6.1b
Overall Survival– Sensitivity Analysis

Treatment Group: Placebo

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [2]	Date of Death	Duration of Overall Survival (Months) [3]	If Censored, Reason	Date of Last Telephone Contact
101-0002/70/M/OTH	29JUL2011	07NOV2011	3	04JUN2012	10.4		04JUL2012
101-0004/78/F/A2	05AUG2011				47.7+	Follow-up visit	06JUL2015
101-0010/43/M/BL	14SEP2011	20SEP2011	3	27OCT2011	1.5		20SEP2012
101-0014/61/M/W2	06JAN2012	26OCT2012	3	26OCT2012	9.8		05NOV2013
101-0015/65/M/A4	06JAN2012	03JAN2013	3	03JAN2013	12.1		03JAN2013
101-0017/60/M/W2	21FEB2012	19JAN2013	3	19JAN2013	11.1		19JAN2013
101-0020/86/M/W2	12MAR2012	30DEC2012	3	30DEC2012	9.8		30DEC2012
101-0027/72/M/W2	22MAY2012	11AUG2012	3	11AUG2012	2.7		16AUG2012
101-0031/69/F/W2	17JUL2012	22OCT2012	3	15NOV2012	4.1		15NOV2012

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Censored records are indicated with '+'. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.
Cut-off date: 22JUL2015.

Listing 16.2.6.1b
Overall Survival– Sensitivity Analysis

Treatment Group: Placebo

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [2]	Date of Death	Duration of Overall Survival (Months) [3]	If Censored, Reason	Date of Last Telephone Contact
101-0034/44/M/OTH	11SEP2012	04DEC2013	3	04DEC2013	15.0		04DEC2013
101-0035/37/M/A6	14SEP2012	27JAN2013	3	25JAN2013	4.5		27JAN2013
101-0043/69/M/W1	22OCT2013	26MAY2014	3	26MAY2014	7.2		26MAY2014
101-0051/70/F/W2	27JAN2014	23MAY2014	5	23MAY2014	3.9		23MAY2014
102-0006/66/M/BL	11DEC2013	07OCT2014	5	11OCT2014	10.2		07OCT2014
102-0007/61/M/W2	02JAN2014	09MAY2014	3	19MAY2014	4.6		
103-0002/74/M/W2	12DEC2012	09FEB2015	3	09FEB2015	26.3		10FEB2015
103-0006/57/M/W2	19NOV2014				7+	Follow-up visit	16JUN2015
104-0002/80/M/W2	07MAY2012	29JUL2013	3	27JUL2013	14.9		29JUL2013

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Censored records are indicated with '+'. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.
Cut-off date: 22JUL2015.

Listing 16.2.6.1b
Overall Survival– Sensitivity Analysis

Treatment Group: Placebo

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [2]	Date of Death	Duration of Overall Survival (Months) [3]	If Censored, Reason	Date of Last Telephone Contact
104-0007/89/M/A1	07AUG2013				23.8+	Ongoing	
105-0003/57/M/W2	05NOV2013	16JUN2015			19.6+	Study completed	16JUN2015
105-0006/60/F/BL	29DEC2014				6.9+	Ongoing	
108-0003/85/M/W2	19NOV2012	30NOV2013	3	30NOV2013	12.6		30NOV2013
109-0002/63/M/W2	22MAR2013				27+	Follow-up visit	10JUN2015
109-0005/64/F/W2	30JUL2013	08OCT2013	99: Kidney and heart failure	08OCT2013	2.4		
109-0012/21/F/W2	25SEP2014				8.6+	Follow-up visit	10JUN2015

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Censored records are indicated with '+'. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.
Cut-off date: 22JUL2015.

Listing 16.2.6.1b
Overall Survival– Sensitivity Analysis

Treatment Group: Placebo

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [2]	Date of Death	Duration of Overall Survival (Months) [3]	If Censored, Reason	Date of Last Telephone Contact
109-0014/50/F/W2	26JAN2015	03APR2015	5	11APR2015	2.5		
111-0003/37/M/A1	08JAN2013	20MAR2013	3	19MAR2013	2.4		
112-0010/56/F/W2	06DEC2013	25APR2014	1	26APR2014	4.7		26APR2014
113-0007/74/M/W2	30JAN2014	21JUL2014	3	27JUL2014	6.0		29JUL2014
113-0015/58/F/BL	26NOV2014				7.1+	Follow-up visit	25JUN2015
114-0001/25/F/OTH	02AUG2012	12NOV2012	3	05DEC2012	4.2		12NOV2012
114-0004/54/F/A1	06FEB2013	09JUN2014	3	09JUN2014	16.3		09JUN2014
115-0005/60/M/W2	15MAR2013	07JUN2013	3	16MAY2013	2.1		
115-0006/62/M/W2	11APR2013	31JUL2013	3	31JUL2013	3.7		31JUL2013

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Censored records are indicated with '+'. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.
Cut-off date: 22JUL2015.

Listing 16.2.6.1b
Overall Survival– Sensitivity Analysis

Treatment Group: Placebo

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [2]	Date of Death	Duration of Overall Survival (Months) [3]	If Censored, Reason	Date of Last Telephone Contact
115-0007/57/M/W2	19APR2013	25JUN2013	3	23JUN2013	2.2		25JUN2013
115-0010/54/M/A4	14APR2014	21OCT2014	3	21OCT2014	6.4		21OCT2014
121-0003/65/M/BL	01JUL2014	13MAY2015	3	12JAN2015	6.5		13MAY2015
201-0002/76/M/W2	15MAR2012	07OCT2013	3	02OCT2013	18.9		07OCT2013
201-0006/71/M/W2	12JUL2012	11NOV2013	2	10NOV2013	16.2		11NOV2013
201-0007/71/M/W2	26JUL2012	30JUL2014	3	14JUL2014	24.0		30JUL2014
201-0009/65/M/W2	20JUN2013				25.4+	Ongoing	
201-0010/81/F/W2	27JUN2013	27JAN2014	3	26JAN2014	7.1		27JAN2014
201-0014/73/M/W2	17JUL2013	14APR2014	99: Cardiac arrest	18MAR2014	8.2		14APR2014
201-0015/49/M/W2	08AUG2013	30OCT2014	99: Renal failure	28OCT2014	14.9		30OCT2014

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Censored records are indicated with '+'. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.
Cut-off date: 22JUL2015.

Listing 16.2.6.1b
Overall Survival– Sensitivity Analysis

Treatment Group: Placebo

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [2]	Date of Death	Duration of Overall Survival (Months) [3]	If Censored, Reason	Date of Last Telephone Contact
201-0022/80/F/W2	09MAY2014				13.6+	Follow-up visit	19JUN2015
203-0004/81/M/W2	30MAR2012	09MAY2013	2	09MAY2013	13.5		09MAY2013
203-0006/76/M/W2	11APR2012	07JUL2012	3	07JUL2012	2.9		
203-0007/59/M/W2	04JUN2012	19OCT2012	3	02OCT2012	4.0		
203-0009/73/M/W2	13SEP2012	07JAN2015	3	07JAN2015	28.2		07JAN2015
203-0010/74/M/W2	26SEP2012				33.1+	Follow-up visit	15JUN2015
203-0014/73/M/W2	23JAN2014	29OCT2014	3	13OCT2014	8.8		29OCT2014
203-0016/57/M/W2	04FEB2014	08OCT2014	3	22SEP2014	7.7		08OCT2014
203-0019/68/M/W2	22MAY2014	16SEP2014	3	18AUG2014	3.0		16SEP2014

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Censored records are indicated with '+'. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.
Cut-off date: 22JUL2015.

Listing 16.2.6.1b
Overall Survival– Sensitivity Analysis

Treatment Group: Placebo

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [2]	Date of Death	Duration of Overall Survival (Months) [3]	If Censored, Reason	Date of Last Telephone Contact
204-0003/64/M/W2	08JUL2013	20JAN2014	1	08JAN2014	6.2		20JAN2014
204-0004/76/F/W2	15SEP2013	23JUL2014	3	25JUN2014	9.5		23JUL2014
205-0002/71/M/W2	24FEB2012	06JUL2012	3	14JUN2012	3.7		06JUL2012
205-0003/79/M/W2	27MAR2012	17OCT2013	3	18DEC2013	21.1		17OCT2013
205-0005/71/M/W2	20MAR2012	13NOV2012	3	09NOV2012	7.8		06NOV2012
205-0014/70/M/W2	18JUN2013	02OCT2013	3	02NOV2013	4.6		02OCT2013
205-0023/72/M/W2	08NOV2013	25JUN2015	5	10JUN2014	7.2		25JUN2015
205-0026/61/F/W2	09FEB2015				4.2+	Follow-up visit	15JUN2015
205-0028/73/F/W2	27JAN2015	15FEB2015	3	15FEB2015	0.7		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Censored records are indicated with '+'. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.
Cut-off date: 22JUL2015.

Listing 16.2.6.1b
Overall Survival– Sensitivity Analysis

Treatment Group: Placebo

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [2]	Date of Death	Duration of Overall Survival (Months) [3]	If Censored, Reason	Date of Last Telephone Contact
207-0002/71/M/W2	21MAR2012	02OCT2012	3	02OCT2012	6.5		03OCT2012
207-0007/72/M/W2	02JUL2012	04JAN2013	3	04JAN2013	6.2		04JAN2013
207-0012/67/M/W2	21MAR2013	19MAY2014	3	12APR2014	12.9		19MAY2014
207-0016/82/F/W2	10OCT2013	19DEC2014	5	04OCT2014	12.0		14OCT2014
207-0017/81/F/W2	22NOV2013	09APR2014	3	07MAR2014	3.5		
207-0019/55/M/W2	03JUN2014	01AUG2014	3	25JUL2014	1.8		
209-0006/68/M/W2	02MAY2013	17JUL2014	3	16JUL2014	14.7		17JUL2014
209-0011/69/M/W2	03DEC2013				18.7+	Follow-up visit	15JUN2015
209-0014/80/M/W2	17MAR2014				15.3+	Follow-up visit	17JUN2015

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Censored records are indicated with '+'. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.
Cut-off date: 22JUL2015.

Listing 16.2.6.1b
Overall Survival– Sensitivity Analysis

Treatment Group: Placebo

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [2]	Date of Death	Duration of Overall Survival (Months) [3]	If Censored, Reason	Date of Last Telephone Contact
210-0003/74/M/W2	04NOV2013	22JUL2014	3	18JUL2014	8.6		22JUL2014
210-0004/71/M/W2	08JAN2014	25AUG2014	3	22AUG2014	7.6		25AUG2014
210-0005/53/M/W2	20FEB2014	15JAN2015	3	23DEC2014	10.2		15JAN2015
210-0006/45/M/W2	23JUN2014	26NOV2014	3	26NOV2014	5.2		28NOV2014
251-0002/69/M/W2	07AUG2013	20NOV2013	5	20NOV2013	3.5		13NOV2013
251-0003/68/M/W2	05NOV2013	22OCT2014	3	26NOV2014	12.9		07JAN2015
252-0001/65/M/A3	08MAY2012	15OCT2012	3	23DEC2012	7.7		15OCT2012
252-0004/50/M/A1	28MAY2013	01SEP2013	3	06SEP2013	3.4		12SEP2013
252-0006/64/M/W2	01OCT2013	24APR2015	3	23APR2015	19.0		24APR2015
252-0008/76/M/W2	27MAY2014	14JAN2015	3	07MAR2015	9.5		14JAN2015

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Censored records are indicated with '+'. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.
Cut-off date: 22JUL2015.

Listing 16.2.6.1b
Overall Survival– Sensitivity Analysis

Treatment Group: Placebo

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [2]	Date of Death	Duration of Overall Survival (Months) [3]	If Censored, Reason	Date of Last Telephone Contact
252-0010/56/F/W2	04NOV2014	19MAR2015	3	31MAR2015	4.9		19MAR2015
253-0003/75/M/W2	15JUN2012	26JUN2013	3	30SEP2013	15.8		26JUN2013
253-0004/79/M/W2	07SEP2012	26FEB2013	3	16MAR2013	6.4		26FEB2013
253-0005/74/F/W2	02NOV2012	08JAN2013	3	08MAR2013	4.2		08JAN2013
253-0006/63/M/A3	28DEC2012	01SEP2014	3	09SEP2014	20.7		01SEP2014
253-0011/67/M/W2	06OCT2014				9.7+	Ongoing	
253-0012/67/M/W2	08DEC2014	20JAN2015	3	20JAN2015	1.5		
257-0005/66/M/W2	03JAN2013	22MAY2013	3	19MAY2013	4.6		
257-0013/63/M/W2	30MAY2013	07AUG2013	3	07AUG2013	2.3		
257-0020/72/M/A1	27OCT2014	22DEC2014	3	21JAN2015	2.9		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Censored records are indicated with '+'. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.
Cut-off date: 22JUL2015.

Listing 16.2.6.1b
Overall Survival– Sensitivity Analysis

Treatment Group: Placebo

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [2]	Date of Death	Duration of Overall Survival (Months) [3]	If Censored, Reason	Date of Last Telephone Contact
258-0002/69/F/W2	11APR2013	14AUG2014	5	21JUL2014	15.6		14AUG2014
258-0003/67/F/W2	15MAY2013				25.5+	Follow-up visit	17JUN2015
258-0004/66/M/W2	21MAY2013	21JUN2013	3	23JUN2013	1.1		
258-0006/69/M/W2	15OCT2013	12DEC2013	3	07DEC2013	1.8		
258-0013/59/M/W2	11NOV2014	09APR2015	3	21MAR2015	4.4		09APR2015
259-0003/73/M/W2	11JUN2014	06MAY2015	3	10JUL2015	13.2		
259-0004/52/M/W2	21JUL2014	08SEP2014	3	31DEC2014	5.5		
260-0002/66/M/W2	02OCT2013	14JUL2014	1	24JUL2014	9.9		27AUG2014
301-0001/47/F/A2	01NOV2011	13MAY2013	3	18APR2013	17.8		13MAY2013

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Censored records are indicated with '+'. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.
Cut-off date: 22JUL2015.

Listing 16.2.6.1b
Overall Survival– Sensitivity Analysis

Treatment Group: Placebo

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [2]	Date of Death	Duration of Overall Survival (Months) [3]	If Censored, Reason	Date of Last Telephone Contact
301-0003/61/F/A2	01MAR2012	19SEP2012	3	28AUG2012	6.0		19SEP2012
301-0008/53/M/A2	04JAN2013	10JUN2013	3	22MAY2013	4.6		10JUN2013
302-0006/49/M/A2	10JAN2012	27MAR2012	3	24MAR2012	2.5		27MAR2012
302-0009/73/M/A2	17APR2012	10JUL2012	3	04JUL2012	2.6		10JUL2012
302-0012/62/M/A2	24APR2012	11OCT2012	3	11OCT2012	5.7		11OCT2012
302-0013/62/M/A2	26MAR2013	17DEC2013	3	14DEC2013	8.8		17DEC2013
302-0020/52/M/A2	21MAY2013	26NOV2013	3	26NOV2013	6.3		26NOV2013
302-0021/75/F/A2	11JUN2013	14FEB2014	3	14FEB2014	8.3		14FEB2014
304-0003/56/F/A2	14MAR2013				27.8+	Follow-up visit	24JUN2015

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Censored records are indicated with '+'. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.
Cut-off date: 22JUL2015.

Listing 16.2.6.1b
Overall Survival– Sensitivity Analysis

Treatment Group: Placebo

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [2]	Date of Death	Duration of Overall Survival (Months) [3]	If Censored, Reason	Date of Last Telephone Contact
304-0004/69/M/A2	03JUN2013	07OCT2013	3	25SEP2013	3.8		07OCT2013
304-0007/72/M/A2	13NOV2013	20OCT2014	99: Terminal statge hepatic encephalopathy	28SEP2014	10.7		20OCT2014
305-0004/79/M/A2	24FEB2012	03JUL2012	3	03JUL2012	4.4		03JUL2012
305-0007/67/M/A2	09MAR2012	08NOV2013	3	08NOV2013	20.3		08NOV2013
305-0015/84/M/A2	06JUL2012	28NOV2012	3	28NOV2012	4.9		24DEC2012
305-0016/78/M/A2	10JUL2012	12NOV2012	3	12NOV2012	4.2		12NOV2012
305-0021/83/F/A2	22NOV2012	28APR2013	3	23MAR2013	4.1		28APR2013
305-0024/69/M/A2	15JAN2013	08AUG2013	3	08AUG2013	6.9		08AUG2013
305-0033/37/F/A2	02JUL2013	22JUL2014	3	19JUL2014	12.8		22JUL2014

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Censored records are indicated with '+'. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.
Cut-off date: 22JUL2015.

Listing 16.2.6.1b
Overall Survival– Sensitivity Analysis

Treatment Group: Placebo

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [2]	Date of Death	Duration of Overall Survival (Months) [3]	If Censored, Reason	Date of Last Telephone Contact
305-0035/60/M/A2	28AUG2013	29SEP2014	3	29SEP2014	13.3		29SEP2014
305-0046/60/M/A2	07NOV2014				7.4+	Follow-up visit	16JUN2015
306-0004/46/M/A2	21FEB2012	07APR2012	3	07APR2012	1.6		07APR2012
306-0010/69/M/A2	21MAR2012	10APR2013	3	30MAR2013	12.5		10APR2013
306-0013/42/M/A2	16APR2012	18JUN2012	3	18JUN2012	2.1		
306-0015/73/M/A2	17MAY2012	27MAY2013	3	14MAY2013	12.1		23JUL2013
306-0016/58/M/A2	25JUN2012	14OCT2013	3	21SEP2013	15.1		14OCT2013
306-0022/56/M/A2	13NOV2012	04FEB2014	3	03FEB2014	14.9		04FEB2014
306-0028/53/M/A2	28MAR2013	16JAN2014	3	23DEC2013	9.0		16JAN2014

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Censored records are indicated with '+'. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.
Cut-off date: 22JUL2015.

Listing 16.2.6.1b
Overall Survival– Sensitivity Analysis

Treatment Group: Placebo

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [2]	Date of Death	Duration of Overall Survival (Months) [3]	If Censored, Reason	Date of Last Telephone Contact
306-0045/60/F/A1	20JUN2014	30JUN2015	3	12JUN2015	11.9		30JUN2015
307-0006/72/M/A2	29NOV2011	23DEC2011	3	23DEC2011	0.8		
307-0009/53/M/A2	03JAN2012	12JUN2015	3	29MAR2012	2.9		12JUN2015
307-0012/42/M/A2	07FEB2012	10APR2012	5	10APR2012	2.1		10APR2012
307-0015/75/M/A2	25APR2012	28MAR2013	3	05MAR2013	10.5		28MAR2013
307-0021/68/M/A2	21AUG2012	21FEB2013	3	10FEB2013	5.8		21FEB2013
307-0028/69/F/A2	14JAN2013	01JUL2013	3	15JUN2013	5.1		01JUL2013
307-0034/48/M/A2	13AUG2013	20FEB2014	3	04FEB2014	5.9		20FEB2014
307-0036/76/M/A2	02OCT2013	08JUL2014	3	30JUN2014	9.1		08JUL2014

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Censored records are indicated with '+'. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.
Cut-off date: 22JUL2015.

Listing 16.2.6.1b
Overall Survival– Sensitivity Analysis

Treatment Group: Placebo

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [2]	Date of Death	Duration of Overall Survival (Months) [3]	If Censored, Reason	Date of Last Telephone Contact
307-0042/55/M/A2	19JUN2014				11+	Follow-up visit	14MAY2015
308-0002/36/F/A2	31DEC2012	18FEB2014	3	16FEB2014	13.8		18FEB2014
308-0004/52/M/A2	05FEB2013	30APR2015	3	07APR2015	26.4		30APR2015
308-0006/64/M/A2	14MAY2013	28NOV2014	3	14NOV2014	18.3		28NOV2014
308-0008/47/M/A2	23JUL2013	26DEC2013	3	26DEC2013	5.2		26DEC2013
308-0009/61/M/A2	19JUL2013	12SEP2013	99: Sepsis	12SEP2013	1.9		
309-0006/56/M/A2	26NOV2012	11JUN2015	3	24MAY2015	30.3		11JUN2015
309-0007/58/M/A2	17DEC2012	25JUN2013	3	12JUN2013	5.9		25JUN2013
309-0013/45/M/A2	20JUN2013	24NOV2014	3	17NOV2014	17.2		24NOV2014

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Censored records are indicated with '+'. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.
Cut-off date: 22JUL2015.

Listing 16.2.6.1b
Overall Survival– Sensitivity Analysis

Treatment Group: Placebo

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [2]	Date of Death	Duration of Overall Survival (Months) [3]	If Censored, Reason	Date of Last Telephone Contact
309-0014/39/M/A2	20JUN2013	29JAN2014	3	18JAN2014	7.1		29JAN2014
309-0019/68/M/A2	24JUN2014				13.1+	Ongoing	
309-0027/49/M/A2	03NOV2014	17JUN2015	3	12JUN2015	7.4		17JUN2015
309-0029/50/M/A2	01DEC2014	11MAY2015	3	09APR2015	4.3		11MAY2015
310-0004/50/F/A2	06FEB2013	19AUG2013	5		6.5		19AUG2013
310-0005/59/M/A2	27MAR2013	30DEC2013	3	07DEC2013	8.5		30DEC2013
310-0006/50/F/A2	01MAY2013	13OCT2014	3	05OCT2014	17.4		13OCT2014
310-0007/74/M/A2	13JUN2013				24.7+	Follow-up visit	23JUN2015
310-0009/46/M/A2	07AUG2013	24JAN2014	3	10JAN2014	5.2		24JAN2014

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Censored records are indicated with '+'. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.
Cut-off date: 22JUL2015.

Listing 16.2.6.1b
Overall Survival– Sensitivity Analysis

Treatment Group: Placebo

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [2]	Date of Death	Duration of Overall Survival (Months) [3]	If Censored, Reason	Date of Last Telephone Contact
310-0010/34/F/A2	26AUG2013	25DEC2013	3	11DEC2013	3.6		25DEC2013
310-0011/52/M/A2	24OCT2013				20.3+	Follow-up visit	23JUN2015
310-0014/64/M/A2	24SEP2014	25JUN2015	3	16JUN2015	8.9		25JUN2015
311-0003/44/M/A2	25SEP2013	03DEC2014	3	22NOV2014	14.1		03DEC2014
311-0004/68/M/A2	30SEP2013	21OCT2013	3	16NOV2013	1.6		
311-0005/58/M/A2	21OCT2013	14AUG2014	3	03AUG2014	9.6		14AUG2014
311-0006/73/F/A2	07NOV2013	19MAR2014	3	16MAR2014	4.3		19MAR2014
311-0009/51/F/A2	15JUL2014				11.3+	Follow-up visit	18JUN2015
311-0010/47/M/A2	02SEP2014				10.8+	Ongoing	

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Censored records are indicated with '+'. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.
Cut-off date: 22JUL2015.

Listing 16.2.6.1b
Overall Survival– Sensitivity Analysis

Treatment Group: Placebo

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [2]	Date of Death	Duration of Overall Survival (Months) [3]	If Censored, Reason	Date of Last Telephone Contact
311-0011/46/M/A2	30OCT2014				7.7+	Follow-up visit	18JUN2015
311-0012/55/M/A2	29JAN2015				5.8+	Ongoing	
401-0001/70/M/A7	04JUN2013	18AUG2013	3	18AUG2013	2.5		18AUG2013
401-0002/56/M/A7	19JUN2013	07MAY2015	5	21FEB2014	8.3		07MAY2015
402-0001/35/M/A7	22APR2013	24JUN2013	3	03AUG2013	3.5		07FEB2014
402-0002/58/M/A7	23APR2013	10JUN2014	3	08MAY2014	12.7		10JUN2014
402-0005/70/M/A7	09MAY2013	16OCT2013	3	02OCT2013	4.9		16OCT2013
402-0010/50/M/A7	20MAY2013	25JUL2013	3	13JUL2013	1.8		25JUL2013
402-0022/60/F/A7	19AUG2013	03MAR2014	3	03MAR2014	6.6		25MAR2014

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Censored records are indicated with '+'. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.
Cut-off date: 22JUL2015.

Listing 16.2.6.1b
Overall Survival– Sensitivity Analysis

Treatment Group: Placebo

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [2]	Date of Death	Duration of Overall Survival (Months) [3]	If Censored, Reason	Date of Last Telephone Contact
402-0023/57/M/A7	02SEP2013	17JAN2014	3	29DEC2013	4.0		17JAN2014
402-0029/49/M/A7	11NOV2013	04JAN2014	3	04JAN2014	1.8		07JAN2014
402-0032/49/F/A7	06DEC2013	01JUL2014	3	19JUN2014	6.5		01JUL2014
402-0034/43/F/A7	19DEC2013				18.3+	Follow-up visit	19JUN2015
403-0004/37/M/A7	11JUL2013	07MAY2015	3	01MAY2015	22.0		07MAY2015
404-0003/53/M/A7	10SEP2013	07NOV2013	3	20OCT2013	1.4		07NOV2013
404-0004/62/F/A7	15OCT2013	25DEC2013	3	25DEC2013	2.4		
405-0001/55/M/A7	22APR2013	02APR2014	3	15MAR2014	10.9		02APR2014
405-0005/35/M/A6	24APR2013	20MAY2015	3	01MAY2015	24.6		20MAY2015

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Censored records are indicated with '+'. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.
Cut-off date: 22JUL2015.

Listing 16.2.6.1b
Overall Survival– Sensitivity Analysis

Treatment Group: Placebo

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [2]	Date of Death	Duration of Overall Survival (Months) [3]	If Censored, Reason	Date of Last Telephone Contact
405-0012/72/M/A7	15MAY2013	25DEC2013	3	02DEC2013	6.7		26DEC2013
405-0019/62/M/A7	26JUN2013	11AUG2013	3	11AUG2013	1.6		
405-0024/69/M/A7	03JUL2013	05AUG2013	3	05AUG2013	1.1		
405-0026/67/M/A7	08JUL2013	24FEB2014	3	13FEB2014	7.4		24FEB2014
405-0036/70/M/A7	19AUG2013	15JAN2014	3	15JAN2014	5.0		17FEB2014
405-0041/57/M/A7	13SEP2013				21+	Follow-up visit	03JUN2015
501-0003/22/M/A1	11DEC2013	28JUL2014	3	01JUL2014	6.8		28JUL2014
501-0004/26/M/A1	18DEC2013	08AUG2014	3	31JUL2014	7.5		08AUG2014
501-0011/61/M/A1	25SEP2014	12JAN2015	3	07JAN2015	3.5		12JAN2015

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Censored records are indicated with '+'. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.
Cut-off date: 22JUL2015.

Listing 16.2.6.1b
Overall Survival– Sensitivity Analysis

Treatment Group: Placebo

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [2]	Date of Death	Duration of Overall Survival (Months) [3]	If Censored, Reason	Date of Last Telephone Contact
502-0001/70/M/A1	13DEC2013	16JAN2014	2	14JAN2014	1.1		
502-0003/48/M/A1	14JAN2014	05AUG2014	2	10JUL2014	5.9		05AUG2014
503-0002/71/F/A1	20FEB2014	18MAY2015	3	20APR2015	14.2		18MAY2015
503-0003/47/F/A1	07MAR2014	15JUL2014	5		3.4		15JUL2014
503-0005/72/M/A1	25MAR2014				15.5+	Follow-up visit	02JUL2015
504-0003/53/M/A1	13MAR2014	09JUN2014	3	16MAY2014	2.2		09JUN2014
504-0005/41/F/A1	03SEP2014	11NOV2014	3	08NOV2014	2.2		
504-0006/51/M/A1	04SEP2014	27MAR2015	3	13MAR2015	6.4		27MAR2015
506-0001/43/M/A1	15APR2014	30JUL2014	3	29JUL2014	3.5		30JUL2014

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Censored records are indicated with '+'. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.
Cut-off date: 22JUL2015.

Listing 16.2.6.1b
Overall Survival– Sensitivity Analysis

Treatment Group: Placebo

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [2]	Date of Death	Duration of Overall Survival (Months) [3]	If Censored, Reason	Date of Last Telephone Contact
506-0005/24/M/A1	22DEC2014	26JAN2015	3	20JAN2015	1.0		26JAN2015
507-0001/51/M/A1	24JUL2014				11.5+	Follow-up visit	02JUL2015
507-0002/44/M/A1	29JUL2014	10NOV2014	99: Respiratory and circulatory failure	10NOV2014	3.5		10NOV2014
508-0002/64/M/A1	19FEB2014	16APR2014	3	15APR2014	1.9		
508-0004/58/M/A1	27AUG2014	30SEP2014			1.2+	Lost to Follow-up	
509-0003/39/M/A1	24JUL2014	12JAN2015	3	01JAN2015	5.4		12JAN2015
510-0001/67/M/A1	26FEB2014				16.3+	Follow-up visit	30JUN2015

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Censored records are indicated with '+'. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.
Cut-off date: 22JUL2015.

Listing 16.2.6.1b
Overall Survival– Sensitivity Analysis

Treatment Group: Placebo

Subject No./Age[1]/ Gender/Race[2]	Date of Randomization	Date of Study Termination	Most Probable Cause of Death [2]	Date of Death	Duration of Overall Survival (Months) [3]	If Censored, Reason	Date of Last Telephone Contact
510-0003/43/M/A1	05JUN2014	27NOV2014	5	20NOV2014	5.6		27NOV2014
513-0003/46/M/A1	30APR2014	15JUN2014	5	12JUN2014	1.5		15JUL2014
515-0005/45/M/A1	23JUN2014	10OCT2014	3	04OCT2014	3.5		
517-0003/45/M/A1	14MAY2014	18MAR2015			10.3+	Lost to Follow-up	29JAN2015
517-0010/67/M/A1	12NOV2014	08APR2015	3	24MAR2015	4.4		08APR2015

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Most Probable Cause of Death: 1=Cirrhosis, 2=GI Bleeding, 3=Malignant Disease, 4=Toxicity of Study Medication, 5=Unknown (not assessable, insufficient data), 99=Other.
[4] Duration of Overall Survival is calculated as (date of death – date of randomization + 1) / 30. Censored records are indicated with '+'. Subjects lost to follow-up are censored at date of last contact. Subjects alive at time of study termination are censored at this time.
Cut-off date: 22JUL2015.

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
101-0001 /59/M/A2	SCREENING/25JUL2011	TL:1/BONE	ANTERIOR CHEST WALL	CT		15	SLD = 15
	SCREENING/25JUL2011	NTL:1/LIVE		CT		.	
	WEEK12/11OCT2011	TL:1/BONE	ANTERIOR CHEST WALL	CT		17	
	WEEK12/11OCT2011	NTL:1/LIVE		CT	Present	.	
	Summary:					.	SLD = 17, %CN = 13.33, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK24/03JAN2012	TL:1/BONE	ANTERIOR CHEST WALL	CT		27	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
101-0001 /59/M/A2	WEEK24/03JAN2012	NTL:1/LIVE		CT	Present	.	
	Summary:					.	SLD = 27, %CN = 80, TL: PD, NTL: IncompleteResponse/SD, OR: PD, PD confirmed: Yes, 03JAN2012
101-0005 /77/M/W2	SCREENING/14JUL2011	TL:1/LIVER		CT		36	
	SCREENING/14JUL2011	TL:2/LIVER		CT		20	
	SCREENING/14JUL2011	TL:3/LUNG		CT		20	
	SCREENING/14JUL2011	TL:4/LUNG		CT		19	SLD = 95

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
101-0005 /77/M/W2	WEEK12/25OCT2011	TL:1/LIVER		CT		57	
	WEEK12/25OCT2011	TL:2/LIVER		CT		18	
	WEEK12/25OCT2011	TL:3/LUNG		CT		30	
	WEEK12/25OCT2011	TL:4/LUNG		CT		27	
	WEEK12/25OCT2011	NTL:1/LIVE		CT	New	.	
	WEEK12/25OCT2011	NTL:2/LIVE		CT	New	.	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
101-0005 /77/M/W2	Summary:					.	SLD = 132, %CN = 38.95, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 25OCT2011
101-0006 /62/M/W2	SCREENING/14JUL2011	TL:1/LIVER		CT		29	SLD = 29
	WEEK12/12OCT2011	TL:1/LIVER		CT		43	
	WEEK12/12OCT2011	NTL:1/LIVE		CT	New	.	
	WEEK12/12OCT2011	NTL:2/LIVE		CT	New	.	
	Summary:					.	SLD = 43, %CN = 48.28, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 12OCT2011

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
101-0007 /77/M/A1	SCREENING/22JUL2011	TL:1/LIVER	SERIES 100, IMAGE 20	CT		16	
	SCREENING/22JUL2011	TL:2/BONE	SERIES 101, IMAGE 96	CT		71	SLD = 87
	WEEK12/08NOV2011	TL:1/LIVER	SERIES 100, IMAGE 20	CT		22	
	WEEK12/08NOV2011	TL:2/BONE	SERIES 101, IMAGE 96	CT		73	
	WEEK12/08NOV2011	NTL:1/LIVE	SERIES 3, IMAGE 22	CT	New	.	
	WEEK12/08NOV2011	NTL:2/LIVE	SERIES 3, IMAGE 10	CT	New	.	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
101-0007 /77/M/A1	Summary:					.	SLD = 95, %CN = 9.2, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 08NOV2011
101-0008 /83/M/BL	SCREENING/19AUG2011	TL:1/LIVER	SEGMENT 3	CT		34	
	SCREENING/19AUG2011	TL:2/LIVER	SEGMENT 2	CT		17	
	SCREENING/19AUG2011	TL:3/GI	IVC	CT		16	
	SCREENING/19AUG2011	TL:4/GI	PERITONEUM	CT		28	SLD = 95
	WEEK12/12NOV2011	TL:1/LIVER	SEGMENT 3	CT		50	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
101-0008 /83/M/BL	WEEK12/12NOV2011	TL:2/LIVER	SEGMENT 2	CT		24	
	WEEK12/12NOV2011	TL:3/GI	IVC	CT		17	
	WEEK12/12NOV2011	TL:4/GI	PERITONEUM	CT		34	
	Summary:					.	SLD = 125, %CN = 31.58, TL: PD, NTL: NotEvaluable, OR: PD, PD confirmed: Yes, 15NOV2011
101-0009 /82/M/A1	SCREENING/16AUG2011	TL:1/LIVER	SEGMENT 6	CT		34	
	SCREENING/16AUG2011	TL:2/LIVER	SEGMENT 7	CT		17	

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[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
101-0009 /82/M/A1	SCREENING/16AUG2011	TL:3/LIVER	PERITONEAL	CT		19	SLD = 70
	WEEK12/20DEC2011	TL:1/LIVER	SEGMENT 6	CT		62	
	WEEK12/20DEC2011	TL:2/LIVER	SEGMENT 7	CT		56	
	WEEK12/20DEC2011	TL:3/LIVER	PERITONEAL	CT		21	
	Summary:					.	SLD = 139, %CN = 98.57, TL: PD, NTL: NotAssessed, OR: PD, PD confirmed: Yes, 20DEC2011
101-0011 /75/F/W2	SCREENING/01NOV2011	TL:1/LIVER	SERIES 101 IMAGE 48	CT		85	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
101-0011 /75/F/W2	SCREENING/01NOV2011	TL:2/LUNG	SERIES 4 IMAGE 23	CT		11	SLD = 96
	SCREENING/01NOV2011	NTL:3/LIVE	SERIES 101 IMAGE 73	CT		.	
	UNSCHEDULED/29NOV2011	TL:1/LIVER	SERIES 101, IMAGE 48	CT		104	
	UNSCHEDULED/29NOV2011	TL:2/LUNG	SERIES 4, IMAGE 23	CT		17	
	UNSCHEDULED/29NOV2011	NTL:1/LIVE	SERIES 101, IMAGE 51	CT	New	.	
	UNSCHEDULED/29NOV2011	NTL:2/LUNG	SERIES 4, IMAGE 38	CT	New	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
101-0011 /75/F/W2	UNSCHEDULED/29NOV2011	NTL:3/LIVE	SERIES 101, IMAGE 73	CT	Present	.	
	Summary:					.	SLD = 121, %CN = 26.04, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 29NOV2011
101-0012 /68/M/W2	SCREENING/18NOV2011	TL:1/LIVER	SERIES 100, IMAGE 17	CT		21	
	SCREENING/18NOV2011	TL:2/LIVER	SERIES 100, IMAGE 20	CT		17	SLD = 38
	SCREENING/18NOV2011	NTL:1/LIVE		CT		.	
	SCREENING/18NOV2011	NTL:2/GI		CT		.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
101-0012 /68/M/W2	WEEK12/18JAN2012	TL:1/LIVER	SERIES 100, IMAGE 17	CT		46	
	WEEK12/18JAN2012	TL:2/LIVER	SERIES 100, IMAGE 20	CT		39	
	WEEK12/18JAN2012	NTL:1/LIVE		CT	Present	.	
	WEEK12/18JAN2012	NTL:2/GI		CT	Present	.	
	Summary:					.	SLD = 85, %CN = 123.68, TL: PD, NTL: IncompleteResponse/SD, OR: PD, PD confirmed: Yes, 18JAN2012
101-0013 /66/F/A5	SCREENING/06JAN2012	TL:1/NODES	PORTOCAVAL HYPERVASCULAR NODE	CT		11	SLD = 11

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
101-0013 /66/F/A5	WEEK12/23MAR2012	TL:1/NODES	PORTOCAVAL HYPERVASCULAR NODE	CT		14	
	Summary:					.	SLD = 14, %CN = 27.27, TL: PD, NTL: NotAssessed, OR: PD, PD confirmed: Yes, 23MAR2012
101-0016 /61/M/A4	SCREENING/28DEC2011	TL:1/LIVER	SEGMENT 4B	CT		16	SLD = 16
	SCREENING/28DEC2011	NTL:1/LIVE		MRI		.	
	WEEK12/28MAR2012	TL:1/LIVER	SEGMENT 4B	MRI		17	
	WEEK12/28MAR2012	NTL:1/LIVE		MRI	Present	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
101-0016 /61/M/A4	Summary:					.	SLD = 17, %CN = 6.25, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK24/22JUN2012	TL:1/LIVER	SEGMENT 4B	MRI		17	
	WEEK24/22JUN2012	NTL:1/LIVE		MRI	Present	.	
	Summary:					.	SLD = 17, %CN = 6.25, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK36/11SEP2012	TL:1/LIVER	SEGMENT 4B	MRI		23	
	WEEK36/11SEP2012	NTL:1/LIVE		MRI	Present	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
101-0016 /61/M/A4	Summary:					.	SLD = 23, %CN = 43.75, TL: PD, NTL: IncompleteResponse/SD, OR: PD, PD confirmed: Yes, 11SEP2012
	WEEK48/04DEC2012	TL:1/LIVER	SEGMENT 4B	MRI		22	
	WEEK48/04DEC2012	NTL:1/LIVE		MRI	UP	.	
	Summary:					.	SLD = 22, %CN = 37.5, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 04DEC2012
	WEEK60/05MAR2013	TL:1/LIVER	SEGMENT 4B	MRI		17	
	WEEK60/05MAR2013	NTL:1/LIVE		MRI	UP	.	

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[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
101-0016 /61/M/A4	Summary:					.	SLD = 17, %CN = 6.25, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 11SEP2012
101-0018 /51/M/A1	SCREENING/16FEB2012	TL:1/LUNG	S4 I41	CT		30	
	SCREENING/16FEB2012	TL:2/LUNG	S4 I31	CT		37	
	SCREENING/16FEB2012	TL:3/LIVER	S101 I65	CT		199	
	SCREENING/16FEB2012	TL:4/NODES	MEDIASTINAL. S101 I26	CT		21	SLD = 287
101-0019 /68/M/W2	SCREENING/10FEB2012	TL:1/LIVER	S100 I10	CT		78	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
101-0019 /68/M/W2	SCREENING/10FEB2012	TL:2/LIVER	S100 I27	CT		30	
	SCREENING/10FEB2012	TL:3/BONE	S101 I37	CT		103	
	SCREENING/10FEB2012	TL:4/BONE	S101 I33	CT		36	SLD = 247
	WEEK12/15MAY2012	TL:1/LIVER	S100 I10	CT		81	
	WEEK12/15MAY2012	TL:2/LIVER	S100 I27	CT		24	
	WEEK12/15MAY2012	TL:3/BONE	S101 I37	CT		151	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
101-0019 /68/M/W2	WEEK12/15MAY2012	TL:4/BONE	S101 I33	CT		46	
	Summary:					.	SLD = 302, %CN = 22.27, TL: PD, NTL: NotAssessed, OR: PD, PD confirmed: Yes, 15MAY2012
101-0021 /74/M/W2	SCREENING/02MAR2012	TL:1/LIVER	S100 I9	CT		35	
	SCREENING/02MAR2012	TL:2/LIVER	S100 I11	CT		14	SLD = 49
	SCREENING/02MAR2012	NTL:2/LUNG	S4 I18	CT		.	
	SCREENING/02MAR2012	NTL:3/LUNG	S4 I42	CT		.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
101-0021 /74/M/W2	SCREENING/02MAR2012	NTL:4/		CT		.	
	SCREENING/02MAR2012	NTL:5/		CT		.	
	WEEK12/29MAY2012	TL:1/LIVER	S100 I9	CT		35	
	WEEK12/29MAY2012	TL:2/LIVER	S100 I11	CT		13	
	WEEK12/29MAY2012	NTL:2/LUNG	S4 I18	CT	Present	.	
	WEEK12/29MAY2012	NTL:3/LUNG	S4 I42	CT	Present	.	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
101-0021 /74/M/W2	WEEK12/29MAY2012	NTL:4/LIVE	"ABOVE LIVER"	CT	New	.	
	WEEK12/29MAY2012	NTL:5/LUNG	"LUNG R UPPER LOBE"	CT	New	.	
	Summary:					.	SLD = 48, %CN = -2.04, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 29MAY2012
101-0022 /55/M/BL	SCREENING/28FEB2012	TL:1/BONE	S10I21	CT		29	
	SCREENING/28FEB2012	TL:2/NODES	S01I59	CT		82	SLD = 111
	SCREENING/28FEB2012	NTL:1/NODE		CT		.	

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[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
101-0022 /55/M/BL	SCREENING/28FEB2012	NTL:2/LIVE		CT		.	
	SCREENING/28FEB2012	NTL:3/LIVE	PORTAL VEIN THROMBOSIS	CT		.	
	UNSCHEDULED/13APR2012	TL:1/BONE	SERIES 101, IMAGE 21	CT		29	
	UNSCHEDULED/13APR2012	TL:2/NODES	SERIES 101, IMAGE 59	CT		83	
	UNSCHEDULED/13APR2012	NTL:1/NODE	NOT SPECIFIED	CT	Present	.	
	UNSCHEDULED/13APR2012	NTL:2/LIVE	NOT SPECIFIED	CT	Present	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
101-0022 /55/M/BL	UNSCHEDULED/13APR2012	NTL:3/LIVE	PORTAL VEIN THROMBOSIS	CT	UP	.	
	Summary:					.	SLD = 112, %CN = 0.9, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 13APR2012
101-0023 /70/M/W2	SCREENING/30MAR2012	TL:1/LIVER		CT		58	
	SCREENING/30MAR2012	TL:2/LIVER		CT		21	SLD = 79
	SCREENING/30MAR2012	NTL:1/LUNG		CT		.	
	WEEK12/14JUN2012	TL:1/LIVER		CT		62	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
101-0023 /70/M/W2	WEEK12/14JUN2012	TL:2/LIVER		CT		23	
	WEEK12/14JUN2012	NTL:1/LUNG		CT	Present	.	
	Summary:					.	SLD = 85, %CN = 7.59, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
101-0024 /35/F/A4	SCREENING/16APR2012	TL:1/LUNG	S4 I33	CT		11	SLD = 11
	SCREENING/16APR2012	NTL:1/LUNG	S4 I27	CT		.	
	SCREENING/16APR2012	NTL:2/LUNG		CT		.	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
101-0024 /35/F/A4	WEEK12/10JUL2012	TL:1/LUNG	S4 I33	CT		21	
	WEEK12/10JUL2012	NTL:1/LUNG	S4 I27	CT	UP	.	
	WEEK12/10JUL2012	NTL:2/LUNG		CT	UP	.	
	Summary:					.	SLD = 21, %CN = 90.91, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 10JUL2012
101-0025 /57/F/W2	SCREENING/20APR2012	TL:1/LUNG	SERIES 4, IMAGE 47	CT		40	
	SCREENING/20APR2012	TL:2/LUNG	SERIES 4, IMAGE 34	CT		38	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
101-0025 /57/F/W2	SCREENING/20APR2012	TL:3/LIVER	SERIES 100, IMAGE 27	CT		23	
	SCREENING/20APR2012	TL:4/LIVER	SERIES 101, IMAGE 87	CT		43	
	SCREENING/20APR2012	TL:5/NODES	MEDIASTINAL LYMPH NODE. SERIES 101, IMAGE 29.	CT		35	SLD = 179
	UNSCHEDULED/15JUN2012	TL:1/LUNG	SERIES 4, IMAGE 47	CT		46	
	UNSCHEDULED/15JUN2012	TL:2/LUNG	SERIES 4, IMAGE 34	CT		43	
	UNSCHEDULED/15JUN2012	TL:3/LIVER	SERIES 100, IMAGE 27	CT		18	

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[3] UP=Unequivocally Progressed
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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
101-0025 /57/F/W2	UNSCHEDULED/15JUN2012	TL:4/NODES	SERIES 101, IMAGE 29	CT		35	
	UNSCHEDULED/15JUN2012	TL:5/LIVER	SERIES 100, IMAGE 87	CT		91	
	Summary:					.	SLD = 233, %CN = 30.17, TL: PD, NTL: IncompleteResponse/SD, OR: PD, PD confirmed: Yes, 15JUN2012
101-0026 /82/M/W2	SCREENING/30APR2012	TL:1/LIVER	S7 I53	CT		39	
	SCREENING/30APR2012	TL:2/LIVER	S6 I26	CT		36	SLD = 75
	WEEK12/31JUL2012	TL:1/LIVER	S7 I53	CT		37	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
101-0026 /82/M/W2	WEEK12/31JUL2012	TL:2/LIVER	S6 I26	CT		36	
	Summary:					.	SLD = 73, %CN = -2.67, TL: SD, NTL: NotAssessed, OR: SD, PD confirmed: No
	WEEK24/19OCT2012	TL:1/LIVER	S7 I53	CT		33	
	WEEK24/19OCT2012	TL:2/LIVER	S6 I26	CT		37	
	Summary:					.	SLD = 70, %CN = 0, TL: SD, NTL: NotEvaluable, OR: SD, PD confirmed: No
	UNSCHEDULED/11JAN2013	TL:1/LIVER	SERIES 7, IMAGE 53	CT		45	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
101-0026 /82/M/W2	UNSCHEDULED/11JAN2013	TL:2/LIVER	SERIES 6, IMAGE 26	CT		58	
	UNSCHEDULED/11JAN2013	NTL:1/LIVE	PORTAL VEIN. SERIES 5, IMAGE 51	CT	New	.	
	Summary:					.	SLD = 103, %CN = 47.14, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 11JAN2013
101-0028 /60/M/W2	SCREENING/22MAY2012	TL:1/LIVER	S101 I66	CT		39	
	SCREENING/22MAY2012	TL:2/LIVER	S101 I55	CT		23	
	SCREENING/22MAY2012	TL:3/NODES	UPPER ABDOMINAL ADENOPATHY	CT		28	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
101-0028 /60/M/W2	SCREENING/22MAY2012	TL:4/GI	RIGHT ADRENAL	CT		49	
	SCREENING/22MAY2012	TL:5/LUNG	RIGHT LUNG	CT		61	SLD = 200
	WEEK12/07SEP2012	TL:1/LIVER	S101 I66	CT		60	
	WEEK12/07SEP2012	TL:2/LIVER	S101 I55	CT		27	
	WEEK12/07SEP2012	TL:3/NODES	UPPER ABDOMINAL ADENOPATHY	CT		25	
	WEEK12/07SEP2012	TL:4/GI	RIGHT ADRENAL	CT		56	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
101-0028 /60/M/W2	WEEK12/07SEP2012	TL:5/LUNG	RIGHT LUNG	CT		62	
	Summary:					.	SLD = 230, %CN = 15, TL: SD, NTL: NotAssessed, OR: SD, PD confirmed: No
101-0029 /70/M/A1	SCREENING/15JUN2012	TL:1/NODES	LEFT THORACIC NODE (S5 I8)	CT		24	SLD = 24
	SCREENING/15JUN2012	NTL:1/NODE	RETROPERITONEAL NODE S5 I70	CT		.	
	WEEK12/28AUG2012	TL:1/NODES	LEFT THORACIC NODE (S5 I8)	CT		24	
	WEEK12/28AUG2012	NTL:1/NODE	RETROPERITONEAL NODE S5 I70	CT	UP	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
101-0029 /70/M/A1	WEEK12/28AUG2012	NTL:2/NODE	RIGHT PARATRACHEAL NODE	CT	New	.	
	Summary:					.	SLD = 24, %CN = 0, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 28AUG2012
101-0030 /51/M/W2	SCREENING/18JUN2012	TL:1/LIVER	NOT SPECIFIED	CT		44	
	SCREENING/18JUN2012	TL:2/LIVER	NOT SPECIFIED	CT		55	SLD = 99
	SCREENING/18JUN2012	NTL:1/LUNG	NOT SPECIFIED	CT		.	
	UNSCHEDULED/05SEP2012	TL:1/LIVER	NOT SPECIFIED	CT		62	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
101-0030 /51/M/W2	UNSCHEDULED/05SEP2012	TL:2/LIVER	NOT SPECIFIED	CT		73	
	UNSCHEDULED/05SEP2012	NTL:1/LUNG	NOT SPECIFIED	CT	UP	.	
	Summary:					.	SLD = 135, %CN = 36.36, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 05SEP2012
101-0032 /84/M/W2	SCREENING/11JUL2012	TL:1/LUNG		CT		10	SLD = 10
	WEEK12/09OCT2012	TL:1/LUNG		CT		5	
	Summary:					.	SLD = 5, %CN = -50, TL: PR, NTL: NotAssessed, OR: PR, PD confirmed: No

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
101-0033 /66/F/W2	SCREENING/13JUL2012	TL:1/LIVER	SERIES 101, IMAGE 49	CT		28	
	SCREENING/13JUL2012	TL:2/LIVER	SERIES 101, IMAGE 73	CT		19	SLD = 47
	WEEK12/05OCT2012	TL:1/LIVER	SERIES 101, IMAGE 49	CT		29	
	WEEK12/05OCT2012	TL:2/LIVER	SERIES 101, IMAGE 73	CT		27	
	Summary:					.	SLD = 56, %CN = 19.15, TL: SD, NTL: NotEvaluable, OR: SD, PD confirmed: No
	WEEK24/04JAN2013	TL:1/LIVER	SERIES 101, IMAGE 49	CT		36	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
101-0033 /66/F/W2	WEEK24/04JAN2013	TL:2/LIVER	SERIES 101, IMAGE 73	CT		32	
	WEEK24/04JAN2013	NTL:1/LIVE	SERIES 5, IMAGE 52	CT	New	.	
	Summary:					.	SLD = 68, %CN = 44.68, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 04JAN2013
101-0036 /67/M/A4	SCREENING/19OCT2012	TL:1/LIVER	SERIES 4, IMAGE 22	CT		177	
	SCREENING/19OCT2012	TL:2/LUNG	SERIES 6, IMAGE 40	CT		18	
	SCREENING/19OCT2012	TL:3/LUNG	SERIES 6, IMAGE 30	CT		21	SLD = 216

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
101-0036 /67/M/A4	SCREENING/19OCT2012	NTL:1/NODE	LYMPH NODE	CT		.	
	SCREENING/19OCT2012	NTL:2/LIVE	LIVER LESION	CT		.	
	SCREENING/19OCT2012	NTL:3/LUNG	LUNG LESION	CT		.	
	UNSCHEDULED/12DEC2012	TL:1/LIVER	SERIES 4, IMAGE 22	CT		186	
	UNSCHEDULED/12DEC2012	TL:2/LUNG	SERIES 6, IMAGE 40	CT		36	
	UNSCHEDULED/12DEC2012	TL:3/LUNG	SERIES 6, IMAGE 30	CT		30	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
101-0036 /67/M/A4	UNSCHEDULED/12DEC2012	NTL:1/NODE	SERIES 4, IMAGE 14	CT	UP	.	
	UNSCHEDULED/12DEC2012	NTL:2/LIVE	LIVER LESION	CT	UP	.	
	UNSCHEDULED/12DEC2012	NTL:3/LUNG	LUNG LESION	CT	UP	.	
	Summary:					.	SLD = 252, %CN = 16.67, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 12DEC2012
101-0037 /57/M/A1	SCREENING/30NOV2012	TL:1/LIVER	S100 I12	CT		77	
	SCREENING/30NOV2012	TL:2/LIVER	S100 I10	CT		23	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
101-0037 /57/M/A1	SCREENING/30NOV2012	TL:3/LUNG	S102 I20	CT		16	
	SCREENING/30NOV2012	TL:4/LUNG	S102 I18	CT		14	SLD = 130
	SCREENING/30NOV2012	NTL:1/LIVE		CT		.	
101-0038 /56/M/W2	SCREENING/30JAN2013	TL:1/NODES	LYMPH NODE. SERIES 2, IMAGE 55	CT		38	
	SCREENING/30JAN2013	TL:2/GI	PERITONEUM. SERIES 2, IMAGE 58	CT		33	
	SCREENING/30JAN2013	TL:3/GI	PERITONEUM. SERIES 2, IMAGE 64	CT		15	SLD = 86

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
101-0039 /77/F/W2	Summary:					.	SLD = 109, %CN = 13.54, TL: SD, NTL: NotEvaluable, OR: SD, PD confirmed: No
	WEEK12/14JUN2012	TL:1/LIVER	RT HEPATIC MASS (S3 I37)	CT		99	
	SCREENING/12MAR2013	TL:1/LIVER	RT HEPATIC MASS (S3 I37)	CT		96	SLD = 96
	Summary:					.	SLD = 99, %CN = 3.13, TL: SD, NTL: NotAssessed, OR: SD, PD confirmed: No
	WEEK24/07SEP2013	TL:1/LIVER	RT HEPATIC MASS (S3 I37)	CT		109	
	WEEK36/27NOV2013	TL:1/LIVER	RT HEPATIC MASS (S3 I37)	CT		117	

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[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
101-0039 /77/F/W2	Summary:					.	SLD = 117, %CN = 21.88, TL: PD, NTL: NotEvaluable, OR: PD, PD confirmed: Yes, 27NOV2013
101-0040 /60/M/W2	SCREENING/10JUN2013	TL:1/LIVER	LIVER (S4 I18)	CT		20	
	SCREENING/10JUN2013	TL:2/BONE	LEFT RIB (S5 I27)	CT		56	
	SCREENING/10JUN2013	TL:3/GI	LT ADRENAL (S5 I60)	CT		39	
	SCREENING/10JUN2013	TL:4/GI	RT ADRENAL (S5 I59)	CT		19	SLD = 134
	WEEK12/06AUG2013	TL:1/LIVER	LIVER (S4 I18)	CT		21	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
101-0040 /60/M/W2	WEEK12/06AUG2013	TL:2/BONE	LEFT RIB (S5 I27)	CT		73	
	WEEK12/06AUG2013	TL:3/GI	LT ADRENAL (S5 I60)	CT		41	
	WEEK12/06AUG2013	TL:4/GI	RT ADRENAL (S5 I59)	CT		22	
	WEEK12/06AUG2013	NTL:1/LIVE	LIVER (S5 I60)	CT	New	.	
	Summary:					.	SLD = 157, %CN = 17.16, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 06AUG2013
101-0041 /54/M/W2	SCREENING/12JUL2013	TL:1/NODES	SERIES 5, IMAGE 63	CT		43	SLD = 43

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
101-0042 /64/M/W2	SCREENING/15JUL2013	TL:1/LIVER	SERIES 5, IMAGE 52	CT		64	
	SCREENING/15JUL2013	TL:2/LIVER	SERIES 5, IMAGE 47	CT		44	SLD = 108
101-0044 /78/M/W2	SCREENING/11OCT2013	TL:1/LIVER	SERIES 3, IMAGE 26	CT		23	SLD = 23
	SCREENING/11OCT2013	NTL:1/LIVE	SERIES 3, IMAGE 11	CT		.	
	WEEK12/27DEC2013	TL:1/LIVER	SERIES 3, IMAGE 26	CT		29	
	WEEK12/27DEC2013	NTL:1/LIVE	SERIES 3, IMAGE 11	CT	Present	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
101-0044 /78/M/W2	Summary:					.	SLD = 29, %CN = 26.09, TL: PD, NTL: IncompleteResponse/SD, OR: PD, PD confirmed: Yes, 27DEC2013
101-0045 /74/F/W2	SCREENING/15OCT2013	TL:1/LIVER	SERIES 5, IMAGE 46	CT		45	
	SCREENING/15OCT2013	TL:2/LIVER	SERIES 5, IMAGE 46	CT		12	
	SCREENING/15OCT2013	TL:3/BONE	SERIES 5, IMAGE 35	CT		14	SLD = 71
	SCREENING/15OCT2013	NTL:1/GI	PORTAL VEIN - SERIES 5, IMAGE 47	CT		.	
	SCREENING/15OCT2013	NTL:2/LIVE	SERIES 5, IMAGE 52	CT		.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
101-0045 /74/F/W2	SCREENING/15OCT2013	NTL:3/BONE	SERIES 5, IMAGE 35	CT		.	
	WEEK12/16JAN2014	TL:1/LIVER	SERIES 5, IMAGE 46	CT		73	
	WEEK12/16JAN2014	TL:2/LIVER	SERIES 5, IMAGE 46	CT		15	
	WEEK12/16JAN2014	TL:3/BONE	SERIES 5, IMAGE 35	CT		22	
	WEEK12/16JAN2014	NTL:1/GI	PORTAL VEIN - SERIES 5, IMAGE 47	CT	Present	.	
	WEEK12/16JAN2014	NTL:2/LIVE	SERIES 5, IMAGE 52	CT	UP	.	

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[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
101-0045 /74/F/W2	WEEK12/16JAN2014	NTL:3/BONE	SERIES 5, IMAGE 35	CT	UP	.	
	Summary:					.	SLD = 110, %CN = 54.93, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 16JAN2014
101-0046 /70/M/OTH	SCREENING/21OCT2013	TL:1/LIVER	SERIES 5, IMAGE 51	CT		21	
	SCREENING/21OCT2013	TL:2/LIVER	SERIES 5, IMAGE 48	CT		25	SLD = 46
	SCREENING/21OCT2013	NTL:1/LUNG	SERIES 6, IMAGE 16	CT		.	
	SCREENING/21OCT2013	NTL:2/BONE	SERIES 5, IMAGE 82	CT		.	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
101-0046 /70/M/OTH	WEEK12/02JAN2014	TL:1/LIVER	SERIES 5, IMAGE 51	CT		27	
	WEEK12/02JAN2014	TL:2/LIVER	SERIES 5, IMAGE 48	CT		35	
	WEEK12/02JAN2014	NTL:1/LUNG	SERIES 6, IMAGE 16	CT	UP	.	
	WEEK12/02JAN2014	NTL:2/BONE	SERIES 5, IMAGE 82	CT	Present	.	
	Summary:					.	SLD = 62, %CN = 34.78, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 02JAN2014
101-0047 /52/M/W2	SCREENING/20OCT2013	TL:1/LIVER	SERIES 101, IMAGE 17	CT		34	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
101-0047 /52/M/W2	SCREENING/20OCT2013	TL:2/LIVER	SERIES 101, IMAGE 23	CT		61	SLD = 95
	SCREENING/20OCT2013	NTL:1/LIVE		CT		.	
	UNSCHEDULED/16DEC2013	TL:1/LIVER	SERIES 101, IMAGE 17	CT		39	
	UNSCHEDULED/16DEC2013	TL:2/LIVER	SERIES 101, IMAGE 23	CT		67	
	UNSCHEDULED/16DEC2013	NTL:1/LIVE	NOT SPECIFIED	CT	UP	.	
	Summary:					.	SLD = 106, %CN = 11.58, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 16DEC2013

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
101-0048 /66/F/W2	SCREENING/29SEP2013	TL:1/NODES	LT HILAR LYMPH NODE. SERIES 103D, IMAGE 20	CT		24	SLD = 24
	SCREENING/29SEP2013	NTL:1/LUNG	SERIES 103K, IMAGE 8	CT		.	
	SCREENING/29SEP2013	NTL:2/LUNG	SERIES 103, IMAGE 18	CT		.	
	WEEK12/30DEC2013	TL:1/NODES	LT HILAR LYMPH NODE. SERIES 103D, IMAGE 20	CT		23	
	WEEK12/30DEC2013	NTL:1/LUNG	SERIES 103K, IMAGE 8	CT	Present	.	
	WEEK12/30DEC2013	NTL:2/LUNG	SERIES 103, IMAGE 18	CT	UP	.	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
101-0048 /66/F/W2	Summary:					.	SLD = 23, %CN = -4.17, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 30DEC2013
101-0049 /71/M/A8	SCREENING/23OCT2013	TL:1/LIVER	SERIES 4, IMAGE 15	CT		10	
	SCREENING/23OCT2013	TL:2/GI	PERITONEUM: SERIES 5, IMAGE 91	CT		52	
	SCREENING/23OCT2013	TL:3/GI	PERITONEUM: SERIES 5, IMAGE 121	CT		41	SLD = 103
	SCREENING/23OCT2013	NTL:1/GI	PERITONEUM: SERIES 4, IMAGE 5	CT		.	
	SCREENING/23OCT2013	NTL:2/GI	PERITONEUM: SERIES 4, IMAGE 9	CT		.	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
101-0049 /71/M/A8	WEEK12/08JAN2014	TL:1/LIVER	SERIES 4, IMAGE 15	CT		12	
	WEEK12/08JAN2014	TL:2/GI	PERITONEUM: SERIES 5, IMAGE 91	CT		67	
	WEEK12/08JAN2014	TL:3/GI	PERITONEUM: SERIES 5, IMAGE 121	CT		49	
	WEEK12/08JAN2014	NTL:1/GI	PERITONEUM: SERIES 4, IMAGE 5	CT	Present	.	
	WEEK12/08JAN2014	NTL:2/GI	PERITONEUM: SERIES 4, IMAGE 9	CT	Present	.	
	Summary:					.	SLD = 128, %CN = 24.27, TL: PD, NTL: IncompleteResponse/SD, OR: PD, PD confirmed: Yes, 08JAN2014

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
101-0050 /59/M/W2	SCREENING/22OCT2013	TL:1/LIVER	SERIES 5, IMAGE 53	CT		38	
	SCREENING/22OCT2013	TL:2/LIVER	SERIES 5, IMAGE 51	CT		49	
	SCREENING/22OCT2013	TL:3/NODES	SERIES 5, IMAGE 63	CT		52	
	SCREENING/22OCT2013	TL:4/NODES	SERIES 5, IMAGE 71	CT		16	SLD = 155
	SCREENING/22OCT2013	NTL:1/LUNG	SERIES 6, IMAGE 21	CT		.	
	UNSCHEDULED/05DEC2013	TL:1/LIVER	SERIES 5, IMAGE 53	CT		39	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
101-0050 /59/M/W2	UNSCHEDULED/05DEC2013	TL:2/LIVER	SERIES 5, IMAGE 51	CT		49	
	UNSCHEDULED/05DEC2013	TL:3/NODES	SERIES 5, IMAGE 63	CT		69	
	UNSCHEDULED/05DEC2013	TL:4/NODES	SERIES 5, IMAGE 71	CT		34	
	UNSCHEDULED/05DEC2013	NTL:1/LUNG	SERIES 6, IMAGE 21	CT	Present	.	
	Summary:					.	SLD = 191, %CN = 23.23, TL: PD, NTL: IncompleteResponse/SD, OR: PD, PD confirmed: Yes, 05DEC2013
102-0001 /53/M/BL	SCREENING/03APR2012	TL:1/LIVER	MULTIFOCAL	MRI		23	SLD = 23

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
102-0001 /53/M/BL	SCREENING/03APR2012	NTL:1/LIVE	THROMBOSIS OF LEFT PORTAL VEIN	MRI		.	
	WEEK12/07JUN2012	TL:1/LIVER	MULTIFOCAL	MRI	UP	.	
	WEEK12/07JUN2012	NTL:1/LIVE	THROMBOSIS OF LEFT PORTAL VEIN	MRI	UP	.	
	Summary:					.	SLD = ., %CN = ., TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 07JUN2012
102-0003 /63/M/BL	SCREENING/07SEP2012	TL:1/LIVER	DOME OF RT LOBE OF LIVER	CT		34	
	SCREENING/07SEP2012	TL:2/LIVER	LATERAL PART OF RT LOBE (LARGER HYPODENSITY)	CT		27	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
102-0003 /63/M/BL	SCREENING/07SEP2012	TL:3/LIVER	LATERAL PART OF RIGHT LOBE (SMALLER HYPODENSITY)	CT		19	
	SCREENING/07SEP2012	TL:4/LIVER	INFERIOR PART OF RIGHT LOBE OF LIVER (SEGMENT 5/6)	CT		27	SLD = 107
	WEEK12/23NOV2012	TL:1/LIVER	DOME OF RT LOBE OF LIVER	CT	NE	.	
	WEEK12/23NOV2012	TL:2/LIVER	LATERAL PART OF RT LOBE (LARGER HYPODENSITY)	CT	NE	.	
	WEEK12/23NOV2012	TL:3/LIVER	LATERAL PART OF RIGHT LOBE (SMALLER HYPODENSITY)	CT	NE	.	
	WEEK12/23NOV2012	TL:4/LIVER	INFERIOR PART OF RIGHT LOBE OF LIVER (SEGMENT 5/6)	CT	NE	.	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
102-0003 /63/M/BL	Summary:					.	SLD = ., %CN = ., TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 23NOV2012
102-0008 /64/M/BL	SCREENING/02JAN2014	TL:1/LIVER	LARGE MASS IN RIGHT LOBE OF LIVER	CT		153	
	SCREENING/02JAN2014	TL:2/LIVER	SMALL MASS IN ANTERIOR RIGHT LOBE OF LIVER	CT		23	SLD = 176
102-0009 /58/M/W2	SCREENING/03OCT2014	TL:1/SOFTT	ANTERIOR SUPERIOR MEDIASTINAL MASS	CT		55	
	SCREENING/03OCT2014	TL:2/SOFTT	ANTERIOR INFERIOR MEDIASTINAL MASS	CT		50	
	SCREENING/03OCT2014	TL:3/LIVER	LIVER MASS CLUSTER	CT		145	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
102-0009 /58/M/W2	SCREENING/03OCT2014	TL:4/NODES	PORTACAVAL LYMPH NODE	CT		68	
	SCREENING/03OCT2014	TL:5/SOFTT	L3 LEFT VERTEBRAL SOFT TISSUE MASS	CT		50	SLD = 368
	SCREENING/03OCT2014	NTL:1/ASCI	ABDOMINAL PELVIC ASCITES (SMALL AMOUNT)	CT		.	
	UNSCHEDULED/09DEC2014	TL:1/SOFTT	ANTERIOR SUPERIOR MEDIASTINAL MASS	CT		61	
	UNSCHEDULED/09DEC2014	TL:2/SOFTT	ANTERIOR INFERIOR MEDIASTINAL MASS	CT		64	
	UNSCHEDULED/09DEC2014	TL:3/LIVER	LIVER MASS CLUSTER	CT		159	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
102-0009 /58/M/W2	UNSCHEDULED/09DEC2014	TL:4/NODES	PORTACAVAL LYMPH NODE	CT		65	
	UNSCHEDULED/09DEC2014	TL:5/SOFTT	L3 LEFT VERTEBRAL SOFT TISSUE	CT		54	
	UNSCHEDULED/09DEC2014	NTL:1/ASCI	ABDOMINAL PELVIC ASCITIES (TRACE)	CT	Present	.	
	WEEK12/09DEC2014	NTL:2/PLEU	RIGHT PLEURAL EFFUSION	CT	New	.	
	UNSCHEDULED/09DEC2014	NTL:2/PLEU	PLEURAL EFFUSION	CT	New	.	
	WEEK12/09DEC2014	NTL:3/SOFT	LEFT ADRENAL MASS (42 MM)	CT	New	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
102-0009 /58/M/W2	UNSCHEDULED/09DEC2014	NTL:3/SOFT	LEFT ADRENAL MASS (42 MM)	CT	New	.	
	Summary:					.	SLD = 403, %CN = 9.51, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 09DEC2014
103-0001 /56/M/W2	SCREENING/07MAY2012	TL:1/LIVER	SEGMENT 5 AND/OR 8	CT		32	
	SCREENING/07MAY2012	TL:2/LIVER	SEGMENT 6 CAUDAL TIP	CT		42	SLD = 74
	WEEK12/26JUL2012	TL:1/LIVER	SEGMENT 5 AND/OR 8	CT		41	
	WEEK12/26JUL2012	TL:2/LIVER	SEGMENT 6 CAUDAL TIP	CT		42	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
103-0001 /56/M/W2	Summary:					.	SLD = 83, %CN = 12.16, TL: PD, NTL: NotAssessed, OR: PD, PD confirmed: Yes, 26JUL2012
103-0003 /66/M/W2	SCREENING/11FEB2013	TL:1/LIVER	LIVER DOME	CT		29	SLD = 29
	WEEK12/29APR2013	TL:1/LIVER	LIVER DOME	CT	NE	.	
	Summary:					.	SLD = ., %CN = ., TL: NotEvaluable, NTL: NotEvaluable, OR: NotEvaluable, PD confirmed: No
	WEEK24/23JUL2013	TL:1/LIVER	LIVER	CT	UP	.	
	Summary:					.	SLD = ., %CN = ., TL: PD, NTL: NotEvaluable, OR: PD, PD confirmed: Yes, 23JUL2013

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
103-0004 /40/F/A1	SCREENING/14APR2014	TL:1/LIVER	SEGMENT 2/3	CT		17	SLD = 17
	SCREENING/14APR2014	NTL:1/LUNG	MULTIPLE LUNG NODULES	CT		.	
	UNSCHEDULED/03JUN2014	TL:1/LIVER	SEGMENT 2/3	MRI	NE	.	
	UNSCHEDULED/03JUN2014	NTL:2/BONE	C6-C7 EPIDURAL TUMOR	MRI	New	.	
	Summary:					.	SLD = ., %CN = ., TL: NotAssessed, NTL: PD, OR: PD, PD confirmed: Yes, 03JUN2014
104-0003 /56/F/W2	SCREENING/16JUL2012	TL:1/LIVER	RIGHT LOBE ARTERIAL IMG94	CT		100	SLD = 100

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
104-0004 /74/M/W2	SCREENING/01OCT2012	TL:1/LIVER	INFERIOR RIGHT HEPATIC LOBE(SEGMENTS 5 AND6)	CT		50	SLD = 50
104-0008 /55/M/PI	SCREENING/31AUG2013	TL:1/LIVER	MEDIAL LEFT HEPATIC	CT		45	
	SCREENING/31AUG2013	TL:2/NODES	PERIPANCREATIC NODE	CT		39	
	SCREENING/31AUG2013	TL:3/NODES	PERINEPHRIC NODE	CT		26	SLD = 110
	WEEK12/29NOV2013	TL:1/LIVER	MEDIAL LEFT HEPATIC	CT		58	
	WEEK12/29NOV2013	TL:2/NODES	PERIPANCREATIC NODE	CT		40	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
104-0008 /55/M/PI	WEEK12/29NOV2013	TL:3/NODES	PERINEPHRIC NODE	CT		30	
	Summary:					.	SLD = 128, %CN = 16.36, TL: SD, NTL: NotAssessed, OR: SD, PD confirmed: No
104-0010 /71/F/A8	SCREENING/04JAN2014	TL:1/LUNG	RIGHT UPPER LOBE	CT		22	
	SCREENING/04JAN2014	TL:2/LUNG	LEFT POSTERIOR UPPER LOBE	CT		23	SLD = 45
	WEEK12/29MAR2014	TL:1/LUNG	RIGHT UPPER LOBE	CT		20	
	WEEK12/29MAR2014	TL:2/LUNG	LEFT POSTERIOR UPPER LOBE	CT		22	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
104-0010 /71/F/A8	Summary:					.	SLD = 42, %CN = -6.67, TL: SD, NTL: NotAssessed, OR: SD, PD confirmed: No
	WEEK24/25JUN2014	TL:1/LUNG	RIGHT UPPER LOBE	CT		36	
	WEEK24/25JUN2014	TL:2/LUNG	LEFT POSTERIOR UPPER LOBE	CT		18	
	Summary:					.	SLD = 54, %CN = 28.57, TL: SD, NTL: NotAssessed, OR: SD, PD confirmed: No
	WEEK36/17SEP2014	TL:1/LUNG	RIGHT UPPER LOBE	CT		27	
	WEEK36/17SEP2014	TL:2/LUNG	LEFT POSTERIOR UPPER LOBE	CT		15	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
104-0010 /71/F/A8	WEEK36/17SEP2014	NTL:1/LUNG	MEDIAL RIGHT UPPER LOBE	CT	New	.	
	Summary:					.	SLD = 42, %CN = 0, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 17SEP2014
104-0012 /78/F/A2	SCREENING/13SEP2014	TL:1/LIVER	HEPATIC DOME LESION RIGHT LOBE SEG 8	CT		30	
	SCREENING/13SEP2014	TL:2/LIVER	SEGMENT 7, POSTERIOR SEG, RIGHT HEPATIC LOBE	CT		29	SLD = 59
	UNSCHEDULED/29NOV2014	TL:1/LIVER	SEGMENT 7, POSTERIOR SEG, RIGHT HEPATIC LOBE	CT		31	
	UNSCHEDULED/29NOV2014	TL:2/LIVER	SEGMENT 7, POSTERIOR SEG, RIGHT HEPATIC LOBE	CT		44	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
104-0012 /78/F/A2	UNSCHEDULED/29NOV2014	NTL:1/BONE	T9 VERTEBRAL BODY	CT	New	.	
	Summary:					.	SLD = 75, %CN = 27.12, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 29NOV2014
106-0001 /42/F/W2	SCREENING/24FEB2012	TL:1/LIVER	LEFT LOBE OF LIVER	CT		110	
	SCREENING/24FEB2012	TL:2/LIVER	RIGHT LOBE OF LIVER	CT		134	
	SCREENING/24FEB2012	TL:3/SOFTT	RIGHT ADRENAL GLAND	CT		44	
	SCREENING/24FEB2012	TL:4/SOFTT	LEFT ADRENAL GLAND	CT		20	SLD = 308

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
106-0001 /42/F/W2	WEEK12/14MAY2012	TL:1/LIVER	LEFT LOBE OF LIVER	CT		136	
	WEEK12/14MAY2012	TL:2/LIVER	RIGHT LOBE OF LIVER	CT		138	
	WEEK12/14MAY2012	TL:3/SOFTT	RIGHT ADRENAL GLAND	CT		54	
	WEEK12/14MAY2012	TL:4/SOFTT	LEFT ADRENAL GLAND	CT		31	
	Summary:					.	SLD = 359, %CN = 16.56, TL: SD, NTL: NotEvaluable, OR: SD, PD confirmed: No
	WEEK24/29JUN2012	TL:1/LIVER	LEFT LOBE OF LIVER	CT		169	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
106-0001 /42/F/W2	WEEK24/29JUN2012	TL:2/LIVER	RIGHT LOBE OF LIVER	CT		164	
	WEEK24/29JUN2012	TL:3/SOFTT	RIGHT ADRENAL GLAND	CT		54	
	WEEK24/29JUN2012	TL:4/SOFTT	LEFT ADRENAL GLAND	CT		38	
	Summary:					.	SLD = 425, %CN = 37.99, TL: PD, NTL: NotAssessed, OR: PD, PD confirmed: Yes, 29JUN2012
107-0002 /71/M/W2	SCREENING/08AUG2012	TL:1/NODES	LEFT PERIAORTIC	CT		37	
	SCREENING/08AUG2012	TL:2/LIVER	RIGHT HEPATIC DOME	CT		23	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
107-0002 /71/M/W2	SCREENING/08AUG2012	TL:3/LIVER	RIGHT HEPATIC LOBE	CT		19	SLD = 79
	SCREENING/08AUG2012	NTL:1/LIVE	INFERIOR RIGHT LOBE	CT		.	
	WEEK12/07NOV2012	TL:1/NODES	LEFT PERIAORTIC	CT		47	
	WEEK12/07NOV2012	TL:2/LIVER	RIGHT HEPATIC DOME	CT		20	
	WEEK12/07NOV2012	TL:3/LIVER	RIGHT HEPATIC LOBE	CT		19	
	WEEK12/07NOV2012	NTL:1/LIVE	INFERIOR RIGHT LOBE	CT	Present	.	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
107-0002 /71/M/W2	WEEK12/07NOV2012	NTL:2/NODE	AORTOCAVAL	CT	New	.	
	Summary:					.	SLD = 86, %CN = 8.86, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 07NOV2012
107-0003 /73/M/BL	SCREENING/07FEB2013	TL:1/LIVER	RIGHT POSTERIOR SEGMENT	CT		150	
	SCREENING/07FEB2013	TL:2/LUNG	LEFT LOWER LOBE	CT		14	SLD = 164
	SCREENING/07FEB2013	NTL:1/LIVE	HEPATIC METS	CT		.	
	SCREENING/07FEB2013	NTL:2/LUNG	PULMONARY METS	CT		.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
107-0004 /63/M/W2	SCREENING/26FEB2013	TL:2/NODES	AORTOCAVAL	CT		69	
	SCREENING/26FEB2013	TL:3/GI	LEFT ADRENAL MASS	CT		146	
	SCREENING/26FEB2013	TL:4/LIVER	LATERAL SEGMENT DOME	CT		20	SLD = 235
	SCREENING/26FEB2013	NTL:1/LIVE	HYPERENHANCING HEPATIC LESIONS	CT		.	
	SCREENING/26FEB2013	NTL:2/LIVE	ABLATION DEFECT POSTERIOR HEPATIC DOME	CT		.	
	WEEK12/21MAY2013	TL:2/NODES	AORTOCAVAL	CT		77	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
107-0004 /63/M/W2	WEEK12/21MAY2013	TL:3/GI	LEFT ADRENAL MASS	CT		146	
	WEEK12/21MAY2013	TL:4/LIVER	LATERAL SEGMENT DOME	CT		20	
	WEEK12/21MAY2013	NTL:1/LIVE	HYPERENHANCING HEPATIC LESIONS	CT	Present	.	
	WEEK12/21MAY2013	NTL:2/LIVE	ABLATION DEFECT POSTERIOR HEPATIC DOME	CT	Present	.	
	Summary:					.	SLD = 243, %CN = 3.4, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
107-0006 /60/M/W2	SCREENING/17APR2013	TL:1/LIVER	POSTERIOR SEGMENT	CT		16	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
107-0006 /60/M/W2	SCREENING/17APR2013	TL:2/LIVER	INFERIOR RIGHT HEPATIC MARGIN	CT		12	
	SCREENING/17APR2013	TL:3/NODES	PORTACAVAL	CT		34	SLD = 62
	WEEK12/29JUL2013	TL:1/LIVER	POSTERIOR SEGMENT	CT		26	
	WEEK12/29JUL2013	TL:2/LIVER	INFERIOR RIGHT HEPATIC MARGIN	CT		30	
	WEEK12/29JUL2013	TL:3/NODES	PORTACAVAL	CT		68	
	WEEK12/29JUL2013	NTL:1/LIVE	MULTIPLE NEW HYPERENHANCING LESIONS	CT	New	.	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
107-0006 /60/M/W2	WEEK12/29JUL2013	NTL:2/BONE	LYTIC LEFT RIB LESION	CT	New	.	
	WEEK12/29JUL2013	NTL:3/LUNG	RIGHT LOWER LOBE	CT	New	.	
	Summary:					.	SLD = 124, %CN = 100, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 29JUL2013
108-0001 /60/F/W2	SCREENING/13MAR2012	TL:1/NODES	RIGHT GROIN 1	CT		58	
	SCREENING/13MAR2012	TL:2/NODES	RIGHT GROIN 2	CT		27	
	SCREENING/13MAR2012	TL:3/NODES	RIGHT GROIN 3	CT		25	SLD = 110

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
108-0001 /60/F/W2	SCREENING/13MAR2012	NTL:1/LUNG	LUNG NODULE	CT		.	
	WEEK12/04MAY2012	TL:1/NODES	RIGHT GROIN 1	CT		70	
	WEEK12/04MAY2012	TL:2/NODES	RIGHT GROIN 2	CT		45	
	WEEK12/04MAY2012	TL:3/NODES	RIGHT GROIN 3	CT		32	
	WEEK12/04MAY2012	NTL:1/LUNG	LUNG NODULE	CT	UP	.	
	Summary:					.	SLD = 147, %CN = 33.64, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 18JUN2012

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
108-0002 /78/M/BL	SCREENING/29MAY2012	TL:1/LIVER	LIVER LESION #1	CT		31	
	SCREENING/29MAY2012	TL:2/LIVER	LIVER LESION #2	CT		28	SLD = 59
	SCREENING/29MAY2012	NTL:1/LIVE	LIVER	CT		.	
	UNSCHEDULED/05JUL2012	TL:1/LIVER	LIVER LESION #1	CT		34	
	UNSCHEDULED/05JUL2012	TL:2/LIVER	LIVER LESION #2	CT		41	
	UNSCHEDULED/05JUL2012	NTL:1/LIVE	LIVER	CT	UP	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
108-0002 /78/M/BL	Summary:					.	SLD = 75, %CN = 27.12, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 10JUL2012
108-0004 /61/M/W2	SCREENING/17APR2013	TL:1/LIVER	RIGHT PORTAL VEIN TUMOR	CT		37	
	SCREENING/17APR2013	TL:2/LIVER	SEGMENT 7	CT		16	SLD = 53
	UNSCHEDULED/16MAY2013	TL:1/LIVER	RIGHT PORTAL VEIN TUMOR	CT		54	
	UNSCHEDULED/16MAY2013	TL:2/LIVER	SEGMENT 7	CT		12	
	Summary:					.	SLD = 66, %CN = 24.53, TL: PD, NTL: NotEvaluable, OR: PD, PD confirmed: No

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
108-0005 /68/M/W2	SCREENING/26APR2013	TL:1/LIVER	LIVER #1	CT		124	
	SCREENING/26APR2013	TL:2/LIVER	LIVER #2	CT		67	SLD = 191
	SCREENING/26APR2013	NTL:1/BONE	BONE LESIONS	CT		.	
	SCREENING/26APR2013	NTL:2/HEAD	RADIATED SINUS LESION	CT		.	
	UNSCHEDULED/14JUN2013	TL:1/LIVER	LIVER#1	CT		125	
	UNSCHEDULED/14JUN2013	TL:2/LIVER	LIVER #2	CT		65	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
108-0005 /68/M/W2	UNSCHEDULED/14JUN2013	NTL:/BONE	BONE LESIONS	CT	Present	.	
	UNSCHEDULED/14JUN2013	NTL:/HEAD&	RADIATED SINUS LESIONS	CT	Present	.	
	Summary:					.	SLD = 190, %CN = 0, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK12/29JUL2013	TL:1/LIVER	LIVER #1	CT		137	
	WEEK12/29JUL2013	TL:2/LIVER	LIVER #2	CT		74	
	WEEK12/29JUL2013	NTL:1/BONE	BONE LESIONS	CT	UP	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
108-0005 /68/M/W2	WEEK12/29JUL2013	NTL:2/HEAD	RADIATED SINUS LESION	CT	Present	.	
	Summary:					.	SLD = 211, %CN = 10.47, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 29JUL2013
108-0008 /77/M/W2	SCREENING/22SEP2014	TL:1/BONE	RIB	CT		51	
	SCREENING/22SEP2014	TL:2/LIVER	LIVER: SEGMENT 8, RIGHT LOBE	CT		29	
	SCREENING/22SEP2014	TL:3/LIVER	LIVER; LEFT LOBE	CT		34	SLD = 114
	SCREENING/22SEP2014	NTL:1/LIVE	INNUMERABLE LIVER	CT		.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
108-0008 /77/M/W2	UNSCHEDULED/17NOV2014	TL:1/BONE	RIB	CT		52	
	UNSCHEDULED/17NOV2014	TL:2/LIVER	LIVER: SEGMENT 8, RIGHT LOBE	CT		28	
	UNSCHEDULED/17NOV2014	TL:3/LIVER	LIVER: LEFT LOBE	CT		37	
	UNSCHEDULED/17NOV2014	NTL:1/LIVE	INNUMERABLE LIVER	CT	Present	.	
	Summary:					.	SLD = 117, %CN = 2.63, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK12/29DEC2014	TL:1/BONE	RIB	CT		54	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
108-0008 /77/M/W2	WEEK12/29DEC2014	TL:2/LIVER	LIVER: SEGMENT 8, RIGHT LOBE	CT		28	
	WEEK12/29DEC2014	TL:3/LIVER	LIVER; LEFT LOBE	CT		44	
	WEEK12/29DEC2014	NTL:1/LIVE	INNUMERABLE LIVER	CT	Present	.	
	Summary:					.	SLD = 126, %CN = 10.53, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK24/17MAR2015	TL:1/BONE	RIB	CT		58	
	WEEK24/17MAR2015	TL:2/LIVER	LIVER: SEGMENT 8, RIGHT LOBE	CT		30	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
108-0008 /77/M/W2	WEEK24/17MAR2015	TL:3/LIVER	LIVER; LEFT LOBE	CT		67	
	WEEK24/17MAR2015	NTL:1/LIVE	INNUMERABLE LIVER	CT	Present	.	
	Summary:					.	SLD = 155, %CN = 35.96, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 17MAR2015
109-0003 /68/M/W2	Summary:					.	SLD = 116, %CN = 90.16,
	SCREENING/06MAY2013	TL:1/LIVER	RIGHT UPPER LOBE	CT		15	
	SCREENING/06MAY2013	TL:2/LIVER	RIGHT LOWER LOBE	CT		19	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
109-0003 /68/M/W2	SCREENING/06MAY2013	TL:3/LIVER	MEDIAL RIGHT LOBE LIVER MASS	CT		43	SLD = 77
	SCREENING/06MAY2013	NTL:1/LIVE	DOMINANT INFILTRATIVE LIVER MASS	CT		.	
	SCREENING/06MAY2013	NTL:2/LIVE	R POSTERIOR INFERIOR LIVER LESION	CT		.	
	SCREENING/06MAY2013	NTL:3/LIVE	R MIDDLE LOBE NODULE	CT		.	
	SCREENING/06MAY2013	NTL:4/LIVE	RIGHT LOWER LOBE NODULES	CT		.	
	UNSCHEDULED/01JUL2013	TL:1/LIVER	RIGHT UPPER LOBE	CT		23	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
109-0003 /68/M/W2	UNSCHEDULED/01JUL2013	TL:2/LIVER	RIGHT LOWER LOBE	CT		32	
	UNSCHEDULED/01JUL2013	TL:3/LIVER	MEDIAL RIGHT LOBE LIVER MASS			61	
	WEEK12/01JUL2013	TL:3/	MEDIAL RIGHT LOBE LIVER MASS	CT		61	
	UNSCHEDULED/01JUL2013	NTL:1/LIVE	DOMINANT INFILTRATIVE LIVER MASS	CT	UP	.	
	UNSCHEDULED/01JUL2013	NTL:2/LIVE	RIGHT POSTERIOR INFERIOR LIVER LESION	CT	Present	.	
	UNSCHEDULED/01JUL2013	NTL:3/LIVE	RIGHT MIDDLE LOBE NODULE	CT	UP	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
109-0003 /68/M/W2	UNSCHEDULED/01JUL2013	NTL:4/LIVE	RIGHT LOWER LOBE NODULES	CT	UP	.	
	UNSCHEDULED/01JUL2013	NTL:5/LIVE	CAUDATE LESION	CT	New	.	
	UNSCHEDULED/01JUL2013	NTL:5/LIVE	RIGHT LOWER LOBE NODULE	CT	New	.	
	Summary:					.	SLD = 61, %CN = -20.78, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 01JUL2013
109-0004 /57/M/W2	SCREENING/12JUL2013	TL:1/LIVER	RIGHT LIVER MASS	CT		88	
	SCREENING/12JUL2013	TL:2/BONE	L5 SPINOUS PROCESS BONE LESION	CT		35	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
109-0004 /57/M/W2	SCREENING/12JUL2013	TL:3/BONE	RIGHT ILIAC WING LESION	CT		75	SLD = 198
	SCREENING/12JUL2013	NTL:1/LIVE	RIGHT HEPATIC VEIN TUMOR THROMBUS	CT		.	
	SCREENING/12JUL2013	NTL:2/LUNG	RIGHT UPPER LOBE, LEFT UPPER LOBE, RIGHT MIDDLE LOBE, RIGHT LOWER LOBE PULMONARY NODULES	CT		.	
	SCREENING/12JUL2013	NTL:3/BONE	SACRAL BONE LESION	CT		.	
	SCREENING/12JUL2013	NTL:4/BONE	LEFT FOURTH RIB LESION	CT		.	
	SCREENING/12JUL2013	NTL:5/BONE	RIGHT FIFTH POSTERIOR RIB LESION	CT		.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
109-0004 /57/M/W2	SCREENING/12JUL2013	NTL:6/BONE	SATELLITE NODULE ADJACENT TO L5 BONE LESION	CT		.	
	WEEK12/07OCT2013	TL:1/LIVER	RIGHT LIVER MASS	CT		104	
	WEEK12/07OCT2013	TL:2/BONE	L5 SPINOUS PROCESS BONE LESION	CT		35	
	WEEK12/07OCT2013	TL:3/BONE	RIGHT ILIAC WING LESION	CT		75	
	WEEK12/07OCT2013	NTL:1/LIVE	RIGHT HEPATIC VEIN TUMOR THROMBUS	CT	Present	.	
	WEEK12/07OCT2013	NTL:2/LUNG	RIGHT UPPER LOBE, LEFT UPPER LOBE, RIGHT MIDDLE LOBE, RIGHT LOWER LOBE PULMONARY NODULES	CT	Present	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
109-0004 /57/M/W2	WEEK12/07OCT2013	NTL:3/BONE	SACRAL BONE LESION	CT	Present	.	
	WEEK12/07OCT2013	NTL:4/BONE	LEFT FOURTH RIB LESION	CT	Present	.	
	WEEK12/07OCT2013	NTL:5/BONE	RIGHT FIFTH POSTERIOR RIB LESION	CT	Present	.	
	WEEK12/07OCT2013	NTL:6/BONE	SATELLITE NODULE ADJACENT TO L5 BONE LESION	CT	Present	.	
	WEEK12/07OCT2013	NTL:7/LUNG	NUMEROUS LUNG LESIONS	CT	New	.	
	WEEK12/07OCT2013	NTL:8/NODE	AORTOCAVAL NODE	CT	New	.	

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Tumor Assessment Summary Listing
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Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
109-0004 /57/M/W2	Summary:					.	SLD = 214, %CN = 8.08, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 07OCT2013
109-0006 /62/M/PI	SCREENING/19AUG2013	TL:1/LIVER	LEFT HEPATIC LOBE	CT		24	
	SCREENING/19AUG2013	TL:2/LIVER	RIGHT HEPATIC LOBE	CT		27	SLD = 51
	SCREENING/19AUG2013	NTL:1/LIVE	HEPATIC METASTASES	CT		.	
	WEEK12/06NOV2013	TL:1/LIVER	LEFT HEPATIC LOBE	CT		36	
	WEEK12/06NOV2013	TL:2/LIVER	RIGHT HEPATIC LOBE	CT		35	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
109-0006 /62/M/PI	WEEK12/06NOV2013	NTL:1/LIVE	ADDITIONAL HEPATIC METASTASES	CT	UP	.	
	Summary:					.	SLD = 71, %CN = 39.22, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 06NOV2013
109-0007 /55/M/W2	SCREENING/02DEC2013	TL:1/NODES	RIGHT CARDIOPHRENIC NODE	CT		25	
	SCREENING/02DEC2013	TL:2/NODES	HEPATIC HILAR NODE	CT		36	SLD = 61
	SCREENING/02DEC2013	NTL:1/NODE	CARDIOPHRENIC NODES	CT		.	
	SCREENING/02DEC2013	NTL:2/NODE	PORTA HEPATIS NODES	CT		.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
109-0007 /55/M/W2	SCREENING/02DEC2013	NTL:3/LIVE	LIVER LESIONS	CT		.	
	SCREENING/02DEC2013	NTL:4/NODE	PORTACAVAL NODE	CT		.	
	UNSCHEDULED/30JAN2014	TL:1/NODES	RIGHT CARDIOPHRENIC NODE	CT		24	
	UNSCHEDULED/30JAN2014	TL:2/NODES	HEPATIC HILAR NODE	CT		36	
	UNSCHEDULED/30JAN2014	NTL:1/NODE	CARDIOPHRENIC NODES	CT	Present	.	
	UNSCHEDULED/30JAN2014	NTL:2/NODE	PORTA HEPATIS NODES	CT	Present	.	

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Tumor Assessment Summary Listing
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Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
109-0007 /55/M/W2	UNSCHEDULED/30JAN2014	NTL:3/LIVE	LIVER LESIONS	CT	Present	.	
	UNSCHEDULED/30JAN2014	NTL:4/NODE	PORTACAVAL NODES	CT	Present	.	
	Summary:					.	SLD = 60, %CN = 7.14, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	Summary:					.	SLD = ., %CN = ., TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK24/23APR2014	TL:1/NODES	RIGHT CARDIOPHRENIC NODE	CT		22	
	WEEK24/23APR2014	TL:2/NODES	HEPATIC HILAR NODE	CT		34	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
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Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
109-0007 /55/M/W2	WEEK24/23APR2014	NTL:1/NODE	CARDIOPHRENIC NODES	CT	UP	.	
	WEEK24/23APR2014	NTL:2/NODE	PORTA HEPATIS NODES	CT	Present	.	
	WEEK24/23APR2014	NTL:3/LIVE	LIVER LESIONS	CT	Present	.	
	WEEK24/23APR2014	NTL:4/NODE	PORTACAVAL NODE	CT	Present	.	
	Summary:					.	SLD = 56, %CN = 0, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 23APR2014
109-0008 /70/F/W2	SCREENING/03JUN2014	TL:1/LUNG	LEFT LOWER LOBE LUNG S#1 I#162	CT		13	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
109-0008 /70/F/W2	SCREENING/03JUN2014	TL:2/LUNG	LEFT LOWER LOBE LUNG S#1 I#139	CT		13	
	SCREENING/03JUN2014	TL:3/SOFTT	LEFT DIAPHRAGMATIC/SUBPHRENIC IMPLANT	CT		83	SLD = 109
	SCREENING/03JUN2014	NTL:1/LUNG	ADDITIONAL LUNG NODULES	CT		.	
	SCREENING/03JUN2014	NTL:2/LIVE	ARTERIAL ENHANCING FOCUS HEPATIC DOME.	CT		.	
	WEEK12/19AUG2014	TL:1/LUNG	LEFT LOWER LOBE LUNG S#1 I#162	CT		18	
	WEEK12/19AUG2014	TL:2/LUNG	LEFT LOWER LOBE LUNG S#1 I#139	CT		17	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
109-0008 /70/F/W2	WEEK12/19AUG2014	TL:3/SOFTT	LEFT DIAPHRAGMATIC/SUBPHRENIC IMPLANT	CT		88	
	WEEK12/19AUG2014	NTL:1/LUNG	ADDITIONAL LUNG NODULES	CT	Present	.	
	WEEK12/19AUG2014	NTL:2/LIVE	ARTERIAL ENHANCING FOCUS HEPATIC DOME.	CT	Present	.	
	Summary:					.	SLD = 123, %CN = 12.84, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK24/13NOV2014	TL:1/LUNG	LEFT LOWER LOBE LUNG S#1 I#162	CT		21	
	WEEK24/13NOV2014	TL:2/LUNG	LEFT LOWER LOBE LUNG S#1 I#139	CT		20	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
109-0008 /70/F/W2	WEEK24/13NOV2014	TL:3/SOFTT	LEFT DIAPHRAGMATIC/SUBPHRENIC IMPLANT	CT		88	
	WEEK24/13NOV2014	NTL:1/LUNG	ADDITIONAL LUNG NODULES	CT	Present	.	
	WEEK24/13NOV2014	NTL:2/LIVE	ARTERIAL ENHANCING FOCUS HEPATIC DOME.	CT	Present	.	
	WEEK24/13NOV2014	NTL:3/SOFT	DOME ARTERIAL ENHANCING LESION	CT	New	.	
	WEEK24/13NOV2014	NTL:4/SOFT	ARTERIAL ENHANCING SEGMENT 8 LESION	CT	New	.	
	Summary:					.	SLD = 129, %CN = 18.35, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 18NOV2014

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
109-0009 /57/M/W2	SCREENING/25JUN2014	TL:1/LIVER	RIGHT HEPATIC DOME MASS	CT		49	
	SCREENING/25JUN2014	TL:2/LIVER	SEGMENT 4A MASS	CT		41	SLD = 90
	SCREENING/25JUN2014	NTL:1/LIVE	OTHER LIVER MASSES	CT		.	
	WEEK12/22SEP2014	TL:1/LIVER	RIGHT HHEPATIC DOME MASS	CT		61	
	WEEK12/22SEP2014	TL:2/LIVER	SEGMENT 4A MASS	CT		41	
	WEEK12/22SEP2014	NTL:1/LIVE	OTHER LIVER MASSES	CT	UP	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
109-0009 /57/M/W2	Summary:					.	SLD = 102, %CN = 13.33, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 22SEP2014
109-0010 /65/M/W2	SCREENING/25JUN2014	TL:1/NODES	PORTACAVAL LYMPH NODE	CT		28	SLD = 28
	SCREENING/25JUN2014	NTL:1/LIVE	TREATED LIVER LESIONS	CT		.	
	WEEK12/24SEP2014	TL:1/NODES	PORTACAVAL LYMPH NODE	CT		29	
	WEEK12/24SEP2014	NTL:1/LIVE	TREATED LIVER LESIONS	CT	UP	.	
	Summary:					.	SLD = 29, %CN = 3.57, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 24SEP2014

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
109-0011 /64/M/A4	SCREENING/23SEP2014	TL:1/LUNG	LINGULA	CT		16	SLD = 16
	SCREENING/23SEP2014	NTL:1/LUNG	MULTIPLE PULMONARY NODULES	CT		.	
	WEEK12/09DEC2014	TL:1/LUNG	LINGULA	CT		19	
	WEEK12/09DEC2014	NTL:1/LUNG	MULTIPLE PULMONARY NODULES	CT	UP	.	
	WEEK12/09DEC2014	NTL:2/LUNG	MULTIPLE PULMONARY NODULES	CT	New	.	
	Summary:					.	SLD = 19, %CN = 18.75, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 09DEC2014

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
109-0013 /64/F/W2	WEEK24/13APR2014	TL:1/LIVER	IRREGULAR MASS IN SEGMENT 8	CT	NE	.	
	WEEK24/13APR2014	NTL:2/NODE	ENLARGING PORTA HEPATIS, PORTACAVAL AND RETROPERITONEAL LYMPH NODES	CT	New	.	
	SCREENING/13OCT2014	TL:1/LIVER	IRREGULAR MASS IN SEGMENT 8	CT		57	SLD = 57
	SCREENING/13OCT2014	NTL:1/LIVE	SCATTERED SMALLER HYPERVASCULAR LESIONS	CT		.	
	WEEK12/20JAN2015	TL:1/LIVER	IRREGULAR MASS IN SEGMENT 8	CT		47	
	WEEK12/20JAN2015	NTL:1/LIVE	SCATTERED SMALLER HYPERVASCULAR LESIONS	CT	Present	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
109-0013 /64/F/W2	Summary:					.	SLD = 47, %CN = -17.54, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK24/13APR2015	NTL:1/LIVE	SCATTERED SMALLER HYPERVASCULAR LESIONS	CT	Present	.	
	Summary:					.	SLD = ., %CN = ., TL: NotEvaluable, NTL: PD, OR: PD, PD confirmed: Yes, 13APR2015
110-0003 /63/M/OTH	SCREENING/03JUL2012	TL:1/BONE	INFERIOR ASPECT OF STERNUM	CT		79	
	SCREENING/03JUL2012	TL:2/BONE	MID TO UPPER PORTION OF STERNUM	CT		49	SLD = 128
	SCREENING/03JUL2012	NTL:1/LUNG	RIGHT LOWER LOBE, LUNG NODULE	CT		.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
110-0003 /63/M/OTH	WEEK12/24SEP2012	TL:1/BONE	INFERIOR ASPECT OF STERNUM	CT		80	
	WEEK12/24SEP2012	TL:2/BONE	MID TO UPPER PORTION OF STERNUM	CT		50	
	WEEK12/24SEP2012	NTL:1/LUNG	RIGHT LOWER LOBE, LUNG NODULE	CT	Present	.	
	Summary:					.	SLD = 130, %CN = 1.56, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK24/17DEC2012	TL:1/BONE	INFERIOR ASPECT OF STERNUM	CT		97	
	WEEK24/17DEC2012	TL:2/BONE	MID TO UPPER PORTION OF STERNUM	CT		46	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
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Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
110-0003 /63/M/OTH	WEEK24/17DEC2012	NTL:1/LUNG	RIGHT LOWER LOBE, LUNG NODULE	CT	Present	.	
	Summary:					.	SLD = 143, %CN = 11.72, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
110-0004 /53/M/A4	SCREENING/08OCT2012	TL:1/LUNG	BASILAR POSTERIOR RIGHT LOWER LOBE	CT		23	
	SCREENING/08OCT2012	TL:2/LUNG	LOW DENSITY ADENOPATHY IN SUBCARINAL SPACE	CT		20	
	SCREENING/08OCT2012	TL:3/LUNG	PULMONARY NODULE IN LEFT LOWER LOBE	CT		15	
	SCREENING/08OCT2012	TL:4/LUNG	LARGE CONFLUENT/MULTI LOBILATED REGION OF NODULARITY IN RIGHT LOWER LOBE	CT		51	SLD = 109

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
110-0004 /53/M/A4	SCREENING/08OCT2012	NTL:1/LUNG	PULMONARY NODULE, RIGHT UPPER LOBE	CT		.	
	SCREENING/08OCT2012	NTL:2/LUNG	MULTIPLE PULMONARY NODULES	CT		.	
	WEEK12/08JAN2013	TL:1/LUNG	BASILAR POSTERIOR RIGHT LOWER LOBE	CT		28	
	WEEK12/08JAN2013	TL:2/LUNG	LOW DENSITY ADENOPATHY IN SUBCARINAL SPACE	CT		18	
	WEEK12/08JAN2013	TL:3/LUNG	PULMONARY NODULE IN LEFT LOWER LOBE	CT		16	
	WEEK12/08JAN2013	TL:4/LUNG	LARGE CONFLUENT/MULTI LOBILATED REGION OF NODULARITY IN RIGHT LOWER LOBE	CT		62	

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Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
110-0004 /53/M/A4	WEEK12/08JAN2013	NTL:1/LUNG	PULMONARY NODULE, RIGHT UPPER LOBE	CT	Present	.	
	WEEK12/08JAN2013	NTL:2/LUNG	MULTIPLE PUMONARY NODULES	CT	Present	.	
	Summary:					.	SLD = 124, %CN = 13.76, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
110-0005 /77/M/W2	SCREENING/06MAR2013	TL:1/LIVER	MASS, ABUTTING CAUDATE LOBE AND INFERIOR VENA CAVA	CT		33	
	SCREENING/06MAR2013	TL:2/LIVER	MASS, PERIPORTAL NODE	CT		24	SLD = 57
	WEEK12/24MAY2013	TL:1/LIVER	MASS, ABUTTING CAUDATE LOBE AND INFERIOR VENA CAVA	CT		37	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
110-0005 /77/M/W2	WEEK12/24MAY2013	TL:2/LIVER	MASS, PERIPORTAL NODE	CT		31	
	Summary:					.	SLD = 68, %CN = 19.3, TL: SD, NTL: NotAssessed, OR: SD, PD confirmed: No
110-0007 /62/M/A4	SCREENING/26APR2013	TL:1/LIVER	LESION, MEDIAL ASPECT OF SEGMENT 7	CT		35	
	SCREENING/26APR2013	TL:2/LIVER	LESION, MEDIAL ASPECT OF SEGMENT 6	CT		35	
	SCREENING/26APR2013	TL:3/LIVER	INFILTRATING APPEARING ENHANCEMENT, SEGMENT 2/3	CT		34	SLD = 104
	SCREENING/26APR2013	NTL:1/LIVE	LESION, LATERAL ASPECT OF SEGMENT 7	CT		.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
110-0007 /62/M/A4	SCREENING/26APR2013	NTL:2/LIVE	LESION, CAUDAL ASPECT OF SEGMENT 7	CT		.	
	SCREENING/26APR2013	NTL:3/LIVE	LESION, CAUDAL ASPECT OF SEGMENT 6	CT		.	
	SCREENING/26APR2013	NTL:4/LIVE	HYPOATTENUATING LESION, SEGMENT 2	CT		.	
	SCREENING/26APR2013	NTL:5/NODE	ARTERIAL ENHANCEMENT IN BULKY PERIPORTAL LYMPH NODES	CT		.	
	SCREENING/26APR2013	NTL:6/NODE	MILDLY PROMINENT ADENOPATHY IN RETROPERITONEAL LYMPH NODES	CT		.	
	WEEK12/31JUL2013	TL:1/LIVER	LESION, MEDIAL ASPECT OF SEGMENT 7	CT		44	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
110-0007 /62/M/A4	WEEK12/31JUL2013	TL:2/LIVER	LESION, MEDIAL ASPECT OF SEGMENT 6	CT		49	
	WEEK12/31JUL2013	TL:3/LIVER	INFILTRATING APPEARING ENHANCEMENT, SEGMENT 2/3	CT	Resolved	.	
	WEEK12/31JUL2013	NTL:1/LIVE	LESION, LATERAL ASPECT OF SEGMENT 7	CT	Present	.	
	WEEK12/31JUL2013	NTL:2/LIVE	LESION, CAUDAL ASPECT OF SEGMENT 7	CT	Present	.	
	WEEK12/31JUL2013	NTL:3/LIVE	LESION, CAUDAL ASPECT OF SEGMENT 6	CT	Present	.	
	WEEK12/31JUL2013	NTL:4/LIVE	HYPOATTENUATING LESION, SEGMENT 2	CT	Present	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
110-0007 /62/M/A4	WEEK12/31JUL2013	NTL:5/NODE	ARTERIAL ENHANCEMENT IN BULKY PERIPORTAL LYMPH NODES	CT	Present	.	
	WEEK12/31JUL2013	NTL:6/NODE	MILDLY PROMINENT ADENOPATHY IN RETROPERITONEAL LYMPH NODES	CT	Present	.	
	Summary:					.	SLD = ., %CN = ., TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK24/23OCT2013	TL:1/LIVER	LESION, MEDIAL ASPECT OF SEGMENT 7	CT		47	
	WEEK24/23OCT2013	TL:2/LIVER	LESION, MEDIAL ASPECT OF SEGMENT 6	CT		49	
	WEEK24/23OCT2013	TL:3/LIVER	INFILTRATING APPEARING ENHANCEMENT, SEGMENT 2/3	CT	Resolved	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
110-0007 /62/M/A4	WEEK24/23OCT2013	NTL:1/LIVE	LESION, LATERAL ASPECT OF SEGMENT 7	CT	Absent	.	
	WEEK24/23OCT2013	NTL:2/LIVE	LESION, CAUDAL ASPECT OF SEGMENT 7	CT	Present	.	
	WEEK24/23OCT2013	NTL:3/LIVE	LESION, CAUDAL ASPECT OF SEGMENT 6	CT	Present	.	
	WEEK24/23OCT2013	NTL:4/LIVE	HYPOATTENUATING LESION, SEGMENT 2	CT	Present	.	
	WEEK24/23OCT2013	NTL:5/NODE	ARTERIAL ENHANCEMENT IN BULKY PERIPORTAL LYMPH NODES	CT	Present	.	
	WEEK24/23OCT2013	NTL:6/NODE	MILDLY PROMINENT ADENOPATHY IN RETROPERITONEAL LYMPH NODES	CT	Present	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
110-0007 /62/M/A4	Summary:					.	SLD = ., %CN = ., TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK36/13JAN2014	TL:1/LIVER	LESION, MEDIAL ASPECT OF SEGMENT 7	CT		61	
	WEEK36/13JAN2014	TL:2/LIVER	LESION, MEDIAL ASPECT OF SEGMENT 6	CT		83	
	WEEK36/13JAN2014	TL:3/LIVER	INFILTRATING APPEARING ENHANCEMENT, SEGMENT 2/3	CT	Resolved	.	
	WEEK36/13JAN2014	NTL:1/LIVE	LESION, LATERAL ASPECT OF SEGMENT 7	CT	Present	.	
	WEEK36/13JAN2014	NTL:2/LIVE	LESION, CAUDAL ASPECT OF SEGMENT 7	CT	Present	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
110-0007 /62/M/A4	WEEK36/13JAN2014	NTL:3/LIVE	LESION, CAUDAL ASPECT OF SEGMENT 6	CT	Present	.	
	WEEK36/13JAN2014	NTL:4/LIVE	HYPOATTENUATING LESION, SEGMENT 2	CT	Present	.	
	WEEK36/13JAN2014	NTL:5/NODE	ARTERIAL ENHANCEMENT IN BULKY PERIPORTAL LYMPH NODES	CT	Present	.	
	WEEK36/13JAN2014	NTL:6/NODE	MILDLY PROMINENT ADENOPATHY IN RETROPERITONEAL LYMPH NODES	CT	Present	.	
	Summary:					.	SLD = ., %CN = ., TL: PD, NTL: IncompleteResponse/SD, OR: PD, PD confirmed: Yes, 13JAN2014
110-0008 /63/F/BL	SCREENING/11JUN2013	TL:1/LIVER	MASS, CENTRALLY IN RIGHT LOBE	CT		34	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
110-0008 /63/F/BL	SCREENING/11JUN2013	TL:2/LIVER	MASS, CENTERED IN SEGMENT 5	CT		69	SLD = 103
	SCREENING/11JUN2013	NTL:1/LIVE	DOME OF RIGHT HEPATIC LOBE	CT		.	
	SCREENING/11JUN2013	NTL:2/LIVE	POSTERIOR RIGHT HEPATIC LOBE	CT		.	
	SCREENING/11JUN2013	NTL:3/LIVE	MULTIPLE LIVER NODULES	CT		.	
	SCREENING/14JUN2013	NTL:4/LUNG	MULTIPLE NODULES IN RIGHT UPPER LOBE	CT		.	
110-0011 /77/M/A1	SCREENING/30DEC2014	TL:1/LIVER	LESION, SEGMENT 8	CT		27	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
110-0011 /77/M/A1	SCREENING/30DEC2014	TL:2/LIVER	LESION, SEGMENT 7	CT		30	SLD = 57
	SCREENING/30DEC2014	NTL:1/LIVE	LESION, SEGMENT 4	CT		.	
	SCREENING/30DEC2014	NTL:2/LIVE	LESION, SEGMENT 4	CT		.	
	SCREENING/30DEC2014	NTL:3/LIVE	LESION, SEGMENT 4	CT		.	
	WEEK12/07APR2015	TL:1/LIVER	LESION, SEGMENT 8	CT		26	
	WEEK12/07APR2015	TL:2/LIVER	LESION, SEGMENT 7	CT		52	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
110-0011 /77/M/A1	WEEK12/07APR2015	NTL:1/LIVE	LESION, SEGMENT 4	CT	Present	.	
	WEEK12/07APR2015	NTL:2/LIVE	LESION, SEGMENT 4	CT	Present	.	
	WEEK12/07APR2015	NTL:3/LIVE	LESION, SEGMENT 4	CT	Present	.	
	Summary:					.	SLD = 78, %CN = 36.84, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 07APR2015
111-0001 /37/M/A4	SCREENING/29JUN2012	TL:1/LUNG	LEFT LUNG	CT		34	
	SCREENING/29JUN2012	TL:2/LUNG	LEFT ANTERIOR LUNG	CT		25	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
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Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
111-0001 /37/M/A4	SCREENING/29JUN2012	TL:3/LUNG	RIGHT LUNG	CT		14	
	SCREENING/29JUN2012	TL:4/LUNG	RIGHT ANTERIOR LUNG	CT		19	
	SCREENING/29JUN2012	TL:5/LUNG	LEFT LUNG	CT		27	SLD = 119
	UNSCHEDULED/27JUL2012	TL:1/LUNG	LEFT LUNG	CT		38	
	UNSCHEDULED/27JUL2012	TL:2/LUNG	LEFT ANTERIOR LUNG	CT		31	
	UNSCHEDULED/27JUL2012	TL:3/LUNG	RIGHT ANTERIOR LUNG	CT		17	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
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Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
111-0001 /37/M/A4	UNSCHEDULED/27JUL2012	TL:4/LUNG	RIGHT ANTERIOR LUNG	CT		27	
	UNSCHEDULED/27JUL2012	TL:5/LUNG	LEFT LUNG	CT		29	
	Summary:					.	SLD = 142, %CN = 19.33, TL: PD, NTL: NotAssessed, OR: PD, PD confirmed: Yes, 27JUL2012
111-0004 /64/M/W2	SCREENING/01MAY2013	TL:1/BRAIN	LEFT OCCIPITAL LOBE	CT		54	SLD = 54
	SCREENING/01MAY2013	NTL:1/BONE	CALVARIUM	MRI		.	
	SCREENING/01MAY2013	NTL:2/NODE	MEDIASTINAL/HILAR NODES	CT		.	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
111-0004 /64/M/W2	UNSCHEDULED/03JUL2013	TL:1/BRAIN	LEFT OCCIPITAL LOBE	MRI		54	
	UNSCHEDULED/03JUL2013	NTL:1/BONE	CALVARIUM	MRI	Present	.	
	UNSCHEDULED/03JUL2013	NTL:2/NODE	MEDIASTINAL/HILAR NODES	CT	NE	.	
	Summary:					.	SLD = 106, %CN = 96.3, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	UNSCHEDULED/31JUL2013	TL:1/BRAIN	LEFT OCCIPITAL LOBE	CT		52	
	UNSCHEDULED/31JUL2013	NTL:1/BONE	CALVARIUM	CT	Present	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
111-0004 /64/M/W2	UNSCHEDULED/31JUL2013	NTL:2/NODE	MEDIASTINAL/HILAR NODES	CT	NE	.	
	Summary:					.	SLD = 106, %CN = 96.3, TL: SD, NTL: NotAssessed, OR: SD, PD confirmed: No
111-0006 /59/M/W2	SCREENING/17SEP2013	TL:1/LIVER	RIGHT LOBE	CT		11	
	SCREENING/17SEP2013	TL:2/LIVER	LEFT LOBE	CT		21	SLD = 32
	SCREENING/17SEP2013	NTL:1/LIVE	LIVER LESIONS	CT		.	
	SCREENING/17SEP2013	NTL:2/NODE	SUB CENTIMETER LYMPH NODES	CT		.	

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[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
111-0006 /59/M/W2	WEEK12/06JAN2014	TL:1/LIVER	RIGHT LOBE	CT		18	
	WEEK12/06JAN2014	TL:2/LIVER	LEFT LOBE	CT		20	
	WEEK12/06JAN2014	NTL:1/LIVE	LIVER LESIONS	CT	Present	.	
	WEEK12/06JAN2014	NTL:2/NODE	SUB CENTIMETER LYMPH NODES	CT	Present	.	
	Summary:					.	SLD = 38, %CN = 18.75, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK24/26MAR2014	TL:1/LIVER	RIGHT LOBE	CT		15	

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[3] UP=Unequivocally Progressed
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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
111-0006 /59/M/W2	WEEK24/26MAR2014	TL:2/LIVER	LEFT LOBE	CT		20	
	WEEK24/26MAR2014	NTL:1/LIVE	LIVER LESIONS	CT	Present	.	
	WEEK24/26MAR2014	NTL:2/NODE	SUB CENTIMETER LYMPH NODES	CT	Present	.	
	Summary:					.	SLD = 35, %CN = 9.38, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
111-0007 /55/M/W2	SCREENING/13JAN2014	TL:1/LIVER	SEGMENT 2	CT		21	SLD = 21
	SCREENING/13JAN2014	NTL:1/BONE	LEFT 9TH RIB LYTIC LESION	CT		.	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
111-0007 /55/M/W2	SCREENING/13JAN2014	NTL:2/BONE	T9 VERTEBRAL BODY	CT		.	
	WEEK12/14APR2014	TL:1/LIVER	SEGMENT 2	CT		24	
	WEEK12/14APR2014	NTL:1/BONE	LEFT 9TH RIB LYTIC LESION	CT	Present	.	
	WEEK12/14APR2014	NTL:2/BONE	T9 VERTEBRAL BODY	CT	Present	.	
	WEEK12/14APR2014	NTL:3/LIVE	LIVER LESIONS	CT	New	.	
	Summary:					.	SLD = 24, %CN = 14.29, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 14APR2014

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
112-0006 /58/M/W2	SCREENING/15MAR2013	TL:1/LUNG	RIGHT CHEST WALL MASS	CT		89	
	SCREENING/15MAR2013	TL:2/	RIGHT ADRENAL MASS	CT		78	
	SCREENING/15MAR2013	TL:3/GI	UPPER ABDOMINAL LN	CT		24	
	SCREENING/15MAR2013	TL:4/GI	UPPER ABDOMINAL	CT		17	SLD = 208
	SCREENING/15MAR2013	NTL:1/LIVE	DIFFUSE INFLITRATIVE AND NODULAR TUMOR, LIVER	CT		.	
	SCREENING/15MAR2013	NTL:2/PERI	PERICARDIAL LN	CT		.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
112-0006 /58/M/W2	SCREENING/15MAR2013	NTL:3/NODE	GE JUNCTION LN	CT		.	
	SCREENING/15MAR2013	NTL:4/NODE	GASTROHEPATIC LN	CT		.	
	SCREENING/15MAR2013	NTL:5/NODE	PERICELIAC LN	CT		.	
	SCREENING/15MAR2013	NTL:6/GI	OMENTAL NODULE	CT		.	
	SCREENING/15MAR2013	NTL:7/NODE	MESENTERIC LN	CT		.	
	WEEK12/03JUN2013	TL:1/LUNG	RIGHT CHEST WALL MASS	CT		120	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
112-0006 /58/M/W2	WEEK12/03JUN2013	TL:2/	RIGHT ADRENAL MASS	CT		91	
	WEEK12/03JUN2013	TL:3/GI	UPPER ABDOMINAL LN	CT		23	
	WEEK12/03JUN2013	TL:4/GI	UPPER ABDOMINAL LN	CT		18	
	WEEK12/03JUN2013	NTL:1/LIVE	DIFFUSE INFLITRATIVE AND NODULAR TUMOR, LIVER	CT	UP	.	
	WEEK12/03JUN2013	NTL:2/PERI	PERICARDIAL LN	CT	UP	.	
	WEEK12/03JUN2013	NTL:3/NODE	GE JUNCTION LN	CT	UP	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
112-0006 /58/M/W2	WEEK12/03JUN2013	NTL:4/NODE	GASTROHEPATIC LN	CT	UP	.	
	WEEK12/03JUN2013	NTL:5/NODE	PERICELIAC LN	CT	UP	.	
	WEEK12/03JUN2013	NTL:6/GI	OMENTAL NODULE	CT	UP	.	
	WEEK12/03JUN2013	NTL:7/NODE	MESENTERIC LN	CT	UP	.	
	Summary:					.	SLD = 252, %CN = 21.15, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 03JUN2013
112-0009 /50/M/A8	SCREENING/12JUN2013	TL:1/LIVER	MASS RIGHT LOBE LIVER, INVOLVING R ADRENAL	CT		136	SLD = 136

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
112-0009 /50/M/A8	SCREENING/12JUN2013	NTL:1/LUNG	NODULE RLL LUNG AND TREATED LESIONS WITH CHEMOEMBO	CT		.	
	WEEK12/04SEP2013	TL:1/LIVER	MASS RIGHT LOBE LIVER, INVOLVING R ADRENAL	CT		153	
	WEEK12/04SEP2013	NTL:1/LUNG	NODULE RLL LUNG AND TREATED LESIONS WITH CHEMOEMBO	CT	Present	.	
	WEEK12/04SEP2013	NTL:2/LIVE	LESION LEFT LOBE LIVER	CT	New	.	
	WEEK12/04SEP2013	NTL:3/NODE	BILATERAL PULMONARY NODULES, LESION T10 VERTEBRAL BODY	CT	New	.	
	Summary:					.	SLD = 153, %CN = 12.5, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 04SEP2013

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
112-0011 /56/M/A4	SCREENING/03JAN2014	TL:1/LIVER	LESION CENTER LIVER	CT		41	
	SCREENING/03JAN2014	TL:2/LIVER	RIGHT LOBE LESION	CT		15	SLD = 56
	SCREENING/03JAN2014	NTL:1/LIVE	SMALL LIVER LESIONS	CT		.	
	SCREENING/03JAN2014	NTL:2/GI	CELIAC NODE	CT		.	
	SCREENING/03JAN2014	NTL:3/GI	IMPLANTS	CT		.	
	UNSCHEDULED/28FEB2014	TL:1/LIVER	LESION CENTER LIVER	CT		49	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
112-0011 /56/M/A4	UNSCHEDULED/28FEB2014	TL:2/LIVER	RIGHT LOBE LESION	CT		12	
	UNSCHEDULED/28FEB2014	NTL:1/LIVE	SMALLER LIVER LESIONS	CT	Present	.	
	UNSCHEDULED/28FEB2014	NTL:2/GI	CELIAC NODE	CT	Present	.	
	UNSCHEDULED/28FEB2014	NTL:3/GI	IMPLANTS	CT	Present	.	
	UNSCHEDULED/28FEB2014	NTL:4/LIVE		CT	New	.	
	Summary:					.	SLD = 61, %CN = 8.93, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 28FEB2014

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
112-0012 /71/M/W2	SCREENING/16MAY2014	TL:1/LIVER	LEFT HEPATIC LOBE LESION	CT		26	
	SCREENING/16MAY2014	TL:2/NODES	LEFT POSTERIOR MEDIASTINAL LN	CT		21	
	SCREENING/16MAY2014	TL:3/NODES	LEFT POSTERIOR MEDIASTINAL LN	CT		16	
	SCREENING/16MAY2014	TL:4/NODES	LEFT ADRENAL NODULE	CT		14	
	SCREENING/16MAY2014	TL:5/LUNG	RIGHT LOWER LOBE PULMONARY NODULE	CT		22	SLD = 99
	SCREENING/16MAY2014	NTL:1/LIVE	LARGE INFILTRATIVE MASS R LOBE LIVER	CT		.	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
112-0012 /71/M/W2	SCREENING/16MAY2014	NTL:2/LUNG	LEFT SUPRAHILAR CONSOLIDATION	CT		.	
	SCREENING/16MAY2014	NTL:3/LUNG	MULTIPLE ADDITIONAL PULMONARY NODULES	CT		.	
	SCREENING/16MAY2014	NTL:4/NODE	ADDITIONAL THORACIC LYMPH NODES	CT		.	
	SCREENING/16MAY2014	NTL:5/NODE	ABDOMINAL PELVIC INGUINAL LYMPH NODES	CT		.	
	WEEK12/08AUG2014	TL:1/LIVER	LEFT HEPATIC LOBE LESION	CT		41	
	WEEK12/08AUG2014	TL:2/NODES	LEFT POSTERIOR MEDIASTINAL LN	CT		26	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
112-0012 /71/M/W2	WEEK12/08AUG2014	TL:3/NODES	LEFT POSTERIOR MEDIASTINAL LN	CT		21	
	WEEK12/08AUG2014	TL:4/NODES	LEFT ADRENAL NODULE	CT		28	
	WEEK12/08AUG2014	TL:5/LUNG	RIGHT LOWER LOBE PULMONARY NODULE	CT		25	
	WEEK12/08AUG2014	NTL:1/LIVE	LARGE INFILTRATIVE MASS R LOBE LIVER	CT	Present	.	
	WEEK12/08AUG2014	NTL:2/LUNG	LEFT SUPRAHILAR CONSOLIDATION	CT	Present	.	
	WEEK12/08AUG2014	NTL:3/LUNG	MULTIPLE ADDITIONAL PULMONARY NOLDULES	CT	UP	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
112-0012 /71/M/W2	WEEK12/08AUG2014	NTL:4/NODE	ADDITIONAL THORACIC LYMPH NODES	CT	UP	.	
	WEEK12/08AUG2014	NTL:5/NODE	ABDOMINAL PELVIC INGUINAL LYMPH NODES	CT	Present	.	
	Summary:					.	SLD = 141, %CN = 42.42, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 08AUG2014
112-0013 /28/F/W2	SCREENING/16MAY2014	TL:1/LIVER	POSTERIOR RIGHT HEPATIC LESION	CT		30	
	SCREENING/16MAY2014	TL:2/NODES	RIGHT PARATRACHEAL LN	CT		28	
	SCREENING/16MAY2014	TL:3/NODES	LEFT HILAR LN	CT		28	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
112-0013 /28/F/W2	SCREENING/16MAY2014	TL:4/LUNG	LEFT LOWER LOBE PLEURAL BASED LESION	CT		19	
	SCREENING/16MAY2014	TL:5/LUNG	RIGHT MIDDLE LOBE PULMONARY NODULE	CT		13	SLD = 118
	SCREENING/16MAY2014	NTL:1/LIVE	RIGHT HEPATIC NODULE, SEG 7	CT		.	
	SCREENING/16MAY2014	NTL:2/LIVE	RIGHT HEPATIC NODULE, SEG 7	CT		.	
	SCREENING/16MAY2014	NTL:3/LUNG	MULTIPLE ADDITIONAL PULMONARY NODULES	CT		.	
	SCREENING/16MAY2014	NTL:4/GI	ADDITIONAL PLEURAL IMPLANTS	CT		.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
112-0013 /28/F/W2	SCREENING/16MAY2014	NTL:5/NODE	ADDITIONAL MEDIATSINAL AND HILAR LAD	CT		.	
	UNSCHEDULED/12JUL2014	TL:1/LIVER	POSTERIOR RIGHT HEPATIC LESION	CT		33	
	UNSCHEDULED/12JUL2014	TL:2/NODES	RIGHT PARATRACHEAL LN	CT		33	
	UNSCHEDULED/12JUL2014	TL:3/NODES	LEFT HILAR LN	CT		28	
	UNSCHEDULED/12JUL2014	TL:4/LUNG	LEFT LOWER LOBE PLEURAL BASED LESION	CT		22	
	UNSCHEDULED/12JUL2014	TL:5/LUNG	RIGHT MIDDLE LOBE PULMONARY NODULE	CT		21	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
112-0013 /28/F/W2	UNSCHEDULED/12JUL2014	NTL:1/LIVE	RIGHT HEPATIC NODULE, SEG 7	CT	Present	.	
	UNSCHEDULED/12JUL2014	NTL:2/LIVE	RIGHT HEPATIC NODULE, SEG 7	CT	Present	.	
	UNSCHEDULED/12JUL2014	NTL:3/LUNG	MULTIPLE ADDITIONAL PULMONARY NODULES	CT	Present	.	
	UNSCHEDULED/12JUL2014	NTL:4/GI	ADDITIONAL PLEURAL IMPLANTS	CT	Present	.	
	UNSCHEDULED/12JUL2014	NTL:5/NODE	ADDITIONAL MEDIASTINAL AND HILAR LAD	CT	Present	.	
	Summary:					.	SLD = 137, %CN = 16.1, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
112-0014 /79/M/A8	SCREENING/30MAY2014	TL:1/SOFTT	LEFT PARASPINAL MASS L3-4	CT		39	
	SCREENING/30MAY2014	TL:2/BONE	RIGHT PIRIFORMUS MASS	CT		31	
	SCREENING/30MAY2014	TL:3/	SOFT TISSUE COMPONENT OF T8 METS	CT		22	SLD = 92
	SCREENING/30MAY2014	NTL:1/LIVE	MULTIPLE LIVER LESIONS	CT		.	
	SCREENING/30MAY2014	NTL:2/BONE	LYTIC BONE LESIONS	CT		.	
	SCREENING/30MAY2014	NTL:3/	TINY PULMONARY NODULES	CT		.	

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Tumor Assessment Summary Listing
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Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
112-0014 /79/M/A8	UNSCHEDULED/18JUL2014	TL:1/SOFTT	LEFT PARASPINAL MASS L3-4	CT		39	
	UNSCHEDULED/18JUL2014	TL:2/BONE	RIGHT PIRIFORMUS MASS	CT		37	
	UNSCHEDULED/18JUL2014	TL:3/	SOFT TISSUE COMPONENT OF T8 METS	CT		22	
	UNSCHEDULED/18JUL2014	NTL:1/LIVE	MULTIPLE LIVER LESIONS	CT	Present	.	
	UNSCHEDULED/18JUL2014	NTL:2/BONE	LYSTIC AND BLASTIC BONE LESIONS	CT	Present	.	
	UNSCHEDULED/18JUL2014	NTL:3/LUNG	TINY PULMONARY NODULES	CT	Present	.	

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Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
112-0014 /79/M/A8	Summary:					.	SLD = 98, %CN = 6.52, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK12/22AUG2014	TL:1/SOFTT	LEFT PARASPINAL MASS, L3-4	CT		39	
	WEEK12/22AUG2014	TL:2/BONE	RIGHT PIRIFORMUS MASS	CT		42	
	WEEK12/22AUG2014	TL:3/	SOFT TISSUE COMPONENT OF T8 METS	CT		24	
	WEEK12/22AUG2014	NTL:1/LIVE	MULTIPLE LIVER LESIONS	CT	Present	.	
	WEEK12/22AUG2014	NTL:2/BONE	LYTIC AND BLASTIC BONE LESIONS	CT	Present	.	

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Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
112-0014 /79/M/A8	WEEK12/22AUG2014	NTL:3/	TINY PULMONARY NODULES	CT	UP	.	
	Summary:					.	SLD = 105, %CN = 14.13, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 22AUG2014
112-0015 /66/M/A8	SCREENING/17OCT2014	TL:1/LIVER	ENHANCING COMPONENT OF LARGE IRREGULAR PARTIALLY NECROTIC LIVER MASS	CT		54	
	SCREENING/17OCT2014	TL:2/GI	RIGHT ADRENAL METS	CT		63	
	SCREENING/17OCT2014	TL:3/GI	LEFT ADRENAL METS	CT		40	SLD = 157
	SCREENING/17OCT2014	NTL:1/LUNG	INNUMERABLE PULMONARY NODULES <10MM	CT		.	

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Tumor Assessment Summary Listing
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Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
112-0015 /66/M/A8	SCREENING/17OCT2014	NTL:2/LIVE	ILL DEFINED MULTIFOCAL NODULAR ENHANCEMENT IN LIVER	CT		.	
	SCREENING/17OCT2014	NTL:3/GI	CARCINOMATOSIS, RIGHT INGUIJNAL HERNIA AND LEFT MID ABDOMEN	CT		.	
	UNSCHEDULED/12DEC2014	TL:1/LIVER	ENHANCING COMPONENT OF LARGE IRREGULAR PARTIALLY NECROTIC LIVER MASS	CT		74	
	UNSCHEDULED/12DEC2014	TL:2/GI	RIGHT ADRENAL METS	CT		73	
	UNSCHEDULED/12DEC2014	TL:3/GI	LEFT ADRENAL METS	CT		45	
	UNSCHEDULED/12DEC2014	NTL:1/LUNG	INNUMERABLE PULMONARY NODULES < 10MM	CT	Present	.	

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Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
112-0015 /66/M/A8	UNSCHEDULED/12DEC2014	NTL:2/LIVE	ILL-DEFINED MULTIFOCAL NODULAR ENHANCEMENT IN LIVER	CT	Present	.	
	UNSCHEDULED/12DEC2014	NTL:3/GI	CARCINOMATOSIS, RIGHT INGUINAL HERNIA, LEFT MIDABDOMEN	CT	Present	.	
	UNSCHEDULED/12DEC2014	NTL:4/NODE	MEDIASTINAL AND HILAR LYMPHADENOPATHY	CT	New	.	
	Summary:					.	SLD = 192, %CN = 22.29, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 12DEC2014
113-0001 /60/M/W2	SCREENING/23AUG2012	TL:1/LIVER	TARGET LESION #1	CT		13	
	SCREENING/23AUG2012	TL:2/LIVER	TARGET LESION #2	CT		13	SLD = 26

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
113-0001 /60/M/W2	SCREENING/23AUG2012	NTL:1/LIVE	NONTARGET LESION #1	CT		.	
	WEEK12/07NOV2012	TL:1/LIVER	TARGET LESION #1	CT		8	
	WEEK12/07NOV2012	TL:2/LIVER	TARGET LESION #2	CT		18	
	WEEK12/07NOV2012	NTL:1/LIVE	NONTARGET LESION #1	CT	Present	.	
	Summary:					.	SLD = 26, %CN = 0, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK24/05FEB2013	TL:1/LIVER	TARGET LESION #1	CT		17	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
113-0001 /60/M/W2	WEEK24/05FEB2013	TL:2/LIVER	TARGERT LESION #2	CT		21	
	WEEK24/05FEB2013	NTL:1/LIVE	NONTARGET LESION #1	CT	Present	.	
	Summary:					.	SLD = 38, %CN = 46.15, TL: PD, NTL: IncompleteResponse/SD, OR: PD, PD confirmed: Yes, 06FEB2013
113-0002 /64/F/W2	SCREENING/28SEP2012	TL:1/LIVER	SEGMENT 6 OF LIVER	CT		17	
	SCREENING/28SEP2012	TL:2/LIVER	SEGMENT 6 OF LIVER	CT		48	SLD = 65
	SCREENING/28SEP2012	NTL:1/LIVE	SEGMENT 2 OF LIVER	CT		.	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
113-0002 /64/F/W2	WEEK12/20DEC2012	TL:1/LIVER	SEGMENT 6 OF LIVER	CT		16	
	WEEK12/20DEC2012	TL:2/LIVER	SEGMENT 6 OF LIVER	CT		52	
	WEEK12/20DEC2012	NTL:1/LIVE	SEGMENT 2 OF LIVER	CT	Present	.	
	Summary:					.	SLD = 68, %CN = 4.62, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK24/18MAR2013	NTL:1/LIVE	SEGMENT 2 OF LIVER	CT	Present	.	
	Summary:					.	SLD = 68, %CN = 4.62, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
113-0002 /64/F/W2	WEEK24/19MAR2013	TL:1/LIVER	SEGMENT 6 OF LIVER	CT		12	
	WEEK24/19MAR2013	TL:2/LIVER	SEGMENT 6 OF LIVER	CT		56	
	WEEK36/10JUN2013	TL:1/LIVER	SEGMENT 6	CT		14	
	WEEK36/10JUN2013	TL:2/LIVER	SEGMENT 6	CT		54	
	WEEK36/10JUN2013	NTL:1/LIVE	SEGMENT 2 OF LIVER	CT	Present	.	
	Summary:					.	SLD = 68, %CN = 4.62, TL: SD, NTL: IncompleteResponse/SD, OR: PD, PD confirmed: Yes, 10JUN2013

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[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
113-0005 /58/M/W2	SCREENING/09JAN2014	TL:1/LIVER	RIGHT HEPATIC LOBE	CT		28	
	SCREENING/09JAN2014	TL:2/LIVER	RIGHT HEPATIC LOBE	CT		12	
	SCREENING/09JAN2014	TL:3/GI	PANCREATIC BODY	CT		30	SLD = 70
	SCREENING/09JAN2014	NTL:1/LIVE	RIGHT HEPATIC LOBE	CT		.	
	SCREENING/09JAN2014	NTL:2/LIVE	RIGHT HEPATIC LOBE	CT		.	
113-0008 /78/M/A8	SCREENING/31JAN2014	TL:1/LIVER	SEMENT 2 OF THE LIVER	CT		22	SLD = 22

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[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
113-0010 /59/M/W2	SCREENING/18APR2014	TL:1/NODES	CONGLOMERATE PORTOCAVAL LYMPH NODES	CT		90	
	SCREENING/18APR2014	TL:2/NODES	PERICARDIAL LYMPH NODE	CT		51	
	SCREENING/18APR2014	TL:3/LIVER	LIVER SEGMENT 3	CT		10	SLD = 151
	SCREENING/18APR2014	NTL:1/LUNG	LEFT LOWER LOBE (CT THORAX)	CT		.	
	SCREENING/18APR2014	NTL:2/LUNG	LEFT LOBE (CT THORAX)	CT		.	
	SCREENING/18APR2014	NTL:3/NODE	RETROCAVAL LYMPH NODE	CT		.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
113-0010 /59/M/W2	SCREENING/18APR2014	NTL:4/NODE	AORTOCAVAL LYMPH NODES	CT		.	
113-0013 /56/M/W2	SCREENING/28OCT2014	TL:1/LIVER	LIVER SEGMENT 8	CT		15	
	SCREENING/28OCT2014	TL:2/LIVER	LIVER SEGMENT 1	CT		16	SLD = 31
	SCREENING/28OCT2014	NTL:1/LUNG	LEFT UPPPER LOBE	CT		.	
	SCREENING/28OCT2014	NTL:2/LUNG	LEFT UPPER LOBE	CT		.	
	WEEK12/13JAN2015	TL:1/LIVER	LIVER SEGMENT 8	CT		19	

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[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
113-0013 /56/M/W2	WEEK12/13JAN2015	TL:2/LIVER	LIVER SEGMENT 1	CT		19	
	WEEK12/13JAN2015	NTL:1/LUNG	LEFT UPPER LOBE IMAGE 169 SERIES 8	CT	Present	.	
	WEEK12/13JAN2015	NTL:2/LUNG	LUNG UPPER LOBE IMAGE 211 SERIES NUMBER 8	CT	Present	.	
	Summary:					.	SLD = 38, %CN = 22.58, TL: PD, NTL: IncompleteResponse/SD, OR: PD, PD confirmed: Yes, 13JAN2015
113-0016 /72/M/A8	SCREENING/07JAN2015	TL:1/LUNG	SUBCARINAL LYMPH NODE	CT		24	
	SCREENING/07JAN2015	TL:2/LUNG	LEFT PERIBRONCHIAL LYMPH NODE	CT		20	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
113-0016 /72/M/A8	SCREENING/07JAN2015	TL:3/	LEFT LINGULA	CT		18	
	SCREENING/07JAN2015	TL:4/LUNG	LFET LOWER LOBE	CT		23	
	SCREENING/07JAN2015	TL:5/LIVER	SEGMENT 8 OF LIVER	CT		13	SLD = 98
	WEEK12/15APR2015	TL:1/LUNG	SUBCARINAL LYMPH NODE	CT		30	
	WEEK12/15APR2015	TL:2/LUNG	LEFT PERIBRONCHIAL LYMPH NODE	CT		27	
	WEEK12/15APR2015	TL:3/	LEFT LINGULA	CT		24	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
113-0016 /72/M/A8	WEEK12/15APR2015	TL:4/LUNG	LEFT LOWER LOBE	CT		24	
	WEEK12/15APR2015	TL:5/LIVER	SEGMENT 8 OF LIVER	CT		16	
	Summary:					.	SLD = 121, %CN = 23.47, TL: PD, NTL: NotAssessed, OR: PD, PD confirmed: Yes, 21APR2015
114-0003 /59/M/W2	SCREENING/29NOV2012	TL:1/GU	ADRENAL LT	CT		68	
	SCREENING/29NOV2012	TL:2/GU	ADRENAL RT	CT		31	
	SCREENING/29NOV2012	TL:3/GI	ABDOMINAL WALL	CT		72	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
114-0003 /59/M/W2	SCREENING/29NOV2012	TL:4/LIVER	INFERIOR	CT		66	
	SCREENING/29NOV2012	TL:5/LIVER	DOME	CT		51	SLD = 288
	SCREENING/29NOV2012	NTL:1/GI	OMENTUM	CT		.	
	SCREENING/29NOV2012	NTL:2/SOFT	CHEST WALL	CT		.	
	SCREENING/29NOV2012	NTL:3/LUNG	MEDIASTINUM	CT		.	
	SCREENING/29NOV2012	NTL:4/LUNG	RIGHT UPPER LOBE (IRRADIATED)	CT		.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
114-0003 /59/M/W2	WEEK12/13FEB2013	TL:1/GU	ADRENAL LT	CT		79	
	WEEK12/13FEB2013	TL:2/GU	ADRENAL RT	CT		36	
	WEEK12/13FEB2013	TL:3/GI	ABDOMINAL WALL	CT		74	
	WEEK12/13FEB2013	TL:4/LIVER	INFERIOR	CT		71	
	WEEK12/13FEB2013	TL:5/LIVER	DOME	CT		56	
	WEEK12/13FEB2013	NTL:1/GI	OMENTUM	CT	Present	.	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
114-0003 /59/M/W2	WEEK12/13FEB2013	NTL:2/SOFT	CHEST WALL	CT	Present	.	
	WEEK12/13FEB2013	NTL:3/LUNG	MEDIASTINUM	CT	Present	.	
	WEEK12/13FEB2013	NTL:4/LUNG	RIGHT UPPER LOBE (IRRADIATED)	CT	Present	.	
	Summary:					.	SLD = 316, %CN = 9.72, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	UNSCHEDULED/10APR2013	TL:1/GU	ADRENAL LT	CT		88	
	UNSCHEDULED/10APR2013	TL:2/GU	ADRENAL RT	CT		37	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
114-0003 /59/M/W2	UNSCHEDULED/10APR2013	TL:3/GI	ABDOMINAL WALL	CT		82	
	UNSCHEDULED/10APR2013	TL:4/LIVER	INFERIOR	CT		72	
	UNSCHEDULED/10APR2013	TL:5/LIVER	DOME	CT		58	
	UNSCHEDULED/10APR2013	NTL:/LUNG	RIGHT UPPER LOBE (IRRADIATED)	CT	Present	.	
	UNSCHEDULED/10APR2013	NTL:1/GI	OMENTUM	CT	Present	.	
	UNSCHEDULED/10APR2013	NTL:2/SOFT	CHEST WALL	CT	Present	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
114-0003 /59/M/W2	UNSCHEDULED/10APR2013	NTL:3/LUNG	MEDIASTINUM	CT	Present	.	
	Summary:					.	SLD = 337, %CN = 17.01, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
114-0005 /73/M/W2	SCREENING/05DEC2013	TL:1/LIVER	LIVER LEFT LATERAL ANTERIOR	CT		29	
	SCREENING/05DEC2013	TL:2/LIVER	LIVER LEFT LATERAL CENTRAL	CT		24	
	SCREENING/05DEC2013	TL:3/NODES	LYMPH NODE PERI-PORTAL	CT		44	
	SCREENING/05DEC2013	TL:4/GI	ADRENAL RIGHT	CT		22	SLD = 119

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[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
114-0005 /73/M/W2	SCREENING/05DEC2013	NTL:1/LIVE	LIVER VARIOUS	CT		.	
	UNSCHEDULED/06FEB2014	TL:1/LIVER	LIVER LEFT LATERAL ANTERIOR	CT		34	
	UNSCHEDULED/06FEB2014	TL:2/LIVER	LIVER LEFT LATERAL CENTRAL	CT		22	
	UNSCHEDULED/06FEB2014	TL:3/NODES	LYMPH NODE PERI-PORTAL	CT		47	
	UNSCHEDULED/06FEB2014	TL:4/GI	ADRENAL RIGHT	CT		30	
	UNSCHEDULED/06FEB2014	NTL:1/LIVE	LIVER VARIOUS	CT	Present	.	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
114-0005 /73/M/W2	Summary:					.	SLD = 133, %CN = 11.76, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
114-0007 /60/F/W2	SCREENING/29OCT2014	TL:1/LIVER	LIVER INF TIP	MRI		27	
	SCREENING/29OCT2014	TL:2/NODES	RT HILUM	CT		25	
	SCREENING/29OCT2014	TL:3/NODES	RT C-P ANGLE	CT		18	
	SCREENING/29OCT2014	TL:4/LUNG	RLL	CT		16	
	SCREENING/29OCT2014	TL:5/LUNG	LUL	CT		16	SLD = 102

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
114-0007 /60/F/W2	SCREENING/29OCT2014	NTL:1/LUNG	LUNG NODES	CT		.	
	SCREENING/29OCT2014	NTL:2/NODE	MEDIASTIN. LNS	CT		.	
	WEEK12/04FEB2015	TL:1/LIVER	LIVER INF TIP	MRI		25	
	WEEK12/04FEB2015	TL:2/NODES	RT HILUM	CT		15	
	WEEK12/04FEB2015	TL:3/NODES	RT C-P ANGLE	CT		20	
	WEEK12/04FEB2015	TL:4/LUNG	RLL	CT		19	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
114-0007 /60/F/W2	WEEK12/04FEB2015	TL:5/LUNG	LUL	CT		15	
	WEEK12/04FEB2015	NTL:1/LUNG	LUNG NODES	CT	Present	.	
	WEEK12/04FEB2015	NTL:2/NODE	MEDIASTIN.LNS	CT	Present	.	
	Summary:					.	SLD = 94, %CN = -7.84, TL: SD, NTL: NotAssessed, OR: SD, PD confirmed: No
	WEEK24/01MAY2015	TL:1/LIVER	LIVER INF TIP	MRI		24	
	WEEK24/01MAY2015	TL:2/NODES	RT HILIUM	CT		13	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
114-0007 /60/F/W2	WEEK24/01MAY2015	TL:3/NODES	RT C-P ANGLE	CT		23	
	WEEK24/01MAY2015	TL:4/LUNG	RLL	CT		19	
	WEEK24/01MAY2015	TL:5/LUNG	LUL	CT		17	
	WEEK24/01MAY2015	NTL:1/LUNG	LUNG NODES	CT	Present	.	
	WEEK24/01MAY2015	NTL:2/NODE	MEDIASTIN. LNS	CT	Present	.	
	Summary:					.	SLD = 96, %CN = 2.13, TL: SD, NTL: NotAssessed, OR: SD, PD confirmed: No

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
115-0001 /59/F/A4	SCREENING/20NOV2012	TL:1/LIVER	HEPATIC MASS 1	CT		53	
	SCREENING/20NOV2012	TL:2/LIVER	HEPATIC MASS 3	CT		33	SLD = 86
	SCREENING/20NOV2012	NTL:1/LIVE	PERIHEPATIC NODULE	CT		.	
	SCREENING/20NOV2012	NTL:2/LIVE	HEPATIC MASS 2	CT		.	
	WEEK12/11FEB2013	TL:1/LIVER	HEPATIC MASS 1	CT		58	
	WEEK12/11FEB2013	TL:2/LIVER	HEPATIC MASS 3	CT		54	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
115-0001 /59/F/A4	WEEK12/11FEB2013	NTL:1/LIVE	PERIHEPATIC NODULE	CT	Present	.	
	WEEK12/11FEB2013	NTL:2/LIVE	HEPATIC MASS 2	CT	UP	.	
	Summary:					.	SLD = 112, %CN = 30.23, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 11FEB2013
115-0002 /45/F/W2	SCREENING/21NOV2012	TL:1/LIVER	HEPATIC MASS	MRI		44	
	SCREENING/21NOV2012	TL:2/PERIC	CARDIAC THROMBUS	CT		61	SLD = 105
	SCREENING/21NOV2012	NTL:1/LUNG	PULMONARY NODULE	CT		.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
115-0002 /45/F/W2	UNSCHEDULED/10JAN2013	TL:1/LIVER	HEPATIC MASS	MRI		52	
	UNSCHEDULED/10JAN2013	TL:2/PERIC	CARDIAC THROMBUS	CT		79	
	UNSCHEDULED/10JAN2013	NTL:1/LUNG	PULMONARY NODULE	CT	UP	.	
	Summary:					.	SLD = 131, %CN = 24.76, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 10JAN2013
115-0003 /63/M/W2	SCREENING/15JAN2013	TL:1/LIVER		MRI		45	
	SCREENING/15JAN2013	TL:2/LIVER		MRI		40	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
115-0003 /63/M/W2	SCREENING/15JAN2013	TL:3/LUNG		CT		12	
	SCREENING/15JAN2013	TL:4/LUNG		CT		11	SLD = 108
	SCREENING/15JAN2013	NTL:1/LIVE		MRI		.	
	SCREENING/15JAN2013	NTL:2/LUNG		CT		.	
	SCREENING/15JAN2013	NTL:3/GI	RIGHT PARACOLIC DEPOSIT	MRI		.	
	WEEK12/02APR2013	TL:1/LIVER		MRI		47	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
115-0003 /63/M/W2	WEEK12/02APR2013	TL:2/LIVER		MRI		41	
	WEEK12/02APR2013	TL:3/LUNG		CT		13	
	WEEK12/02APR2013	TL:4/LUNG		CT		11	
	WEEK12/02APR2013	NTL:1/LIVE		MRI	Present	.	
	WEEK12/02APR2013	NTL:2/LUNG		CT	Present	.	
	WEEK12/02APR2013	NTL:3/GI	RIGHT PARACOLIC DEPOSIT	MRI	Present	.	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
115-0003 /63/M/W2	Summary:					.	SLD = 112, %CN = 3.7, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK24/24JUN2013	TL:1/LIVER		MRI		47	
	WEEK24/24JUN2013	TL:2/LIVER		MRI		43	
	WEEK24/24JUN2013	TL:3/LUNG		CT		19	
	WEEK24/24JUN2013	TL:4/LUNG		CT		14	
	WEEK24/24JUN2013	NTL:1/LIVE		MRI	Present	.	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
115-0003 /63/M/W2	WEEK24/24JUN2013	NTL:2/LUNG		CT	Present	.	
	WEEK24/24JUN2013	NTL:3/GI	RIGHT PARACOLIC DEPOSIT	MRI	Present	.	
	Summary:					.	SLD = 123, %CN = 13.89, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
115-0008 /51/M/A8	SCREENING/13JUN2013	TL:1/LIVER	HEPATIC MASS	MRI		124	
	SCREENING/13JUN2013	TL:2/LIVER	HEPATIC MASS 2	MRI		46	
	SCREENING/13JUN2013	TL:3/	PELVIC MASS	MRI		61	SLD = 231

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
115-0008 /51/M/A8	SCREENING/13JUN2013	NTL:1/LIVE	HEPATIC MASS 3	MRI		.	
	SCREENING/13JUN2013	NTL:2/	PELVIC MASS 2	MRI		.	
115-0009 /85/M/W2	SCREENING/03DEC2013	TL:1/LUNG	RIGHT UPPER LOBE NODULE	CT		12	
	SCREENING/03DEC2013	TL:2/LIVER	LEFT LIVER LOBE LESION	CT		54	
	SCREENING/03DEC2013	TL:3/LIVER	SEGMENT 5 LIVER LESION	CT		28	
	SCREENING/03DEC2013	TL:4/GI	PERITONEAL MASS	CT		47	SLD = 141

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
115-0009 /85/M/W2	SCREENING/03DEC2013	NTL:1/LUNG	LUNG NODULES	CT		.	
	SCREENING/03DEC2013	NTL:2/LIVE	MULTIPLE LIVER LESIONS	CT		.	
	SCREENING/03DEC2013	NTL:3/PERI	EPINEPHRIC LYMPH NODE	CT		.	
	SCREENING/03DEC2013	NTL:4/ASCI	ASCITES	CT		.	
	WEEK12/21FEB2014	TL:1/LUNG	RIGHT UPPER LOBE NODULE	CT		13	
	WEEK12/21FEB2014	TL:2/LIVER	LEFT LIVER LOBE LESION	CT		53	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
115-0009 /85/M/W2	WEEK12/21FEB2014	TL:3/LIVER	SEGMENT 5 LIVER LESION	CT		29	
	WEEK12/21FEB2014	TL:4/GI	PERITONEAL MASS	CT		49	
	WEEK12/21FEB2014	NTL:1/LUNG	LUNG NODULES	CT	Present	.	
	WEEK12/21FEB2014	NTL:2/LIVE	MULTIPLE LIVER LESIONS	CT	Present	.	
	WEEK12/21FEB2014	NTL:3/PERI	EPINEPHRIC LYMPH NODE	CT	Present	.	
	WEEK12/21FEB2014	NTL:4/ASCI	ASCITES	CT	Present	.	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
115-0009 /85/M/W2	Summary:					.	SLD = 144, %CN = 2.13, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	UNSCHEDULED/03APR2014	TL:1/LUNG	RIGHT UPPER LOBE NODULE	CT		14	
	UNSCHEDULED/03APR2014	TL:2/LIVER	LEFT LIVER LOBE LESION	CT		55	
	UNSCHEDULED/03APR2014	TL:3/LIVER	SEGMENT 5 LIVER LESION	CT		41	
	UNSCHEDULED/03APR2014	TL:4/GI	PERITONEAL MASS	CT		51	
	UNSCHEDULED/03APR2014	NTL:1/LUNG	LUNG NODULES	CT	Present	.	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
115-0009 /85/M/W2	UNSCHEDULED/03APR2014	NTL:2/LIVE	MULTIPLE LIVER LESIONS	CT	Present	.	
	UNSCHEDULED/03APR2014	NTL:3/PERI	EPINEPHRIC LYMPH NODE	CT	Present	.	
	UNSCHEDULED/03APR2014	NTL:4/ASCI	ASCITES	CT	Present	.	
	Summary:					.	SLD = 161, %CN = 14.18, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK24/21MAY2014	TL:1/LUNG	RIGHT UPPER LOBE NODULE	CT		13	
	WEEK24/21MAY2014	TL:2/LIVER	LEFT LIVER LOBE LESION	CT		56	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
115-0009 /85/M/W2	WEEK24/21MAY2014	TL:3/LIVER	SEGMENT 5 LIVER LESION	CT		41	
	WEEK24/21MAY2014	TL:4/GI	PERITONEAL MASS	CT		47	
	WEEK24/21MAY2014	NTL:1/LUNG	LUNG NODULES	CT	UP	.	
	WEEK24/21MAY2014	NTL:2/LIVE	MULTIPLE LIVER LESIONS	CT	Present	.	
	WEEK24/21MAY2014	NTL:3/PERI	EPINEPHRIC LYMPH NODE	CT	Present	.	
	WEEK24/21MAY2014	NTL:4/ASCI	ASCITES	CT	Present	.	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
115-0009 /85/M/W2	WEEK24/21MAY2014	NTL:5/GI	PERITONEAL NODULES	CT	New	.	
	Summary:					.	SLD = 157, %CN = 11.35, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 21MAY2014
115-0011 /56/M/W2	SCREENING/21MAY2014	TL:1/LIVER	LIVER LESION 1	CT		57	
	SCREENING/21MAY2014	TL:2/LIVER	LIVER LESION 2	CT		20	
	SCREENING/21MAY2014	TL:3/LUNG	LUNG NODULE	CT		17	
	SCREENING/21MAY2014	TL:4/NODES	PORTAL LYMPH NODE	CT		29	SLD = 123

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
115-0011 /56/M/W2	SCREENING/21MAY2014	NTL:1/LIVE	PORTAL VEIN TUMOR THROMBUS	CT		.	
	SCREENING/21MAY2014	NTL:2/SOFT	OMENTAL NODULARITY	CT		.	
	SCREENING/21MAY2014	NTL:3/LUNG	LUNG NODULES	CT		.	
	UNSCHEDULED/16JUL2014	TL:1/LIVER	LIVER LESION 1	CT		62	
	UNSCHEDULED/16JUL2014	TL:2/LIVER	LIVER LESION 2	CT		20	
	UNSCHEDULED/16JUL2014	TL:3/LUNG	LUNG NODULE	CT		22	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
115-0011 /56/M/W2	UNSCHEDULED/16JUL2014	TL:4/NODES	PORTAL LYMPH NODES	CT		31	
	UNSCHEDULED/16JUL2014	NTL:1/LIVE	PORTAL VEIN TUMOR THROMBUS	CT	Present	.	
	UNSCHEDULED/16JUL2014	NTL:2/SOFT	OMENTAL NODULARITY	CT	Present	.	
	UNSCHEDULED/16JUL2014	NTL:3/LUNG	LUNG NODULES	CT	Present	.	
	Summary:					.	SLD = 135, %CN = 9.76, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK12/29AUG2014	TL:1/LIVER	LIVER LESION 1	CT		70	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
115-0011 /56/M/W2	WEEK12/29AUG2014	TL:2/LIVER	LIVER LESION 2	CT		20	
	WEEK12/29AUG2014	TL:3/LUNG	LUNG NODULE	CT		26	
	WEEK12/29AUG2014	TL:4/NODES	PORTAL LYMPH NODE	CT		38	
	WEEK12/29AUG2014	NTL:1/LIVE	PORTAL VEIN TUMOR THROMBUS	CT	Present	.	
	WEEK12/29AUG2014	NTL:2/SOFT	OMENTAL NODULARITY	CT	Present	.	
	WEEK12/29AUG2014	NTL:3/LUNG	LUNG NODULES	CT	Present	.	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
115-0011 /56/M/W2	Summary:					.	SLD = 154, %CN = 25.2, TL: PD, NTL: IncompleteResponse/SD, OR: PD, PD confirmed: Yes, 29AUG2014
115-0014 /72/M/W2	SCREENING/21JAN2015	TL:1/LIVER	SEGMENT 4A	MRI		43	
	SCREENING/21JAN2015	TL:2/LIVER	RIGHT INFILTRATIVE MASS	MRI		137	SLD = 180
	SCREENING/21JAN2015	NTL:1/LIVE	MULTIPLE LESIONS	MRI		.	
	SCREENING/21JAN2015	NTL:2/LIVE	RIGHT PORTAL VEIN TUMOR THROMBUS	MRI		.	
116-0002 /67/F/W2	SCREENING/19FEB2013	TL:1/LIVER	CENTRAL HEPATIC MASS	CT		100	SLD = 100

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
116-0002 /67/F/W2	SCREENING/19FEB2013	NTL:1/LIVE	TUMOR THROMBUS ANTERIOR BRANCH OF THE RT. PORTAL VEIN	CT		.	
	SCREENING/19FEB2013	NTL:2/LIVE	EXPANSILE TUMOR THROMBUS LT. PORTAL BRANCH	CT		.	
	SCREENING/19FEB2013	NTL:3/LIVE	PERIPHERAL NODES, NUMEROUS	CT		.	
	WEEK12/29MAY2013	TL:1/LIVER	CENTRAL HEPATIC MASS	CT		98	
	WEEK12/29MAY2013	NTL:1/LIVE	TUMOR THROMBUS ANTERIOR BRANCH OF THE RT. PORTAL VEIN	CT	Present	.	
	WEEK12/29MAY2013	NTL:2/LIVE	EXPANSILE TUMOR THROMUS LT. PORTAL BRANCH	CT	Present	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

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116-0002 /67/F/W2	WEEK12/29MAY2013	NTL:3/LIVE	PERIPHERAL NODES, NUMEROUS	CT	Present	.	
	Summary:					.	SLD = 98, %CN = -2, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK24/23AUG2013	TL:1/LIVER	CENTRAL HEPATIC MASS	CT		112	
	WEEK24/23AUG2013	NTL:1/LIVE	TUMOR THROMBUS ANTERIOR BRANCH OF THE RT. PORTAL VEIN	CT	Present	.	
	WEEK24/23AUG2013	NTL:2/LIVE	EXPANSILE TUMOR THROMUS LT. PORTAL BRANCH	CT	Present	.	
	WEEK24/23AUG2013	NTL:3/LIVE	PERIPHERAL NODES, NUMEROUS	CT	Present	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
116-0002 /67/F/W2	Summary:					.	SLD = 112, %CN = 14.29, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK36/15NOV2013	TL:1/LIVER	CENTRAL HEPATIC MASS	CT		127	
	WEEK36/15NOV2013	NTL:1/LIVE	TUMOR THROMBUS ANTERIOR BRANCH OF THE RT. PORTAL VEIN	CT	Present	.	
	WEEK36/15NOV2013	NTL:2/LIVE	EXPANSILE TUMOR THROMUS LT. PORTAL BRANCH	CT	Present	.	
	WEEK36/15NOV2013	NTL:3/LIVE	PERIPHERAL NODES, NUMEROUS	CT	Present	.	
	Summary:					.	SLD = 127, %CN = 29.59, TL: PD, NTL: IncompleteResponse/SD, OR: PD, PD confirmed: Yes, 18NOV2013

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
116-0003 /66/M/BL	SCREENING/27MAR2013	TL:1/LIVER	RIGHT HEPATIC MASS TO HEPATIC DOME	CT		105	
	SCREENING/27MAR2013	TL:2/LIVER	CENTRAL LYMPH NODE	CT		64	
	SCREENING/27MAR2013	TL:3/NODES	RETROCAVAL LYMPH NODE	CT		44	SLD = 213
	SCREENING/27MAR2013	NTL:1/LIVE	MULTIPLE PARA-AORTIC LYMPH NODES	CT		.	
	SCREENING/27MAR2013	NTL:2/LIVE	EXTRA HEPATIC	CT		.	
	WEEK12/21MAY2013	TL:1/LIVER	RIGHT HEPATIC MASS TO HEPATIC DOME	CT	UP	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
116-0003 /66/M/BL	WEEK12/21MAY2013	TL:2/LIVER	CENTRAL LYMPH NODE	CT		76	
	WEEK12/21MAY2013	TL:3/NODES	RETROCAVAL LYMPH NODE	CT		50	
	WEEK12/21MAY2013	NTL:1/LIVE	MULTIPLE PARA-AORTIC LYMPH NODES	CT	Present	.	
	WEEK12/21MAY2013	NTL:2/LIVE	EXTRA HEPATIC	CT	Present	.	
	Summary:					.	SLD = ., %CN = ., TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 21MAY2013
117-0001 /69/M/W2	SCREENING/11MAR2013	TL:1/SOFTT	LESION RIGHT SACRO ALA	MRI		36	SLD = 36

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Listing 16.2.6.2
Tumor Assessment Summary Listing
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Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
117-0001 /69/M/W2	SCREENING/11MAR2013	NTL:1/SOFT	MASS ADJACENT TO LUMBOSACRAL JUNCTION ON RIGHT	CT		.	
	SCREENING/11MAR2013	NTL:2/BONE	MARROW REPLACEMENT L4, L5 SPINE	MRI		.	
	UNSCHEDULED/25APR2013	TL:1/SOFTT	LESION RIGHT SACRO ALA	MRI		42	
	Summary:					.	SLD = 42, %CN = 16.67, TL: SD, NTL: NotAssessed, OR: SD, PD confirmed: No
	WEEK12/12JUN2013	TL:1/SOFTT	LESION RIGHT SACRO ALA	MRI		55	
	WEEK12/12JUN2013	NTL:1/SOFT	MASS ADJACENT TO LUMBOSACRAL JUNCTION ON RIGHT	CT	Present	.	

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Treatment Group: ADI-PEG 20

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117-0001 /69/M/W2	WEEK12/12JUN2013	NTL:2/BONE	MARROW REPLACEMENT L4, L5	MRI	Present	.	
	Summary:					.	SLD = 55, %CN = 52.78, TL: PD, NTL: IncompleteResponse/SD, OR: PD, PD confirmed: Yes, 12JUN2013
118-0001 /67/F/A8	SCREENING/29JUL2013	TL:1/LIVER	LEFT LOBE	CT		17	
	SCREENING/29JUL2013	TL:2/GI	OMENTAL MASS (RIGHT UPPER QUADRANT)	CT		24	SLD = 41
	SCREENING/29JUL2013	NTL:1/LUNG	MICRONODULES	CT		.	
	WEEK12/29OCT2013	TL:1/LIVER	LEFT LOBE	CT		12	

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Tumor Assessment Summary Listing
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Treatment Group: ADI-PEG 20

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118-0001 /67/F/A8	WEEK12/29OCT2013	TL:2/GI	OMENTAL MASS (RIGHT UPPER QUADRANT)	CT		36	
	WEEK12/29OCT2013	NTL:1/LUNG	MICRONODULES	CT	Absent	.	
	WEEK12/29OCT2013	NTL:2/LIVE	NEW LIVER LESION	CT	UP	.	
	Summary:					.	SLD = 48, %CN = 17.07, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 29OCT2013
119-0001 /80/M/A8	SCREENING/14JAN2014	TL:1/LIVER	ANTERIOR AND POSTERIOR RIGHT LOBE	CT		134	
	SCREENING/14JAN2014	TL:2/LIVER	RIGHT LOBE	CT		15	SLD = 149

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Tumor Assessment Summary Listing
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Treatment Group: ADI-PEG 20

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121-0001 /62/M/W2	SCREENING/11FEB2014	TL:1/NODES	GASTROHEPATIC LYMPH NODE	CT		52	SLD = 52
	SCREENING/11FEB2014	NTL:1/LIVE	PORTAL VEIN TUMOR	CT		.	
	SCREENING/11FEB2014	NTL:2/LIVE	LIVER METS	CT		.	
	WEEK12/06MAY2014	TL:1/NODES	GASTROHEPATIC LYMPH NODE	CT		58	
	WEEK12/06MAY2014	NTL:1/LIVE	PORTAL VEIN TUMOR	CT	Present	.	
	WEEK12/06MAY2014	NTL:2/LIVE	LIVER METS	CT	Present	.	

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121-0001 /62/M/W2	Summary:					.	SLD = 58, %CN = 11.54, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
121-0004 /64/F/W2	SCREENING/30DEC2014	TL:1/LUNG	RIGHT UPPER LOBE	CT		23	
	SCREENING/30DEC2014	TL:2/LUNG	LEFT LOWER LOBE	CT		18	SLD = 41
	SCREENING/30DEC2014	NTL:1/LUNG	PULMONARY NODULES	CT		.	
	SCREENING/30DEC2014	NTL:2/NODE	MEDIASTINAL ADENOPATHY	CT		.	
	SCREENING/30DEC2014	NTL:3/LIVE	RIGHT HEPATIC LOBE	CT		.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
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Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
201-0001 /68/F/W2	SCREENING/12JAN2012	TL:1/LIVER	VII° SEGMENT	CT		44	
	SCREENING/12JAN2012	TL:2/LIVER	VII° SEGMENT	CT		26	SLD = 70
	SCREENING/12JAN2012	NTL:1/LIVE	MULTIPLE HEPATIC LESIONS BETWEEN RIGHT AND LEFT LOBE	CT		.	
	SCREENING/12JAN2012	NTL:2/BONE	BONE LESION VI-IX RIGHT RIB	CT		.	
	SCREENING/12JAN2012	NTL:3/BONE	BONE LESION AT RIGHT VERTEBRA L1	CT		.	
	WEEK12/23APR2012	TL:1/LIVER	VII° SEGMENT	CT		53	

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Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
201-0001 /68/F/W2	WEEK12/23APR2012	TL:2/LIVER	VII° SEGMENT	CT		35	
	WEEK12/23APR2012	NTL:1/LIVE	MULTIPLE HEPATIC LESIONS BETWEEN RIGHT AND LEFT LOBE	CT	New	.	
	WEEK12/23APR2012	NTL:2/BONE	BONE LESION VI-IX RIGHT RIB	CT	UP	.	
	WEEK12/23APR2012	NTL:3/BONE	BONE LESION AT RIGHT VERTEBRA L1	CT	UP	.	
	WEEK12/23APR2012	NTL:4/LIVE	ADRENAL METASTASIS (44 X 31)	CT	New	.	
	WEEK12/23APR2012	NTL:5/LIVE	PORTAL VEIN THROMBOSIS	CT	New	.	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
201-0001 /68/F/W2	Summary:					.	SLD = 88, %CN = 25.71, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 24APR2012
201-0005 /73/M/W2	SCREENING/22JUN2012	TL:1/LIVER	V LIVER SEGMENT	MRI		20	
	SCREENING/22JUN2012	TL:2/LIVER	II LIVER SEGMENT	MRI		13	SLD = 33
	SCREENING/22JUN2012	NTL:1/LIVE	PORTAL VEIN THROMBOSIS	MRI		.	
	WEEK12/08OCT2012	NTL:3/LUNG	LESION OF 6 MM TO UPPER RIGHT PULMONARY LOBE	CT	New	.	
	WEEK12/09OCT2012	TL:1/LIVER	V LIVER SEGMENT	MRI		116	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
201-0005 /73/M/W2	WEEK12/09OCT2012	TL:2/LIVER	II LIVER SEGMENT	MRI		10	
	WEEK12/09OCT2012	NTL:1/LIVE	PORTAL VEIN THROMBOSIS	MRI	UP	.	
	WEEK12/09OCT2012	NTL:2/LIVE	MULTIPLE LESIONS	MRI	New	.	
	Summary:					.	SLD = 126, %CN = 281.82, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 10OCT2012
201-0008 /79/M/W2	SCREENING/23APR2013	TL:1/LIVER	VII-V SEGMENT	CT		37	
	SCREENING/23APR2013	TL:2/LIVER	I SEGMENT	CT		23	SLD = 60

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
201-0008 /79/M/W2	SCREENING/23APR2013	NTL:1/LIVE	SEGMENTAL PORTAL VEIN THROMBOSIS OF THE VII-V SEGMENT	CT		.	
	WEEK12/29JUL2013	TL:1/LIVER	VII-V SEGMENT	CT		47	
	WEEK12/29JUL2013	TL:2/LIVER	I SEGMENT	CT		23	
	WEEK12/29JUL2013	NTL:1/LIVE	SEGMENTAL PORTAL VEIN THROMBOSIS OF THE VII-V SEGMENT	CT	Present	.	
	Summary:					.	SLD = 70, %CN = 16.67, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
201-0011 /73/M/W2	SCREENING/07JUN2013	TL:1/LIVER	IV SEGMENT	CT		19	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
201-0011 /73/M/W2	SCREENING/07JUN2013	TL:2/LIVER	VIII SEGMENT	CT		13	SLD = 32
	SCREENING/07JUN2013	NTL:1/LIVE	HEPATIC LESIONS AT RIGHT LOBE	CT		.	
	SCREENING/07JUN2013	NTL:2/GU	METASTASIS RIGHT ADRENAL	CT		.	
	WEEK12/20SEP2013	TL:1/LIVER	IV SEGMENT	CT		26	
	WEEK12/20SEP2013	TL:2/LIVER	VIII SEGMENT	CT		19	
	WEEK12/20SEP2013	NTL:1/LIVE	HEPATIC LESIONS AT RIGHT LOBE	CT	Present	.	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
201-0011 /73/M/W2	WEEK12/20SEP2013	NTL:2/GU	METASTASIS RIGHT ADRENAL	CT	UP	.	
	Summary:					.	SLD = 45, %CN = 40.63, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 20SEP2013
201-0012 /79/M/W2	SCREENING/28JUN2013	TL:1/LIVER	IV SEGMENT	CT		10	
	SCREENING/28JUN2013	TL:2/LUNG	RIGHT PULMONARY INFERIOR LOBE	CT		18	
	SCREENING/28JUN2013	TL:3/LUNG	LEFT PULMONARY INFERIOR LOBE	CT		16	
	SCREENING/28JUN2013	TL:4/NODES	PERITONEAL RIGHT BAND PARARENAL NODULE	CT		13	SLD = 57

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
201-0012 /79/M/W2	SCREENING/28JUN2013	NTL:1/LIVE	LESIONS	CT		.	
	SCREENING/28JUN2013	NTL:2/LUNG	LESIONS	CT		.	
	SCREENING/28JUN2013	NTL:3/NODE	PERITONEAL LESIONS	CT		.	
	WEEK12/11OCT2013	TL:1/LIVER	IV SEGMENT	CT		8	
	WEEK12/11OCT2013	TL:2/LUNG	RIGHT PULMONARY INFERIOR LOBE	CT		18	
	WEEK12/11OCT2013	TL:3/LUNG	LEFT PULMONARY INFERIOR LOBE	CT		16	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
201-0012 /79/M/W2	WEEK12/11OCT2013	TL:4/NODES	PERITONEAL RIGHT BAND PARARENAL NODULE	CT		14	
	WEEK12/11OCT2013	NTL:1/LIVE	LESIONS	CT	Present	.	
	WEEK12/11OCT2013	NTL:2/LUNG	LESIONS	CT	Present	.	
	WEEK12/11OCT2013	NTL:3/NODE	PERITONEAL LESIONS	CT	Present	.	
	Summary:					.	SLD = 56, %CN = -1.75, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK24/07JAN2014	TL:1/LIVER	IV SEGMENT	CT		10	

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[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
201-0012 /79/M/W2	WEEK24/07JAN2014	TL:2/LUNG	RIGHT PULMONARY INFERIOR LOBE	CT		21	
	WEEK24/07JAN2014	TL:3/LUNG	LEFT PULMONARY INFERIOR LOBE	CT		18	
	WEEK24/07JAN2014	TL:4/NODES	PERITONEAL RIGHT BAND PARARENAL NODULE	CT		16	
	WEEK24/07JAN2014	NTL:1/LIVE	LESIONS	CT	Present	.	
	WEEK24/07JAN2014	NTL:2/LUNG	LESIONS	CT	Present	.	
	WEEK24/07JAN2014	NTL:3/NODE	PERITONEAL LESIONS	CT	Present	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
201-0012 /79/M/W2	Summary:					.	SLD = 65, %CN = 16.07, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK36/28MAR2014	TL:1/LIVER	IV SEGMENT	CT		10	
	WEEK36/28MAR2014	TL:2/LUNG	RIGHT PULMONARY INFERIOR LOBE	CT		21	
	WEEK36/28MAR2014	TL:3/LUNG	LEFT PULMONARY INFERIOR LOBE	CT		18	
	WEEK36/28MAR2014	TL:4/NODES	PERITONEAL RIGHT BAND PARARENAL NODULE	CT		16	
	WEEK36/28MAR2014	NTL:1/LIVE	LESIONS	CT	Present	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
201-0012 /79/M/W2	WEEK36/28MAR2014	NTL:2/LUNG	LESIONS	CT	Present	.	
	WEEK36/28MAR2014	NTL:3/NODE	PERITONEAL LESIONS	CT	Present	.	
	Summary:					.	SLD = 65, %CN = 16.07, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK48/23JUN2014	TL:1/LIVER	IV SEGMENT	CT		8	
	WEEK48/23JUN2014	TL:2/LUNG	RIGHT PULMONARY INFERIOR LOBE	CT		21	
	WEEK48/23JUN2014	TL:3/LUNG	LEFT PULMONARY INFERIOR LOBE	CT		20	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
201-0012 /79/M/W2	WEEK48/23JUN2014	TL:4/NODES	PERITONEAL RIGHT BAND PARARENAL NODULE	CT		16	
	WEEK48/23JUN2014	NTL:1/LIVE	LESIONS	CT	Present	.	
	WEEK48/23JUN2014	NTL:2/LUNG	LESIONS	CT	Present	.	
	WEEK48/23JUN2014	NTL:3/NODE	PERITONEAL LESIONS	CT	Present	.	
	Summary:					.	SLD = 65, %CN = 16.07, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK60/16SEP2014	TL:1/LIVER	IV SEGMENT	CT		10	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
201-0012 /79/M/W2	WEEK60/16SEP2014	TL:2/LUNG	RIGHT PULMONARY INFERIOR LOBE	CT		26	
	WEEK60/16SEP2014	TL:3/LUNG	LEFT PULMONARY INFERIOR LOBE	CT		28	
	WEEK60/16SEP2014	TL:4/NODES	PERITONEAL RIGHT BAND PARARENAL NODULE	CT		17	
	WEEK60/16SEP2014	NTL:1/LIVE	LESIONS	CT	Present	.	
	WEEK60/16SEP2014	NTL:2/LUNG	LESIONS	CT	Present	.	
	WEEK60/16SEP2014	NTL:3/NODE	PERITONEAL LESIONS	CT	Present	.	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
201-0012 /79/M/W2	Summary:					.	SLD = 81, %CN = 44.64, TL: PD, NTL: IncompleteResponse/SD, OR: PD, PD confirmed: Yes, 18SEP2014
201-0013 /67/F/W2	SCREENING/27JUN2013	TL:1/LIVER	V SEGMENT	CT		26	
	SCREENING/27JUN2013	TL:2/LIVER	IV SEGMENT	CT		13	SLD = 39
	SCREENING/27JUN2013	NTL:1/LIVE	LESION	CT		.	
	WEEK12/11OCT2013	TL:1/LIVER	V SEGMENT	CT		29	
	WEEK12/11OCT2013	TL:2/LIVER	IV SEGMENT	CT		26	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
201-0013 /67/F/W2	WEEK12/11OCT2013	NTL:1/LIVE	LESION	CT	UP	.	
	WEEK12/11OCT2013	NTL:2/LIVE	LESION	CT	New	.	
	Summary:					.	SLD = 55, %CN = 41.03, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 11OCT2013
201-0016 /72/M/W2	SCREENING/18OCT2013	TL:1/LIVER	II SEGMENT	CT		13	
	SCREENING/18OCT2013	TL:2/LIVER	VI SEGMENT	CT		13	SLD = 26
	SCREENING/18OCT2013	NTL:1/BONE	VERTEBRAL AND RIB BONE LESIONS	CT		.	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
201-0016 /72/M/W2	WEEK12/03FEB2014	TL:1/LIVER	II SEGMENT	CT		13	
	WEEK12/03FEB2014	TL:2/LIVER	VI SEGMENT	CT		16	
	WEEK12/03FEB2014	NTL:1/BONE	VERTEBRAL AND RIB BONE LESIONS	CT	Present	.	
	Summary:					.	SLD = 29, %CN = 11.54, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK24/18APR2014	TL:1/LIVER	II SEGMENT	CT		13	
	WEEK24/18APR2014	TL:2/LIVER	VI SEGMENT	CT		16	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
201-0016 /72/M/W2	WEEK24/18APR2014	NTL:1/BONE	VERTEBRAL AND RIB BONE LESIONS	CT	UP	.	
	Summary:					.	SLD = 29, %CN = 11.54, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 18APR2014
201-0017 /82/M/W2	SCREENING/25NOV2013	TL:1/LIVER	VIII SEGMENT	MRI		23	
	SCREENING/25NOV2013	TL:2/LIVER	VI SEGMENT	MRI		40	SLD = 63
	SCREENING/25NOV2013	NTL:1/LIVE	LESIONS	MRI		.	
201-0018 /78/F/W2	SCREENING/14NOV2013	TL:1/LIVER	I SEGMENT	CT		100	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
201-0018 /78/F/W2	SCREENING/14NOV2013	TL:2/LIVER	VI SEGMENT	CT		60	SLD = 160
	SCREENING/14NOV2013	NTL:1/LIVE	MULTIPLE LESIONS	CT		.	
	SCREENING/14NOV2013	NTL:2/GI	PERITONEAL CARCINOMATOSIS	CT		.	
201-0019 /68/M/W2	SCREENING/28NOV2013	TL:1/BONE	VII RIGHT RIB	CT		29	
	SCREENING/28NOV2013	TL:2/BONE	S1 VERTEBRA	CT		30	SLD = 59
	SCREENING/28NOV2013	NTL:1/BONE	LESIONS	CT		.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
201-0019 /68/M/W2	WEEK12/07MAR2014	TL:1/BONE	VII RIGHT RIB	CT		35	
	WEEK12/07MAR2014	TL:2/BONE	S1 VERTEBRA	CT		21	
	WEEK12/07MAR2014	NTL:1/BONE	LESIONS	CT	UP	.	
	WEEK12/07MAR2014	NTL:2/BONE	LESIONS	CT	New	.	
	Summary:					.	SLD = 56, %CN = -5.08, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 12MAR2014
201-0020 /67/M/W2	SCREENING/09JAN2014	TL:1/LIVER	VI LIVER SEGMENT	CT		15	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
201-0020 /67/M/W2	SCREENING/09JAN2014	TL:2/LIVER	III LIVER SEGMENT	CT		20	SLD = 35
	SCREENING/09JAN2014	NTL:1/LIVE	LESIONS	CT		.	
	SCREENING/09JAN2014	NTL:2/LUNG	MORE LESIONS	CT		.	
201-0021 /54/M/W2	SCREENING/17JAN2014	TL:1/LIVER	VII LIVER SEGMENT	CT		50	
	SCREENING/17JAN2014	TL:2/LIVER	VI LIVER SEGMENT	CT		18	SLD = 68
	SCREENING/17JAN2014	NTL:1/LIVE	LESIONS	CT		.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
201-0021 /54/M/W2	SCREENING/17JAN2014	NTL:2/NODE	ABDOMINAL LYMPH NODES	CT		.	
	WEEK12/02MAY2014	TL:1/LIVER	VII LIVER SEGMENT	CT		56	
	WEEK12/02MAY2014	TL:2/LIVER	VI LIVER SEGMENT	CT		27	
	WEEK12/02MAY2014	NTL:1/LIVE	LESIONS	CT	UP	.	
	WEEK12/02MAY2014	NTL:2/NODE	ABDOMINAL LYMPH NODES	CT	Present	.	
	WEEK12/02MAY2014	NTL:3/LIVE	LESIONS	CT	New	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
201-0021 /54/M/W2	Summary:					.	SLD = 83, %CN = 22.06, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 05MAY2014
201-0024 /74/M/W2	SCREENING/19JAN2015	TL:3/LUNG	ONE LESION AT APICAL SEGMENT LID	Oth		14	
	SCREENING/19JAN2015	TL:4/LUNG	ONE LESION AT POSTERO-BASAL LID	Oth		30	SLD = 223
	SCREENING/19JAN2015	NTL:2/LUNG	TWO PULMONARY LESIONS	Oth		.	
	SCREENING/21JAN2015	TL:1/LIVER	IV LIVER SEGMENT	MRI		104	
	SCREENING/21JAN2015	TL:2/LIVER	IV LIVER SEGMENT	MRI		75	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
201-0024 /74/M/W2	SCREENING/21JAN2015	NTL:1/LIVE	TWO HEPATIC LESION	MRI		.	
	UNSCHEDULED/13MAR2015	NTL:1/BRAI	CEREBELLAR LESION (50X43 MM)	MRI	New	.	
	Summary:					.	SLD = ., %CN = ., TL: NotAssessed, NTL: PD, OR: PD, PD confirmed: Yes, 13MAR2015
201-0025 /75/M/W2	SCREENING/12JAN2015	TL:1/LIVER	VIII LIVER SEGMENT	CT		24	
	SCREENING/12JAN2015	TL:2/LIVER	IVB LIVER SEGMENT	CT		31	SLD = 55
	SCREENING/12JAN2015	NTL:1/LIVE	MORE HEPATIC LESIONS	CT		.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
203-0001 /61/F/W2	SCREENING/23FEB2012	TL:1/LIVER	V-VI SEGMENT	CT		63	
	SCREENING/23FEB2012	TL:2/LIVER	CRANIAL SATELLITE LESIONS CRA	CT		21	
	SCREENING/23FEB2012	TL:3/LUNG	RIGHT INFERIOR LOBE	CT		48	SLD = 132
	SCREENING/23FEB2012	NTL:1/LUNG	LEFT INFERIOR LOBE	CT		.	
	SCREENING/23FEB2012	NTL:2/LIVE	INTER CAVAL AORTIC LIMPHOADENOPATY	CT		.	
203-0002 /72/M/W2	SCREENING/22FEB2012	TL:2/SOFTT	MUSCLE OF RIGHT ABDOMINAL WALL	CT		50	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
203-0002 /72/M/W2	SCREENING/23FEB2012	TL:1/NODES	RETROPERITONEAL LINFOADENOMEGALY	CT		57	
	SCREENING/23FEB2012	TL:3/GU	LEFT KIDNEY	CT		37	SLD = 144
	SCREENING/23FEB2012	NTL:1/NODE	RETROPERITONEAL LYMPHONODE	CT		.	
	SCREENING/23FEB2012	NTL:2/NODE	MESENTERIC LYMPHONODES	CT		.	
203-0005 /53/M/W2	SCREENING/30MAR2012	TL:1/LIVER	SEGMENT VI	CT		48	
	SCREENING/30MAR2012	TL:2/LIVER	SEGMENT VII	CT		91	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
203-0005 /53/M/W2	SCREENING/30MAR2012	TL:3/LUNG	LEFT SUPERIOR LOBE	CT		25	
	SCREENING/30MAR2012	TL:4/LUNG	MEDIUM LOBE	CT		25	SLD = 189
	SCREENING/30MAR2012	NTL:1/NODE	HEPATIC LYNPHONODE	CT		.	
	SCREENING/30MAR2012	NTL:2/NODE	GASTRIC LYMPH NODES	CT		.	
	SCREENING/30MAR2012	NTL:3/NODE	CELIAC LYMPHONODES	CT		.	
	WEEK12/09JUL2012	TL:1/LIVER	SEGMENT VI	CT		76	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
203-0005 /53/M/W2	WEEK12/09JUL2012	TL:2/LIVER	SEGMENT VII	CT		91	
	WEEK12/09JUL2012	TL:3/LUNG	LEFT SUPERIOR LOBE	CT		33	
	WEEK12/09JUL2012	TL:4/LUNG	MEDIUM LOBE	CT		38	
	WEEK12/09JUL2012	NTL:1/NODE	HEPATIC LYNPHONODE	CT	Present	.	
	WEEK12/09JUL2012	NTL:2/NODE	GASTRIC LYMPH NODES	CT	Present	.	
	WEEK12/09JUL2012	NTL:3/NODE	CELIAC LYMPHONODES	CT	Present	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
203-0005 /53/M/W2	Summary:					.	SLD = 238, %CN = 25.93, TL: PD, NTL: IncompleteResponse/SD, OR: PD, PD confirmed: Yes, 09JUL2012
203-0013 /68/M/W2	SCREENING/03DEC2013	TL:1/LIVER	IV SEGMENT	CT		37	
	SCREENING/03DEC2013	TL:2/LIVER	VIII SEGMENT	CT		47	
	SCREENING/03DEC2013	TL:3/GU	RIGHT ADRENAL GLAND	CT		73	SLD = 157
	SCREENING/03DEC2013	NTL:1/LIVE	NEOPLASTIC THROMBOSIS	CT		.	
203-0015 /85/M/W2	SCREENING/17JAN2014	TL:1/LIVER	VII SEGMENT	CT		64	SLD = 64

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
203-0015 /85/M/W2	WEEK12/10APR2014	TL:1/LIVER	VII SEGMENT	CT		68	
	Summary:					.	SLD = 68, %CN = 6.25, TL: SD, NTL: NotEvaluable, OR: PD, PD confirmed: Yes, 10APR2014
203-0017 /58/M/W2	SCREENING/25FEB2014	TL:1/LIVER	IV SEGMENT	CT		100	
	SCREENING/25FEB2014	TL:2/LIVER	VII SEGMENT	CT		30	SLD = 130
	SCREENING/25FEB2014	NTL:1/NODE	CELIAC	CT		.	
	SCREENING/25FEB2014	NTL:2/NODE	RIGHT PERICARDIAL	CT		.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
203-0018 /58/F/W2	SCREENING/26MAR2014	TL:1/LIVER	IV SEGMENT	CT		99	
	SCREENING/26MAR2014	TL:2/LIVER	IV SEGMENT	CT		24	SLD = 123
	SCREENING/26MAR2014	NTL:1/	TORAX LYMPHONODES	CT		.	
	SCREENING/26MAR2014	NTL:2/	HEPATIC LYMPHONODES	CT		.	
205-0001 /77/M/W2	SCREENING/14FEB2012	TL:1/LIVER	S4	CT		100	
	SCREENING/14FEB2012	TL:2/LIVER	S7-S8	CT		91	SLD = 191

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
205-0001 /77/M/W2	SCREENING/14FEB2012	NTL:1/LIVE	S2-S3	CT		.	
	SCREENING/14FEB2012	NTL:2/LIVE	S3	CT		.	
	WEEK12/08MAY2012	TL:1/LIVER	S4	CT		100	
	WEEK12/08MAY2012	TL:2/LIVER	S7-S8	CT		91	
	WEEK12/08MAY2012	NTL:1/LIVE	S2-S3	CT	Present	.	
	WEEK12/08MAY2012	NTL:2/LIVE	S3	CT	Present	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
205-0001 /77/M/W2	Summary:					.	SLD = 191, %CN = 0, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK24/09AUG2012	TL:1/LIVER	S4	CT		95	
	WEEK24/09AUG2012	TL:2/LIVER	S7-S8	CT		75	
	WEEK24/09AUG2012	NTL:1/LIVE	S2-S3	CT	Present	.	
	WEEK24/09AUG2012	NTL:2/LIVE	S3	CT	Present	.	
	Summary:					.	SLD = 170, %CN = 14.86, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
205-0001 /77/M/W2	WEEK36/23OCT2012	TL:1/LIVER	S4	CT		86	
	WEEK36/23OCT2012	TL:2/LIVER	S7-S8	CT		70	
	WEEK36/23OCT2012	NTL:1/LIVE	S2-S3	CT	Present	.	
	WEEK36/23OCT2012	NTL:2/LIVE	S3	CT	Present	.	
	Summary:					.	SLD = 156, %CN = 5.41, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK48/28JAN2013	TL:1/LIVER	S4	CT		83	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
205-0001 /77/M/W2	WEEK48/28JAN2013	TL:2/LIVER	S7-S8	CT		65	
	WEEK48/28JAN2013	NTL:1/LIVE	S2-S3	CT	Present	.	
	WEEK48/28JAN2013	NTL:2/LIVE	S3	CT	Present	.	
	Summary:					.	SLD = 148, %CN = 0, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK60/16APR2013	TL:1/LIVER	S4	CT		84	
	WEEK60/16APR2013	TL:2/LIVER	S7-S8	CT		65	

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Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
205-0001 /77/M/W2	WEEK60/16APR2013	NTL:1/LIVE	S2-S3	CT	Present	.	
	WEEK60/16APR2013	NTL:2/LIVE	S3	CT	Present	.	
	Summary:					.	SLD = 149, %CN = 0.68, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK72/09JUL2013	TL:1/LIVER	S4	CT		99	
	WEEK72/09JUL2013	TL:2/LIVER	S7-S8	CT		64	
	WEEK72/09JUL2013	NTL:1/LIVE	S2-S3	CT	Present	.	

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Tumor Assessment Summary Listing
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Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
205-0001 /77/M/W2	WEEK72/09JUL2013	NTL:2/LIVE	S3	CT	Present	.	
	Summary:					.	SLD = 163, %CN = 10.14, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK84/01OCT2013	TL:1/LIVER	S4	CT		116	
	WEEK84/01OCT2013	TL:2/LIVER	S7-S8	CT		80	
	WEEK84/01OCT2013	NTL:1/LIVE	S2-S3	CT	UP	.	
	WEEK84/01OCT2013	NTL:2/LIVE	S3	CT	Present	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
205-0001 /77/M/W2	WEEK84/01OCT2013	NTL:3/LIVE	LOW CAVA VEIN NEOPLASTIC SPREAD	CT	New	.	
	Summary:					.	SLD = 196, %CN = 32.43, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 01OCT2013
205-0004 /77/F/W2	SCREENING/21FEB2012	TL:1/LIVER	S2-S3	CT		37	
	SCREENING/21FEB2012	TL:2/NODES	HEPATIC HILUM	CT		58	SLD = 95
	SCREENING/21FEB2012	NTL:1/LIVE	INTRA AND EXTRA HEPATIC NEOPLASTIC THROMBOSIS	CT		.	
	SCREENING/21FEB2012	NTL:2/LIVE	S2-S3	CT		.	

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Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
205-0004 /77/F/W2	WEEK12/05JUN2012	TL:1/LIVER	S2-S3	CT		64	
	WEEK12/05JUN2012	TL:2/NODES	HEPATIC HILUM	CT		56	
	WEEK12/05JUN2012	NTL:1/LIVE	INTRA AND EXTRA HEPATIC NEOPLASTIC THROMBOSIS	CT	Present	.	
	WEEK12/05JUN2012	NTL:2/LIVE	S2-S3	CT	UP	.	
	WEEK12/05JUN2012	NTL:3/LIVE	S5-S8	CT	New	.	
	WEEK12/05JUN2012	NTL:4/LIVE	THROMBOSIS OF INFERIOR VENA CAVA, AND SUPRAHEPATIC VEIN	CT	New	.	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
205-0004 /77/F/W2	WEEK12/05JUN2012	NTL:5/NODE	BETWEEN INFERIOR VENA CAVA, DUODENUM AND RIGHT KIDNEY	CT	New	.	
	WEEK12/05JUN2012	NTL:6/NODE	GASTROHEPATIC REGION	CT	New	.	
	WEEK12/05JUN2012	NTL:7/LUNG	MULTIPLE LESIONS	CT	New	.	
	Summary:					.	SLD = 120, %CN = 26.32, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 05JUN2012
205-0008 /76/M/W2	SCREENING/03APR2012	TL:1/LIVER	S2-S3-S4	CT		120	
	SCREENING/03APR2012	TL:2/LIVER	S6	CT		20	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
205-0008 /76/M/W2	SCREENING/03APR2012	TL:3/LUNG	RIGHT LUNG	CT		140	SLD = 280
	SCREENING/03APR2012	NTL:1/LIVE	PORTAL VEIN LEFT BRANCH THROMBOSIS	CT		.	
	SCREENING/03APR2012	NTL:2/LIVE	PORTAL VEIN COMMON TRUNK THROMBOSIS	CT		.	
	SCREENING/03APR2012	NTL:3/LUNG	RIGHT LUNG	CT		.	
205-0012 /73/F/W2	SCREENING/27NOV2012	TL:1/LIVER	S8	CT		46	
	SCREENING/27NOV2012	TL:2/LIVER	S3	CT		22	SLD = 68

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
205-0012 /73/F/W2	SCREENING/27NOV2012	NTL:1/LIVE	S6	CT		.	
	SCREENING/27NOV2012	NTL:2/LIVE	S4	CT		.	
205-0015 /71/M/W2	SCREENING/11JUN2013	TL:1/LIVER	VI-VII	CT		23	
	SCREENING/11JUN2013	TL:2/LIVER	I	CT		16	
	SCREENING/11JUN2013	TL:3/LIVER	VIII	CT		20	SLD = 59
205-0016 /70/M/W2	SCREENING/11JUN2013	TL:1/LIVER	V	CT		14	SLD = 14

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
205-0016 /70/M/W2	WEEK12/10SEP2013	TL:1/LIVER	V	CT		14	
	Summary:					.	SLD = 14, %CN = 0, TL: SD, NTL: NotAssessed, OR: SD, PD confirmed: No
	WEEK24/10DEC2013	TL:1/LIVER	V	CT		14	
	Summary:					.	SLD = 14, %CN = 0, TL: SD, NTL: NotAssessed, OR: SD, PD confirmed: No
	WEEK36/11MAR2014	TL:1/LIVER	V	CT		14	
	Summary:					.	SLD = 14, %CN = 0, TL: SD, NTL: NotAssessed, OR: SD, PD confirmed: No

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
205-0016 /70/M/W2	WEEK48/20MAY2014	TL:1/LIVER	V	CT		14	
	Summary:					.	SLD = 14, %CN = 0, TL: SD, NTL: NotAssessed, OR: SD, PD confirmed: No
	WEEK60/06AUG2014	TL:1/	V	CT		14	
	Summary:					.	SLD = 14, %CN = 0, TL: SD, NTL: NotAssessed, OR: SD, PD confirmed: No
	WEEK72/28OCT2014	TL:1/LIVER	V	CT		14	
	Summary:					.	SLD = 14, %CN = 0, TL: SD, NTL: NotAssessed, OR: SD, PD confirmed: No

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
205-0016 /70/M/W2	WEEK84/20JAN2015	TL:1/LIVER	V	CT		14	
	Summary:					.	SLD = 14, %CN = 0, TL: SD, NTL: NotAssessed, OR: SD, PD confirmed: No
	WEEK96/21APR2015	TL:1/LIVER	V	CT		14	
	Summary:					.	SLD = 14, %CN = 0, TL: SD, NTL: NotAssessed, OR: SD, PD confirmed: No
205-0017 /71/M/W2	SCREENING/16JUL2013	TL:1/LIVER	S2-S3	CT		122	
	SCREENING/16JUL2013	TL:2/LIVER	S4	CT		22	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
205-0017 /71/M/W2	SCREENING/16JUL2013	TL:3/NODES	PARACARDIAC REGION	CT		37	SLD = 181
	WEEK12/15OCT2013	TL:1/LIVER	S2-S3	CT		122	
	WEEK12/15OCT2013	TL:2/LIVER	S4	CT		23	
	WEEK12/15OCT2013	TL:3/NODES	PARACARDIAC REGION	CT		37	
	Summary:					.	SLD = 182, %CN = 0.55, TL: SD, NTL: NotAssessed, OR: SD, PD confirmed: No
	WEEK24/14JAN2014	TL:1/LIVER	S2-S3	CT		142	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
205-0017 /71/M/W2	WEEK24/14JAN2014	TL:2/LIVER	S4	CT		35	
	WEEK24/14JAN2014	TL:3/NODES	PARACARDIAC REGION	CT		47	
	Summary:					.	SLD = 224, %CN = 23.76, TL: PD, NTL: NotAssessed, OR: PD, PD confirmed: Yes, 14JAN2014
205-0020 /82/M/W2	SCREENING/03SEP2013	TL:1/LIVER	SEGMENT VII	CT		90	
	SCREENING/03SEP2013	TL:2/LIVER	IV SEGMENT	CT		50	
	SCREENING/03SEP2013	TL:3/LUNG	UPPER RIGHT LOBUS	CT		20	SLD = 160

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
205-0020 /82/M/W2	SCREENING/01OCT2013	NTL:1/BONE	RIGHT FEMUR	Oth		.	
	WEEK12/09DEC2013	NTL:1/BONE	RIGHT FEMUR	Oth	UP	.	
	WEEK12/27DEC2013	TL:1/LIVER	SEGMENT VII	CT	UP	.	
	WEEK12/27DEC2013	TL:2/LIVER	IV SEGMENT	CT	UP	.	
	WEEK12/27DEC2013	TL:3/LUNG	UPPER RIGHT LOBUS	CT		27	
	Summary:					.	SLD = ., %CN = ., TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 27DEC2013

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
205-0022 /67/M/W2	SCREENING/08OCT2013	TL:1/LIVER	VIII SEGMENT	CT		25	
	SCREENING/08OCT2013	TL:2/LIVER	LEFT LOBUS	CT		175	SLD = 200
205-0024 /80/M/W2	SCREENING/29OCT2013	TL:1/LIVER	NODULE HCC IN VII SEGMENT	CT		28	
	SCREENING/29OCT2013	TL:2/LIVER	NODULE HCC IN VII SEGMENT	CT		17	SLD = 45
	WEEK12/25FEB2014	TL:1/LIVER	NODULE HCC IN VII SEGMENT	CT	UP	.	
	WEEK12/25FEB2014	TL:2/LIVER	NODULE HCC IN VII SEGMENT	CT	UP	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
205-0024 /80/M/W2	WEEK12/25FEB2014	NTL:1/LIVE	HEPATIC DUCT	CT	New	.	
	Summary:					.	SLD = ., %CN = ., TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 25FEB2014
205-0025 /63/F/W2	SCREENING/29OCT2013	TL:1/LIVER	S7/8	CT		20	
	SCREENING/29OCT2013	TL:2/LIVER	S6	CT		28	SLD = 48
	SCREENING/29OCT2013	NTL:1/NODE	PERILARE HEPATIC REGION	CT		.	
	SCREENING/29OCT2013	NTL:2/NODE	HEPATOGASTRIC REGION	CT		.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
205-0025 /63/F/W2	WEEK12/11FEB2014	TL:1/LIVER	S7/8	CT		25	
	WEEK12/11FEB2014	TL:2/LIVER	S6	CT		32	
	WEEK12/11FEB2014	NTL:1/NODE	PERILARE HEPATIC REGION	CT	Present	.	
	WEEK12/11FEB2014	NTL:2/NODE	HEPATOGASTRIC REGION	CT	Present	.	
	WEEK12/11FEB2014	NTL:3/LIVE	NEW LESION S8	CT	New	.	
	WEEK12/11FEB2014	NTL:4/LIVE	LOWER CAVAL VEIN INFILTRATION	CT	New	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
205-0025 /63/F/W2	Summary:					.	SLD = 57, %CN = 18.75, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 27FEB2014
207-0001 /81/F/W2	SCREENING/06FEB2012	TL:1/LIVER	HEPATIC DOME LESION	CT		90	SLD = 90
	SCREENING/06FEB2012	NTL:1/LIVE	V-VI	CT		.	
207-0005 /74/M/W2	SCREENING/11JUN2012	TL:1/LIVER	VIII HEPATIC SEGMENT	CT		100	SLD = 100
207-0006 /73/M/W2	SCREENING/13JUN2012	TL:1/LIVER	VII SEGMENT	CT		69	
	SCREENING/13JUN2012	TL:2/NODES	MESENTERIAL NODES	CT		15	SLD = 84

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[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
207-0006 /73/M/W2	SCREENING/13JUN2012	NTL:1/BONE	BACK RIB RIGHT PHRENIC	CT		.	
	SCREENING/13JUN2012	NTL:2/NODE	MEDIASTINUM	CT		.	
	SCREENING/13JUN2012	NTL:3/LIVE	EPATIC LOBES	CT		.	
	SCREENING/13JUN2012	NTL:4/GI	MESENTERIAL	CT		.	
	WEEK12/14SEP2012	TL:1/LIVER	VII SEGMENT	CT		70	
	WEEK12/14SEP2012	TL:2/NODES	MESENTERIAL NODES	CT		15	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
207-0006 /73/M/W2	WEEK12/14SEP2012	NTL:1/BONE	BACK RIB RIGHT PHRENIC	CT	Present	.	
	WEEK12/14SEP2012	NTL:2/NODE	MEDIASTINUM	CT	Present	.	
	WEEK12/14SEP2012	NTL:3/LIVE	EPATIC LOBES		UP	.	
	WEEK12/14SEP2012	NTL:4/GI	MESENTERIAL	CT	Present	.	
	WEEK12/14SEP2012	NTL:5/LIVE	HEPATIC LESIONS	CT	New	.	
	Summary:					.	SLD = 85, %CN = 1.19, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 19SEP2012

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
207-0008 /66/M/W2	SCREENING/11JUN2012	TL:1/LUNG	LEFT SUPERIOR LOBE	CT		55	
	SCREENING/11JUN2012	TL:2/LUNG	ANTERIOR LEFT SUPERIOR LOBE	CT		20	
	SCREENING/11JUN2012	TL:3/LIVER	VIII SEGMENT	CT		70	SLD = 145
207-0011 /78/M/W2	SCREENING/11JAN2013	TL:1/LIVER	III SEGMENT	CT		25	
	SCREENING/11JAN2013	TL:2/PERIC	CARDIOFRENIC RIGHT SITE	CT		25	
	SCREENING/11JAN2013	TL:3/NODES	HEPATIC ILO	CT		20	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
207-0011 /78/M/W2	SCREENING/11JAN2013	TL:4/LUNG	SUPERIOR LUNG LOBE	CT		15	SLD = 85
	SCREENING/11JAN2013	NTL:1/NODE	MEDIASTINUM AND ILAR LUNG	CT		.	
	SCREENING/11JAN2013	NTL:2/NODE	INFERIOR CAVA	CT		.	
	SCREENING/11JAN2013	NTL:3/LIVE	MULTIPLE	CT		.	
	SCREENING/11JAN2013	NTL:4/SOFT	CELIAC AND LOMBOAORTIC SITE	CT		.	
207-0015 /77/M/W2	SCREENING/18JUL2013	TL:1/LIVER	EPATIC DOME	CT		35	SLD = 35

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
207-0015 /77/M/W2	WEEK12/23OCT2013	TL:1/LIVER	EPATIC DOME	CT		48	
	Summary:					.	SLD = 48, %CN = 37.14, TL: PD, NTL: NotAssessed, OR: PD, PD confirmed: Yes, 23OCT2013
207-0020 /77/M/W2	SCREENING/06JUN2014	TL:1/LIVER	CAUDATE LOBE OF THE LIVER	CT		50	
	SCREENING/06JUN2014	TL:2/LIVER	HEPATIC HILUM	CT		30	SLD = 80
	SCREENING/06JUN2014	NTL:1/NODE	CARDIOPHRENIC RIGHT CORNER	CT		.	
	WEEK12/03SEP2014	TL:1/LIVER	CAUDATE LOBE OF THE LIVER	CT		120	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
207-0020 /77/M/W2	WEEK12/03SEP2014	TL:2/LIVER	HEPATIC HILUM	CT		30	
	WEEK12/03SEP2014	NTL:1/NODE	CARDIOPHRENIC RIGHT CORNER	CT	Present	.	
	WEEK12/03SEP2014	NTL:2/ASCI	ENDOABDOMINAL LIQUID	CT	New	.	
	Summary:					.	SLD = 150, %CN = 87.5, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 05SEP2014
207-0021 /74/M/W2	SCREENING/05JUN2014	TL:1/LIVER	IV SEGMENT (ANTERIOR AREA OF LIVER)	CT		50	
	SCREENING/05JUN2014	TL:2/LIVER	IV SEGMENT (NEAR HILAR AREA)	CT		51	SLD = 101

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
207-0021 /74/M/W2	SCREENING/05JUN2014	NTL:1/LIVE	HYPERVASCULAR LESIONS	CT		.	
	WEEK12/03SEP2014	TL:1/LIVER	IV SEGMENT (ANTERIOR AREA OF LIVER)	CT		55	
	WEEK12/03SEP2014	TL:2/LIVER	IV SEGMENT (NEAR HILAR AREA)	CT		54	
	WEEK12/03SEP2014	NTL:1/LIVE	HYPERVASCULAR LESIONS	CT	Present	.	
	Summary:					.	SLD = 109, %CN = 7.92, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK24/25NOV2014	TL:1/LIVER	IV SEGMENT (ANTERIOR AREA OF LIVER)	CT		57	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
207-0021 /74/M/W2	WEEK24/25NOV2014	TL:2/LIVER	IV SEGMENT (NEAR HILAR AREA)	CT		60	
	WEEK24/25NOV2014	NTL:1/LIVE	HYPERVASCULAR LESIONS	CT	Present	.	
	Summary:					.	SLD = 117, %CN = 15.84, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK36/13FEB2015	TL:1/LIVER	IV SEGMENT (ANTERIOR AREA OF LIVER)	CT		65	
	WEEK36/13FEB2015	TL:2/LIVER	IV SEGMENT (NEAR HILAR AREA)	CT		70	
	WEEK36/13FEB2015	NTL:1/LIVE	HYPERVASCULAR LESIONS	CT	Present	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
207-0021 /74/M/W2	WEEK36/13FEB2015	NTL:2/NODE	UPPER LEFT LUNG LOBE	CT	New	.	
	Summary:					.	SLD = 135, %CN = 33.66, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 20FEB2015
207-0022 /74/M/W2	SCREENING/30JUN2014	TL:1/LIVER	IV A SEGMENT	CT		35	SLD = 35
	SCREENING/30JUN2014	NTL:1/LIVE	HEPATIC LESIONS	CT		.	
	WEEK12/23SEP2014	TL:1/LIVER	IV A SEGMENT	CT		39	
	WEEK12/23SEP2014	NTL:1/LIVE	HEPATIC LESIONS	CT	Present	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
207-0022 /74/M/W2	Summary:					.	SLD = 39, %CN = 11.43, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
208-0001 /59/M/W2	SCREENING/07SEP2012	TL:1/LIVER	NODULAR LESION WITH ARTERIAL PHASE ENHANCEMENT AND VENOUS PHASE WASH-OUT, 4°/8° SEGMENT	CT		13	SLD = 13
	WEEK12/05DEC2012	TL:1/LIVER	NODULAR LESION WITH ARTERIAL PHASE ENHANCEMENT AND VENOUS PHASE WASH-OUT, 4°/8° SEGMENT	CT		13	
	Summary:					.	SLD = 13, %CN = 0, TL: SD, NTL: NotAssessed, OR: SD, PD confirmed: No

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
	WEEK24/01MAR2013	TL:1/LIVER	NODULAR LESION WITH ARTERIAL PHASE ENHANCEMENT AND VENOUS PHASE WASH-OUT, 4°/8° SEGMENT	CT		13	
	Summary:					.	SLD = 13, %CN = 18.18, TL: SD, NTL: NotAssessed, OR: PR, PD confirmed: No

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
208-0001 /59/M/W2	WEEK36/22MAY2013	TL:1/LIVER	NODULAR LESION WITH ARTERIAL PHASE ENHANCEMENT AND VENOUS PHASE WASH-OUT, 4°/8° SEGMENT	CT		13	
	Summary:					.	SLD = 13, %CN = 18.18, TL: SD, NTL: NotAssessed, OR: SD, PD confirmed: No
	WEEK48/19AUG2013	TL:1/LIVER	NODULAR LESION WITH ARTERIAL PHASE ENHANCEMENT AND VENOUS PHASE WASH-OUT, 4°/8° SEGMENT	CT		11	
	Summary:					.	SLD = 11, %CN = 0, TL: SD, NTL: NotAssessed, OR: SD, PD confirmed: No

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
	WEEK60/06NOV2013	TL:1/LIVER	NODULAR LESION WITH ARTERIAL PHASE ENHANCEMENT AND VENOUS PHASE WASH-OUT, 4°/8° SEGMENT	CT		11	
	Summary:					.	SLD = 11, %CN = 0, TL: SD, NTL: NotAssessed, OR: SD, PD confirmed: No

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
208-0001 /59/M/W2	WEEK72/29JAN2014	TL:1/LIVER	NODULAR LESION WITH ARTERIAL PHASE ENHANCEMENT AND VENOUS PHASE WASH-OUT, 4°/8° SEGMENT	CT		11	
	Summary:					.	SLD = 11, %CN = 0, TL: SD, NTL: NotAssessed, OR: SD, PD confirmed: No
	WEEK84/23APR2014	TL:1/LIVER	NODULAR LESION WITH ARTERIAL PHASE ENHANCEMENT AND VENOUS PHASE WASH-OUT, 4°/8° SEGMENT	CT		11	
	Summary:					.	SLD = 11, %CN = 0, TL: SD, NTL: NotAssessed, OR: SD, PD confirmed: No

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
	WEEK96/16JUL2014	TL:1/LIVER	NODULAR LESION WITH ARTERIAL PHASE ENHANCEMENT AND VENOUS PHASE WASH-OUT, 4°/8° SEGMENT	CT		11	
	Summary:					.	SLD = 11, %CN = 0, TL: SD, NTL: NotAssessed, OR: SD, PD confirmed: No

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
208-0001 /59/M/W2	WEEK108/08OCT2014	TL:1/LIVER	NODULAR LESION WITH ARTERIAL PHASE ENHANCEMENT AND VENOUS PHASE WASH-OUT, 4°/8° SEGMENT	CT		11	
	Summary:					.	SLD = 11, %CN = 0, TL: SD, NTL: NotAssessed, OR: SD, PD confirmed: No
	WEEK120/02JAN2015	TL:1/LIVER	NODULAR LESION WITH ARTERIAL PHASE ENHANCEMENT AND VENOUS PHASE WASH-OUT, 4°/8° SEGMENT	CT		11	
	Summary:					.	SLD = 11, %CN = 0, TL: SD, NTL: NotAssessed, OR: SD, PD confirmed: No

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
	WEEK132/25MAR2015	TL:1/LIVER	NODULAR LESION WITH ARTERIAL PHASE ENHANCEMENT AND VENOUS PHASE WASH-OUT, 4°/8° SEGMENT	CT		11	
	Summary:					.	SLD = 11, %CN = 0, TL: SD, NTL: NotAssessed, OR: SD, PD confirmed: No

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
208-0001 /59/M/W2	UNSCHEDULED/17JUN2015	TL:1/LIVER	NODULAR LESION WITH ARTERIAL PHASE ENHANCEMENT AND VENOUS PHASE WASH-OUT, 4°/8° SEGMENT	CT		11	
	Summary:					.	SLD = 11, %CN = 0, TL: SD, NTL: NotAssessed, OR: SD, PD confirmed: No
208-0002 /82/F/W2	SCREENING/07SEP2012	TL:1/LIVER	NODULAR LESION IN SEGMENT 6 WITH TYPICAL HCC CONTRASTOGRAPHIC BEHAVIOUR	CT		70	
	SCREENING/07SEP2012	TL:2/LIVER	NODULAR LESION IN SEGMENT 8 WITH TYPICAL HCC CONTRASTOGRAPHIC BEHAVIOUR	CT		12	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
	SCREENING/07SEP2012	TL:3/GU	RIGHT SURRENAL GLAND METASTATIC HCC	CT		70	
	SCREENING/07SEP2012	TL:4/GU	LEFT SURRENAL GLAND METASTATIC HCC	CT		120	SLD = 272

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
208-0002 /82/F/W2	WEEK12/12DEC2012	TL:1/LIVER	NODULAR LESION IN SEGMENT 6 WITH TYPICAL HCC CONTRASTOGRAPHI C BEHAVIOUR	CT		87	
	WEEK12/12DEC2012	TL:2/LIVER	NODULAR LESION IN SEGMENT 8 WITH TYPICAL HCC CONTRASTOGRAPHI C BEHAVIOUR	CT		18	
	WEEK12/12DEC2012	TL:3/GU	RIGHT SURRENAL GLAND METASTATIC HCC	CT		94	
	WEEK12/12DEC2012	TL:4/GU	LEFT SURRENAL GLAND METASTATIC HCC	CT		137	
	Summary:					.	SLD = 336, %CN = 23.53, TL: PD, NTL: NotAssessed, OR: PD, PD confirmed: Yes, 12DEC2012
208-0006 /69/F/W2	SCREENING/24JUL2013	TL:1/LIVER	OVALAR LESION ON ANTERIOR EDGE SEGMENT IV	CT		12	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
208-0006 /69/F/W2	SCREENING/24JUL2013	TL:2/LIVER	OVALAR LESION LOCATED CLOSE TO SURGICAL CLIP IN SEGMENT VIII	CT		13	SLD = 25
	SCREENING/24JUL2013	NTL:1/LIVE	ROUND NODULE LOCATED IN SEGMENT VII/VIII 8 MM OF DIAMETER	CT		.	
	SCREENING/24JUL2013	NTL:2/LIVE	ROUND NODULE LOCATED IN SEGMENT VII/VIII 9 MM OF DIAMETER	CT		.	
	SCREENING/24JUL2013	NTL:3/LIVE	OVALAR LESION LOCATED IN SEGMENT III	CT		.	
	WEEK12/13NOV2013	TL:1/LIVER	OVALAR LESION ON ANTERIOR EDGE SEGMENT IV	CT		43	
	WEEK12/13NOV2013	TL:2/LIVER	OVALAR LESION LOCATED CLOSE TO SURGICAL CLIP IN SEGMENT VIII	CT		19	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
208-0006 /69/F/W2	WEEK12/13NOV2013	NTL:1/LIVE	ROUND NODULE LOCATED IN SEGMENT VII/VIII 8 MM OF DIAMETER	CT	Present	.	
	WEEK12/13NOV2013	NTL:2/LIVE	ROUND NODULE LOCATED IN SEGMENT VII/VIII 9 MM OF DIAMETER	CT	Present	.	
	WEEK12/13NOV2013	NTL:3/LIVE	OVALAR LESION LOCATED IN SEGMENT III	CT	UP	.	
	Summary:					.	SLD = 62, %CN = 148, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 13NOV2013
208-0007 /53/M/W2	SCREENING/27JUN2014	TL:1/LIVER	SEGMENT IV	CT		17	
	SCREENING/27JUN2014	TL:2/LIVER	SEGMENT VII	CT		33	SLD = 50

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
208-0007 /53/M/W2	SCREENING/27JUN2014	NTL:1/LIVE	SEGMENT VIII	CT		.	
	SCREENING/27JUN2014	NTL:2/LIVE	SEGMENT VII POSTERIOR TO TREATED LESION	CT		.	
	WEEK12/25SEP2014	TL:1/LIVER	SEGMENT IV	CT		17	
	WEEK12/25SEP2014	TL:2/LIVER	SEGMENT VII	CT		41	
	WEEK12/25SEP2014	NTL:1/LIVE	SEGMENT VIII	CT	Present	.	
	WEEK12/25SEP2014	NTL:2/LIVE	SEGMENT VII POSTERIOR TO TREATED LESION	CT	UP	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
208-0007 /53/M/W2	WEEK12/25SEP2014	NTL:3/LIVE	NODULES	CT	New	.	
	Summary:					.	SLD = 58, %CN = 16, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 08OCT2014
209-0001 /66/M/W2	SCREENING/08NOV2012	TL:1/LIVER	LESION IN S2	CT		98	
	SCREENING/08NOV2012	TL:2/LIVER	LESIONS IN RIGHT LOBE	CT		122	
	SCREENING/08NOV2012	TL:3/GU	LESION IN ADRENAL GLAND	CT		17	SLD = 237
	WEEK12/31JAN2013	TL:1/LIVER	LESION IN S2	CT		120	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
209-0001 /66/M/W2	WEEK12/31JAN2013	TL:2/LIVER	LESION IN RIGHT LOBE	CT		122	
	WEEK12/31JAN2013	TL:3/GU	LESION IN ADRENAL GLAND	CT		24	
	WEEK12/31JAN2013	NTL:1/LIVE	S6 LESION	CT	New	.	
	Summary:					.	SLD = 266, %CN = 12.24, TL: PD, NTL: NotEvaluable, OR: PD, PD confirmed: Yes, 31JAN2013
209-0004 /74/M/W2	SCREENING/28MAR2013	TL:1/LIVER	NODULE IN SIXTH HEPATIC SEGMENT	CT		70	
	SCREENING/28MAR2013	TL:2/LIVER	NODULE IN SEVENTH HEPATIC SEGMENT	CT		51	SLD = 121

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
209-0004 /74/M/W2	SCREENING/28MAR2013	NTL:1/NODE	LYMPHONODE AT HEPATIC HILUM, 10-15 MM	CT		.	
	SCREENING/28MAR2013	NTL:2/NODE	LYMPHONODE AT CARDIAS	CT		.	
	SCREENING/28MAR2013	NTL:3/LIVE	THROMBOSIS OF RIGHT PORTAL VEIN	CT		.	
	WEEK12/24JUN2013	TL:1/LIVER	NODULE IN SIXTH HEPATIC SEGMENT	CT		80	
	WEEK12/24JUN2013	TL:2/LIVER	NODULE IN SEVENTH HEPATIC SEGMENT	CT		62	
	WEEK12/24JUN2013	NTL:1/NODE	LYMPHONODE AT HEPATIC HILUM	CT	Absent	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
209-0004 /74/M/W2	WEEK12/24JUN2013	NTL:2/NODE	LYMPHONODE AT CARDIAS	CT	Absent	.	
	WEEK12/24JUN2013	NTL:3/LIVE	THROMBOSIS OF RIGHT AND LEFT PORTAL VEIN. NEOPLASTIC INFILTRATION OF HEPATIC TISSUE	CT	UP	.	
	WEEK12/24JUN2013	NTL:4/LIVE	HEPATIC INFILTRATION	CT	New	.	
	Summary:					.	SLD = 142, %CN = 17.36, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 24JUN2013
209-0008 /66/M/W2	SCREENING/11JUL2013	TL:1/LIVER	HCC LESION IN S7 WITH PARTIAL ESOPHITIC GROWTH.	CT		44	
	SCREENING/11JUL2013	TL:2/LIVER	HCC LESION IN S4	CT		55	SLD = 99

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
209-0008 /66/M/W2	WEEK12/26SEP2013	TL:1/LIVER	HCC LESION IN S7 WITH PARTIAL ESOPHITIC GROWTH.	CT		48	
	WEEK12/26SEP2013	TL:2/LIVER	HCC LESION IN S4	CT		67	
	WEEK12/26SEP2013	NTL:1/LIVE	MASSIVE PORTAL VEIN THROMBOSIS	CT	New	.	
	Summary:					.	SLD = 115, %CN = 16.16, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 30SEP2013
209-0012 /63/M/W2	SCREENING/04NOV2013	TL:1/LIVER	HCC IN CRANIAL HEPATIC SEGMENTS S7	CT		16	
	SCREENING/04NOV2013	TL:2/LIVER	HCC IN S1	CT		32	SLD = 48

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
209-0012 /63/M/W2	SCREENING/04NOV2013	NTL:1/LIVE	HCC IN S6	CT		.	
	SCREENING/04NOV2013	NTL:2/LIVE	HCC IN S5	CT		.	
	WEEK12/17FEB2014	TL:1/LIVER	HCC IN CRANIAL HEPATIC SEGMENTS S7	CT		18	
	WEEK12/17FEB2014	TL:2/LIVER	HCC IN S1	CT		20	
	WEEK12/17FEB2014	NTL:1/LIVE	HCC IN S6	CT	Present	.	
	WEEK12/17FEB2014	NTL:2/LIVE	HCC IN S5	CT	NE	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
209-0012 /63/M/W2	Summary:					.	SLD = 38, %CN = -20.83, TL: SD, NTL: NotEvaluable, OR: SD, PD confirmed: No
	WEEK24/15MAY2014	TL:1/LIVER	HCC IN CRANIAL HEPATIC SEGMENTS S7	CT	UP	.	
	WEEK24/15MAY2014	TL:2/LIVER	HCC IN S1	CT		33	
	WEEK24/15MAY2014	NTL:1/LIVE	HCC IN S6	CT	UP	.	
	WEEK24/15MAY2014	NTL:2/LIVE	HCC IN S5	CT	UP	.	
	WEEK24/15MAY2014	NTL:3/LIVE	NEOPLASTIC PORTAL VEIN THROMBOSIS	CT	New	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
209-0012 /63/M/W2	WEEK24/15MAY2014	NTL:4/LIVE	MULTIPLE HCC NODULES	CT	New	.	
	Summary:					.	SLD = ., %CN = ., TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 22MAY2014
209-0013 /52/M/W2	Summary:					.	SLD = 61, %CN = 7.02,
	Summary:					.	SLD = 57, %CN = 0,
	SCREENING/05DEC2013	TL:1/NODES	ABDOMINAL MALIGNANT NODE (LOMBOAORTIC)	MRI		45	
	SCREENING/05DEC2013	NTL:1/NODE	MULTIPLE MALIGNANT ABDOMINAL NODES	MRI		.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
209-0013 /52/M/W2	SCREENING/19DEC2013	TL:2/NODES	PERIBRONCHIAL MALIGNANT NODE	CT		23	SLD = 68
	SCREENING/19DEC2013	NTL:2/NODE	MULTIPLE MALIGNANT TORACIC AND MEDIASTINIC NODES	CT		.	
	WEEK12/10MAR2014	TL:1/NODES	ABDOMINAL MALIGNANT NODE (LOMBOAORTIC)	CT		40	
	WEEK12/10MAR2014	TL:2/NODES	PERIBRONCHIAL MALIGNANT NODE	CT		23	
	WEEK12/10MAR2014	NTL:1/NODE	MULTIPLE MALIGNANT ABDOMINAL NODES	CT	Present	.	
	WEEK12/10MAR2014	NTL:2/NODE	MULTIPLE MALIGNANT TORACIC AND MEDIASTINIC NODES	CT	Present	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
209-0013 /52/M/W2	WEEK12/10MAR2014	NTL:3/LUNG	NEW LESION	CT	New	.	
	Summary:					.	SLD = 63, %CN = -7.35, TL: SD, NTL: PD, OR: PD, PD confirmed: No
	WEEK24/03JUN2014	TL:1/NODES	ABDOMINAL MALIGNANT NODE (LOMBOAORTIC)	CT		35	
	WEEK24/03JUN2014	TL:2/NODES	PERIBRONCHIAL MALIGNANT NODE	CT		26	
	WEEK24/03JUN2014	NTL:1/NODE	MULTIPLE MALIGNANT ABDOMINAL NODES	CT	Present	.	
	WEEK24/03JUN2014	NTL:2/NODE	MULTIPLE MALIGNANT TORACIC AND MEDIASTINIC NODES	CT	Present	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
209-0013 /52/M/W2	WEEK36/25AUG2014	TL:1/NODES	ABDOMINAL MALIGNANT NODE (LOMBOAORTIC)	CT		32	
	WEEK36/25AUG2014	TL:2/NODES	PERIBRONCHIAL MALIGNANT NODE	CT		25	
	WEEK36/25AUG2014	NTL:1/NODE	MULTIPLE MALIGNANT ABDOMINAL NODES	CT	Present	.	
	WEEK36/25AUG2014	NTL:2/NODE	MULTIPLE MALIGNANT TORACIC AND MEDIASTINIC NODES	CT	Present	.	
210-0001 /67/M/W2	SCREENING/19AUG2013	TL:1/LIVER	EXPANSIVE OVALAR LESION	CT		80	
	SCREENING/19AUG2013	TL:2/LIVER	LESION	CT		25	SLD = 105

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
210-0001 /67/M/W2	SCREENING/19AUG2013	NTL:1/LIVE	LESION	CT		.	
	WEEK12/11NOV2013	TL:1/LIVER	EXPANSIVE OVALAR LESION	CT		59	
	WEEK12/11NOV2013	TL:2/LIVER	LESION	CT		28	
	WEEK12/11NOV2013	NTL:1/LIVE	LESION	CT	Absent	.	
	Summary:					.	SLD = 87, %CN = -17.14, TL: SD, NTL: CR, OR: SD, PD confirmed: No
	WEEK24/05FEB2014	TL:1/LIVER	EXPANSIVE OVALAR LESION	CT		70	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
210-0001 /67/M/W2	WEEK24/05FEB2014	TL:2/LIVER	LESION	CT		34	
	WEEK24/05FEB2014	NTL:1/LIVE	LESION	CT	Absent	.	
	Summary:					.	SLD = 104, %CN = 19.54, TL: SD, NTL: CR, OR: SD, PD confirmed: No
	UNSCHEDULED/25FEB2014	NTL:2/NODE	ABDOMINAL LYNPHONODES INTRAAORTIC	CT	New	.	
	Summary:					.	SLD = ., %CN = ., TL: NotAssessed, NTL: PD, OR: PD, PD confirmed: Yes, 06MAR2014
210-0002 /80/M/W2	SCREENING/30SEP2013	TL:1/LIVER	LESION IV SEGMENTUM	CT		30	SLD = 30

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Tumor Assessment Summary Listing
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Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
210-0002 /80/M/W2	SCREENING/30SEP2013	NTL:1/LIVE	LESION BETWEEN SEGMENTS 2 AND 4	CT		.	
	WEEK12/19DEC2013	TL:1/LIVER	LESION IV SEGMENTUM	CT		30	
	WEEK12/19DEC2013	NTL:1/LIVE	LESION BETWEEN SEGMENTS 2 AND 4	CT	Present	.	
	Summary:					.	SLD = 30, %CN = 0, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK24/13MAR2014	TL:1/LIVER	LESION IV SEGMENTUM	CT		30	
	WEEK24/13MAR2014	NTL:1/LIVE	LESION BETWEEN SEGMENTS 2 AND 4	CT	Present	.	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
210-0002 /80/M/W2	Summary:					.	SLD = 30, %CN = 0, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK36/12JUN2014	TL:1/LIVER	LESION IV SEGMENTUM	CT		30	
	WEEK36/12JUN2014	NTL:1/LIVE	LESION BETWEEN SEGMENTS 2 AND 4	CT	Present	.	
	Summary:					.	SLD = 30, %CN = 0, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK48/04SEP2014	TL:1/LIVER	LESION IV SEGMENTUM	CT		35	
	WEEK48/04SEP2014	NTL:1/LIVE	LESION BETWEEN SEGMENTS 2 AND 4	CT	UP	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
210-0002 /80/M/W2	Summary:					.	SLD = 35, %CN = 16.67, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 04SEP2014
210-0007 /72/M/W2	SCREENING/26JUN2014	TL:1/LIVER	SEGMENTUM VIII-V	CT		65	
	SCREENING/26JUN2014	TL:2/LIVER	LESION VII SEGMENT	CT		34	SLD = 99
	SCREENING/26JUN2014	NTL:1/NODE	ADENOPATHY	CT		.	
	SCREENING/26JUN2014	NTL:2/LIVE	VIII SEGMENT: PARENCHYMAL HYPODENSE AREA	CT		.	
	WEEK12/18NOV2014	TL:1/LIVER	SEGMENTUM VIII-V	CT		72	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
210-0007 /72/M/W2	WEEK12/18NOV2014	TL:2/LIVER	LESION VII SEGMENT	CT		45	
	WEEK12/18NOV2014	NTL:1/NODE	ADENOPATHY	CT	Present	.	
	WEEK12/18NOV2014	NTL:2/LIVE	VIII SEGMENT: PARENCHYMAL HYPODENSE AREA	CT	Present	.	
	Summary:					.	SLD = 117, %CN = 18.18, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK24/16FEB2015	TL:1/LIVER	SEGMENTUM VIII-V	CT		62	
	WEEK24/16FEB2015	TL:2/LIVER	LESION VII SEGMENT	CT		48	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
210-0007 /72/M/W2	WEEK24/16FEB2015	NTL:1/NODE	ADENOPATHY	CT	Absent	.	
	WEEK24/16FEB2015	NTL:2/LIVE	VIII SEGMENT: PARENCHYMAL HYPODENSE AREA	CT	Present	.	
	Summary:					.	SLD = 110, %CN = 11.11, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK36/04JUN2015	TL:1/LIVER	SEGMENTUM VIII-V	CT		62	
	WEEK36/04JUN2015	TL:2/LIVER	LESION VII SEGMENT	CT		48	
	WEEK36/04JUN2015	NTL:1/NODE	ADENOPATHY	CT	Present	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
210-0007 /72/M/W2	WEEK36/04JUN2015	NTL:2/LIVE	VIII SEGMENT: PARENCHYMAL HYPODENSE AREA	CT	Present	.	
	Summary:					.	SLD = 110, %CN = 11.11, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
210-0009 /49/F/W2	SCREENING/31OCT2014	TL:1/BONE	SOLID TISSUE AT THE CRANIAL LEVEL	CT		50	
	SCREENING/31OCT2014	TL:2/BONE	SOLID TISSUE AT THE ILIAC LEVEL	CT		50	SLD = 100
	SCREENING/31OCT2014	NTL:1/LIVE	NODULAR LESIONS	CT		.	
	WEEK12/27JAN2015	TL:1/BONE	SOLID TISSUE AT THE CRANIAL LEVEL	CT		76	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
210-0009 /49/F/W2	WEEK12/27JAN2015	TL:2/BONE	SOLID TISSUE AT THE ILIAC LEVEL	CT		60	
	WEEK12/27JAN2015	NTL:1/LIVE	NODULAR LESIONS	CT	Present	.	
	Summary:					.	SLD = 136, %CN = 36, TL: PD, NTL: IncompleteResponse/SD, OR: PD, PD confirmed: Yes, 29JAN2015
210-0011 /73/M/W2	SCREENING/13NOV2014	TL:1/LIVER	LESION BETWEEN IV AND V SEGMENTS	CT		75	SLD = 75
	WEEK12/03FEB2015	TL:1/LIVER	LESION BETWEEN IV AND V SEGMENTS	CT		110	
	Summary:					.	SLD = 110, %CN = 46.67, TL: PD, NTL: NotAssessed, OR: PD, PD confirmed: Yes, 05FEB2015

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
210-0012 /47/F/W2	SCREENING/09DEC2014	TL:1/LIVER	NODULAR LESION VIII SEGMENT	CT		75	SLD = 75
	SCREENING/09DEC2014	NTL:1/LIVE	MULTIPLE NODULAR LESIONS AT THE LEFT LOBE OF LIVER	CT		.	
	WEEK12/17MAR2015	TL:1/LIVER	NODULAR LESION VIII SEGMENT	CT		110	
	WEEK12/17MAR2015	NTL:1/LIVE	MULTIPLE NODULAR LESIONS AT THE LEFT LOBE OF LIVER	CT	UP	.	
	Summary:					.	SLD = 110, %CN = 46.67, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 26MAR2015
210-0014 /71/F/W2	SCREENING/20JAN2015	TL:1/LIVER	LESION VI SEGMENT	CT		35	SLD = 35

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
210-0014 /71/F/W2	WEEK12/28APR2015	TL:1/LIVER	LESION VI SEGMENT	CT		48	
	Summary:					.	SLD = 48, %CN = 37.14, TL: PD, NTL: NotEvaluable, OR: PD, PD confirmed: Yes, 07MAY2015
251-0001 /55/F/W2	SCREENING/23JUL2012	TL:1/LIVER	LIVER SEGMENT VIII	CT		27	
	SCREENING/23JUL2012	TL:2/LIVER	SEGMENT V-VI	CT		66	
	SCREENING/23JUL2012	TL:3/LIVER	LIVER SEGMENT VII	CT		38	
	SCREENING/23JUL2012	TL:4/GI	PERITONEUM	CT		15	SLD = 146

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
251-0001 /55/F/W2	SCREENING/23JUL2012	NTL:1/LUNG	LUNG NODULES	CT		.	
	SCREENING/23JUL2012	NTL:10/LUN	LEFT LOWER LOBE	CT		.	
	SCREENING/23JUL2012	NTL:2/BONE	T11	CT		.	
	SCREENING/23JUL2012	NTL:3/BONE	T12	CT		.	
	SCREENING/23JUL2012	NTL:4/BONE	SACRUM	CT		.	
	SCREENING/23JUL2012	NTL:5/SOFT	ANTERIOR MEDIASTINUM	CT		.	

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Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
251-0001 /55/F/W2	SCREENING/23JUL2012	NTL:6/NODE	RIGHT HILAR NODE	CT		.	
	SCREENING/23JUL2012	NTL:7/NODE	SUBCARINAL NODE	CT		.	
	SCREENING/23JUL2012	NTL:8/NODE	LEFT HILAR NODE	CT		.	
	SCREENING/23JUL2012	NTL:9/LUNG	RIGHT LOWER LOBE	CT		.	
	WEEK12/10OCT2012	TL:1/LIVER	LIVER SEGMENT VIII	CT		27	
	WEEK12/16OCT2012	TL:2/LIVER	SEGMENT V-VI	CT		72	

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Tumor Assessment Summary Listing
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Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
251-0001 /55/F/W2	WEEK12/16OCT2012	TL:3/LIVER	LIVER SEGMENT VII	CT		38	
	WEEK12/16OCT2012	TL:4/GI	PERITONEUM	CT		18	
	WEEK12/16OCT2012	NTL:1/LUNG	LUNG NODULES	CT	Present	.	
	WEEK12/16OCT2012	NTL:10/LUN	LEFT LOWER LOBE	CT	Present	.	
	WEEK12/16OCT2012	NTL:2/BONE	T11	CT	Present	.	
	WEEK12/16OCT2012	NTL:3/BONE	T12	CT	Present	.	

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Tumor Assessment Summary Listing
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Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
251-0001 /55/F/W2	WEEK12/16OCT2012	NTL:4/BONE	SACRUM	CT	Present	.	
	WEEK12/16OCT2012	NTL:5/SOFT	ANTERIOR MEDIASTINUM	CT	Present	.	
	WEEK12/16OCT2012	NTL:6/NODE	RIGHT HILAR NODE	CT	Present	.	
	WEEK12/16OCT2012	NTL:7/NODE	SUBCARINAL NODE	CT	Present	.	
	WEEK12/16OCT2012	NTL:8/NODE	LEFT HILAR NODE	CT	Present	.	
	WEEK12/16OCT2012	NTL:9/LUNG	RIGHT LOWER LOBE	CT	Present	.	

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Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
251-0001 /55/F/W2	Summary:					.	SLD = 155, %CN = 6.16, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
252-0002 /76/M/W2	SCREENING/31JUL2012	TL:1/LIVER	CONGLOMERATE SEGMENT 2/3 LIVER LESION	CT		126	
	SCREENING/31JUL2012	TL:2/LUNG	RIGHT LOWER LOBE NODULE	CT		13	
	SCREENING/31JUL2012	TL:3/LUNG	LEFT LOWER LOBE NODULE	CT		20	SLD = 159
252-0003 /68/M/W2	SCREENING/21DEC2012	TL:1/LIVER	LEFT LOBE LIVER MASS	CT		112	SLD = 112
	WEEK12/19MAR2013	TL:1/LIVER	LEFT LOBE LIVER MASS	CT		123	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
252-0003 /68/M/W2	WEEK12/19MAR2013	NTL:1/NODE	GASTROHEPATIC NODE	CT	New	.	
	WEEK12/19MAR2013	NTL:2/NODE	RIGHT COELIAC NODE	CT	New	.	
	Summary:					.	SLD = 123, %CN = 9.82, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 19MAR2013
252-0007 /77/M/W2	SCREENING/25MAR2014	TL:1/NODES	SUBCARINAL NODE	CT		19	
	SCREENING/25MAR2014	TL:2/LIVER	SEG 4A LIVER	CT		86	
	SCREENING/25MAR2014	TL:3/LUNG	RIGHT MIDDLE LOBE LUNG NODULE	CT		13	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
252-0007 /77/M/W2	SCREENING/25MAR2014	TL:4/LUNG	LINGULAR PULMONARY NODULE	CT		17	SLD = 135
252-0011 /81/M/BL	SCREENING/21NOV2014	TL:1/LIVER	RIGHT LOBE LIVER	CT		108	SLD = 108
	WEEK12/10FEB2015	TL:1/LIVER	RIGHT LOBE LIVER	CT		113	
	Summary:					.	SLD = 113, %CN = 4.63, TL: SD, NTL: NotAssessed, OR: SD, PD confirmed: No
	WEEK24/07MAY2015	TL:1/LIVER	RIGHT LOBE LIVER	CT		116	
	Summary:					.	SLD = 116, %CN = 7.41, TL: SD, NTL: NotAssessed, OR: SD, PD confirmed: No

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
253-0002 /63/M/W2	SCREENING/02MAR2012	TL:1/LIVER	CENTRAL SEGMENT 4 LESION	CT		153	
	SCREENING/02MAR2012	TL:2/LIVER	SUBCAPSULAR SEGMENT 2 LESION	CT		43	SLD = 196
	SCREENING/02MAR2012	NTL:1/NODE	LEFT GASTRIC NODE	CT		.	
	WEEK12/25MAY2012	TL:1/LIVER	CENTRAL SEGMENT 4 LESION	CT		140	
	WEEK12/25MAY2012	TL:2/LIVER	SUBCAPSULAR SEGMENT 2 LESION	CT		44	
	WEEK12/25MAY2012	NTL:1/NODE	LEFT GASTRIC NODE	CT	Present	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
253-0002 /63/M/W2	Summary:					.	SLD = 184, %CN = -6.12, TL: SD, NTL: IncompleteResponse/SD, OR: PD, PD confirmed: Yes, 25MAY2012
253-0010 /76/M/W2	SCREENING/24MAY2013	TL:1/LIVER	SEGMENT 8	CT		63	SLD = 63
	WEEK12/22AUG2013	TL:1/LIVER	SEGMENT 8	CT		67	
	Summary:					.	SLD = 67, %CN = 6.35, TL: SD, NTL: NotAssessed, OR: SD, PD confirmed: No
	WEEK24/13NOV2013	TL:1/LIVER	SEGMENT 8	CT		81	
	WEEK24/13NOV2013	NTL:1/LIVE	SEGMENT 2	CT	New	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
253-0010 /76/M/W2	Summary:					.	SLD = 81, %CN = 28.57, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 13NOV2013
254-0001 /69/M/W2	SCREENING/16APR2012	TL:1/INTRA	VENA CAVA INTRALUMINAL	CT		23	
	SCREENING/16APR2012	TL:2/LIVER	LEFT LOBE DIFFUSE DISEASE	CT		71	
	SCREENING/16APR2012	TL:3/VASCU	PORTAL VEIN	CT		18	
	SCREENING/16APR2012	TL:4/LIVER	RIGHT PORTAL VEIN	CT		13	SLD = 125
	WEEK12/08AUG2012	TL:1/INTRA	INTRALUMINAL	CT		38	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
254-0001 /69/M/W2	WEEK12/08AUG2012	TL:2/LIVER	LEFT LOBE DIFFUSE DISEASE	CT		84	
	WEEK12/08AUG2012	TL:3/VASCU	PORTAL VEIN	CT		27	
	Summary:					.	SLD = 171, %CN = 36.8, TL: PD, NTL: NotAssessed, OR: PD, PD confirmed: Yes, 08AUG2012
	WEEK12/18AUG2012	TL:4/LIVER	RIGHT PORTAL VEIN	CT		22	
	WEEK12/14FEB2013	NTL:1/LIVE	NEW LESIONS RIGHT LOBE	CT	New	.	
	WEEK12/14FEB2013	NTL:2/LIVE	INCREASED ASCITES AROUND LIVER	CT	Present	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
257-0001 /47/M/A4	SCREENING/19MAR2012	TL:1/BONE	9TH RIGHT RIB WITH SMOOTH TISSUE INVOLVEMENT	CT		100	SLD = 100
257-0002 /56/M/W2	SCREENING/30MAR2012	TL:1/GI	PERITONEAL - OMENTUM	CT		16	
	SCREENING/30MAR2012	TL:2/GI	PERITONEAL - PELVIC NODULE	CT		70	SLD = 86
257-0007 /80/M/W2	SCREENING/14FEB2013	TL:1/LIVER	SEGMENT 6	CT		80	
	SCREENING/14FEB2013	TL:2/LIVER	SEGMENT 8	CT		27	SLD = 107
	SCREENING/14FEB2013	NTL:1/LIVE	MULTILOBAR	CT		.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
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Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
257-0007 /80/M/W2	WEEK12/09MAY2013	TL:1/LIVER	SEGMENT 6	CT		80	
	WEEK12/09MAY2013	TL:2/LIVER	SEGMENT 8	CT		52	
	WEEK12/09MAY2013	NTL:1/LIVE	MULTILOBAR	CT	UP	.	
	Summary:					.	SLD = 132, %CN = 23.36, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 09MAY2013
257-0008 /80/F/W2	SCREENING/28FEB2013	TL:1/LIVER	SEGMENT 8	CT		30	
	SCREENING/28FEB2013	TL:2/LIVER	SEGMENT 2	CT		26	SLD = 56

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
257-0008 /80/F/W2	WEEK12/13JUN2013	TL:1/LIVER	SEGMENT 8	CT		38	
	WEEK12/13JUN2013	TL:2/LIVER	SEGMENT 2	CT		26	
	WEEK12/13JUN2013	NTL:1/LIVE	SEGMENT 2 (NEW LESION)	CT	New	.	
	Summary:					.	SLD = 64, %CN = 14.29, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 13JUN2013
257-0010 /42/M/BL	SCREENING/30APR2013	TL:1/LIVER	SEGMENT 6	CT		55	
	SCREENING/30APR2013	TL:2/LIVER	SEGMENT 3	CT		28	SLD = 83

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
257-0010 /42/M/BL	SCREENING/30APR2013	NTL:1/LIVE	LEFT LOBE	CT		.	
	WEEK12/05AUG2013	TL:1/LIVER	SEGMENT 6	CT		55	
	WEEK12/05AUG2013	TL:2/LIVER	SEGMENT 3	CT		28	
	WEEK12/05AUG2013	NTL:1/LIVE	LEFT LOBE	CT	NE	.	
	WEEK12/05AUG2013	NTL:2/LIVE	MULTIPLE NEW LESIONS	CT	New	.	
	Summary:					.	SLD = 83, %CN = 0, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 05AUG2013

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
257-0012 /75/M/W2	SCREENING/15APR2013	TL:1/LIVER	IN SEGMENT VII ARTERIALISING LESION	CT		27	
	SCREENING/15APR2013	TL:2/LIVER	IN SEGMENT VII ARTERIALISING LESION	CT		27	
	SCREENING/15APR2013	TL:3/LIVER	IN SEGMENT VII ARTERIALISING LESION	CT		27	SLD = 81
	SCREENING/15APR2013	NTL:1/NODE	PERITONEUM	CT		.	
	SCREENING/15APR2013	NTL:2/LIVE	LEFT LATERAL SEGMENT	CT		.	
257-0015 /69/F/BL	SCREENING/07APR2014	TL:1/LIVER	LEFT LOBE	CT		20	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
257-0015 /69/F/BL	SCREENING/07APR2014	TL:2/NODES	INTRA-ABDOMINAL AND RETROPERITONEAL LYMPH NODES	CT		21	SLD = 41
	SCREENING/07APR2014	NTL:1/NODE	PARACARDIAC MEDIASTINAL LYMPH NODE	CT		.	
257-0017 /74/M/A8	SCREENING/22APR2014	TL:1/LIVER	SEGMENT 4	CT		20	SLD = 20
	WEEK12/21JUL2014	TL:1/LIVER	SEGMENT 4	CT		32	
	WEEK12/21JUL2014	NTL:1/LIVE	SEGMENT 3 (NEW LESION)	CT	New	.	
	Summary:					.	SLD = 32, %CN = 60, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 21JUL2014

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
257-0018 /53/M/A6	SCREENING/11APR2014	TL:1/LIVER	INFERIOR SURFACE OF LEFT LIVER	CT		73	
	SCREENING/11APR2014	TL:2/LIVER	SEGMENT 8	CT		48	
	SCREENING/11APR2014	TL:3/LUNG	LEFT LOWER LOBE	CT		10	SLD = 131
	SCREENING/11APR2014	NTL:1/LUNG	PULMONARY DISEASE	CT		.	
257-0022 /60/M/W2	SCREENING/24NOV2014	TL:1/LIVER	SEGMENT 3	CT		52	SLD = 52
	SCREENING/24NOV2014	NTL:1/LIVE	DOMINANT TUMOUR	CT		.	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
257-0022 /60/M/W2	SCREENING/24NOV2014	NTL:2/LIVE	MULTIPLE LESIONS 2/3	CT		.	
	UNSCHEDULED/02FEB2015	TL:1/LIVER	SEGMENT 3			73	
	UNSCHEDULED/02FEB2015	NTL:1/LIVE	DOMINANT LESION	CT	Present	.	
	UNSCHEDULED/02FEB2015	NTL:2/LIVE	SEGMENT 2/3	CT	UP	.	
	UNSCHEDULED/02FEB2015	NTL:3/LIVE	SEGMENT 2/3	CT	New	.	
	Summary:					.	SLD = 73, %CN = 40.38, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 02FEB2015

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
257-0024 /75/M/W2	SCREENING/15DEC2014	TL:1/SOFTT	LEFT ADRENAL	CT		45	
	SCREENING/15DEC2014	TL:2/SOFTT	LEFT LOWER ADRENAL	CT		29	
	SCREENING/15DEC2014	NTL:1/LIVE	DOMINANT TUMOUR - TREATED	CT		.	
	SCREENING/23DEC2014	TL:3/LUNG	LEFT BASE	CT		27	
	SCREENING/23DEC2014	TL:4/LUNG	MEDIAL SEGMENT OF RIGHT MIDDLE LOBE	CT		33	
	SCREENING/23DEC2014	TL:5/NODES	ANTERIOR PERICARDIUM	CT		28	SLD = 162

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
257-0025 /69/M/BL	SCREENING/15DEC2014	TL:1/LIVER	SEGMENT 7	CT		35	
	SCREENING/15DEC2014	TL:2/NODES	ANTERIOR TO RIGHT KIDNEY	CT		29	SLD = 64
	SCREENING/15DEC2014	NTL:1/LIVE	OTHERS	CT		.	
	SCREENING/15DEC2014	NTL:2/LUNG	MULTIPLE LESIONS	CT		.	
	WEEK12/09MAR2015	TL:1/LIVER	SEGMENT 7	CT		74	
	WEEK12/09MAR2015	TL:2/NODES	ANTERIOR TO RIGHT KIDNEY			26	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
257-0025 /69/M/BL	WEEK12/09MAR2015	NTL:1/LIVE	OTHERS	CT	UP	.	
	WEEK12/09MAR2015	NTL:2/LUNG	MULTIPLE LESIONS	CT	UP	.	
	WEEK12/09MAR2015	NTL:3/LUNG	BILATERAL MULTIPLE METASTASIS	CT	New	.	
	Summary:					.	SLD = 100, %CN = 56.25, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 09MAR2015
257-0026 /65/M/W2	SCREENING/05JAN2015	TL:1/LIVER	SEGMENT 8	CT		11	
	SCREENING/05JAN2015	TL:2/LUNG	RIGHT LOWER LOBE	CT		13	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
257-0026 /65/M/W2	SCREENING/05JAN2015	TL:3/LUNG	LEFT (IN LINGULA)	CT		10	
	SCREENING/05JAN2015	TL:4/LUNG	RIGHT UPPER LOBE	CT		10	SLD = 44
	SCREENING/05JAN2015	NTL:1/LIVE	SEGMENT 7	CT		.	
	SCREENING/05JAN2015	NTL:2/LIVE	SEGMENT 8 (ABLATED LESION)	CT		.	
	SCREENING/05JAN2015	NTL:3/NODE	RIGHT RETROCRURAL LYMPH NODE	CT		.	
257-0027 /52/M/A6	SCREENING/29DEC2014	TL:1/LIVER	SEGMENT 7/8	CT		36	

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[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
257-0027 /52/M/A6	SCREENING/29DEC2014	TL:2/LIVER	SEGMENT 8	CT		20	
	SCREENING/29DEC2014	TL:3/NODES	PRETRACEHAL LYMPH NODE	CT		38	
	SCREENING/29DEC2014	TL:4/LUNG	RIGHT UPPER LOBE	CT		35	SLD = 129
	SCREENING/29DEC2014	NTL:1/LIVE	SEGMENT 8	CT		.	
	UNSCHEDULED/18FEB2015	NTL:/BRAIN	LEFT FRONTAL LOBE	CT	Present	.	
258-0005 /64/M/OTH	SCREENING/07AUG2013	TL:1/LIVER	LEFT LOBE	CT		102	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
258-0005 /64/M/OTH	SCREENING/07AUG2013	TL:2/NODES	PORTOCAVAL SPACE	CT		69	
	SCREENING/07AUG2013	TL:3/NODES	PORTAL VEIN	CT		55	
	SCREENING/07AUG2013	TL:4/SOFTT	LOWER THORACIC VERTEBRA	CT		52	
	SCREENING/07AUG2013	TL:5/SOFTT	RIGHT ILEAL	CT		51	SLD = 329
	UNSCHEDULED/09OCT2013	TL:1/LIVER	LEFT LOBE	CT		102	
	UNSCHEDULED/09OCT2013	TL:2/NODES	PORTOCAVAL SPACE	CT		69	

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[3] UP=Unequivocally Progressed
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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
258-0005 /64/M/OTH	UNSCHEDULED/09OCT2013	TL:3/NODES	RELATED TO PORTAL VEIN	CT		58	
	UNSCHEDULED/09OCT2013	TL:4/SOFTT	LOWER THORACIC VERTEBRA	CT		52	
	UNSCHEDULED/09OCT2013	TL:5/SOFTT	RIGHT ILEAL LESION	CT		86	
	Summary:					.	SLD = 367, %CN = 11.55, TL: SD, NTL: NotAssessed, OR: SD, PD confirmed: No
258-0007 /74/M/W2	SCREENING/02OCT2013	TL:1/LIVER	LEFT LOBE	CT		81	
	SCREENING/02OCT2013	TL:2/LUNG	LEFT LOBE	CT		26	SLD = 107

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
258-0008 /70/M/W2	SCREENING/06NOV2013	TL:1/LIVER	SEGMENT 5/6	CT		77	
	SCREENING/06NOV2013	TL:2/LIVER	SEGMENT 4	CT		24	SLD = 101
258-0009 /64/M/W2	SCREENING/28APR2014	TL:1/LIVER	BACK OF RIGHT LOBE	CT		75	
	SCREENING/28APR2014	TL:2/LIVER	RIGHT OF PORTAL VEIN ABOVE GALLBLADDER	CT		32	SLD = 107
	WEEK12/06AUG2014	TL:1/LIVER	BACK OF RIGHT LOBE	CT		75	
	WEEK12/06AUG2014	TL:2/LIVER	RIGHT OF PORTAL VEIN ABOVE GALLBLADDER	CT		37	

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[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
258-0009 /64/M/W2	Summary:					.	SLD = 112, %CN = 4.67, TL: SD, NTL: NotAssessed, OR: SD, PD confirmed: No
	WEEK24/29OCT2014	TL:1/LIVER	BACK OF RIGHT LOBE	CT		78	
	WEEK24/29OCT2014	TL:2/LIVER	RIGHT OF PORTAL VEIN ABOVE GALLBLADDER	CT		39	
	WEEK24/29OCT2014	NTL:1/SOFT	RIGHT ADRENAL GLAND	CT	New	.	
	Summary:					.	SLD = 117, %CN = 9.35, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 29OCT2014
258-0010 /53/M/W2	SCREENING/30MAY2014	TL:1/LIVER	LESION IN PERIPHERY SEGMENT THREE	CT		24	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
258-0010 /53/M/W2	SCREENING/30MAY2014	TL:2/LUNG	LESION IN PERIPHERY OF LEFT LUNG MIDZONE	CT		15	
	SCREENING/30MAY2014	TL:3/NODES	PORTA HEPATIS	CT		19	SLD = 58
	WEEK12/20AUG2014	TL:1/LIVER	LESION IN PERIPHERY SEGMENT THREE	CT		30	
	WEEK12/20AUG2014	TL:2/LUNG	LESION IN PERIPHERY OF LEFT LUNG MIDZONE	CT		15	
	WEEK12/20AUG2014	TL:3/NODES	PORTA HEPATIS	CT		19	
	Summary:					.	SLD = 64, %CN = 10.34, TL: SD, NTL: NotEvaluable, OR: SD, PD confirmed: No

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
258-0010 /53/M/W2	WEEK24/12NOV2014	TL:1/LIVER	LESION IN PERIPHERY SEGMENT THREE	CT		32	
	WEEK24/12NOV2014	TL:2/LUNG	LESION IN PERIPHERY OF LEFT LUNG MIDZONE	CT		17	
	WEEK24/12NOV2014	TL:3/NODES	PORTA HEPATIS	CT		18	
	WEEK24/12NOV2014	NTL:1/LUNG	INCREASE IN SIZE AND NUMBER OF LUNG METS FROM BASELINE	CT	New	.	
	Summary:					.	SLD = 67, %CN = 15.52, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 12NOV2014
258-0012 /66/F/W2	SCREENING/09JUL2014	TL:1/LIVER	LEFT LATERAL SEGMENT	CT		26	

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[3] UP=Unequivocally Progressed
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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
258-0012 /66/F/W2	SCREENING/09JUL2014	TL:2/LIVER	TOP OF RIGHT LOBE OF LIVER	CT		17	SLD = 43
	WEEK12/01OCT2014	TL:1/LIVER	LEFT LATERAL SEGMENT	CT		36	
	WEEK12/01OCT2014	TL:2/LIVER	TOP OF RIGHT LOBE	CT		21	
	Summary:					.	SLD = 57, %CN = 32.56, TL: PD, NTL: NotAssessed, OR: PD, PD confirmed: Yes, 09OCT2014
258-0015 /65/M/W2	SCREENING/02DEC2014	TL:1/LIVER	RIGHT LOBE	CT		83	SLD = 83
259-0001 /68/F/W2	SCREENING/24MAY2013	TL:1/LIVER	RIGHT LIVER TUMOUR	CT		213	SLD = 213

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
259-0001 /68/F/W2	WEEK12/14AUG2013	TL:1/LIVER	RIGHT LIVER TUMOUR	CT		222	
	Summary:					.	SLD = 222, %CN = 4.23, TL: SD, NTL: NotAssessed, OR: SD, PD confirmed: No
	WEEK24/06NOV2013	TL:1/LIVER	RIGHT LIVER TUMOUR	CT		223	
	Summary:					.	SLD = 223, %CN = 4.69, TL: SD, NTL: NotAssessed, OR: SD, PD confirmed: No
	WEEK36/05FEB2014	TL:1/LIVER	RIGHT LIVER TUMOUR	CT		221	
	Summary:					.	SLD = 221, %CN = 3.76, TL: SD, NTL: NotAssessed, OR: SD, PD confirmed: No

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
259-0001 /68/F/W2	WEEK48/30APR2014	TL:1/LIVER	RIGHT LIVER TUMOUR	CT		222	
	Summary:					.	SLD = 222, %CN = 4.23, TL: SD, NTL: NotAssessed, OR: SD, PD confirmed: No
259-0002 /54/F/W2	SCREENING/30AUG2013	TL:1/LIVER	LIVER, SEGMENT 7	CT		37	
	SCREENING/30AUG2013	TL:2/NODES	PRECAVAL NODE	CT		44	SLD = 81
	WEEK12/27NOV2013	TL:1/LIVER	LIVER, SEGMENT 7	CT		49	
	WEEK12/27NOV2013	TL:2/NODES	PRECAVAL NODE	CT		23	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
259-0002 /54/F/W2	WEEK12/27NOV2013	NTL:1/NODE	OESOPHAGEAL HIATUS	CT	New	.	
	WEEK12/27NOV2013	NTL:2/NODE	PORTA HEPATIS	CT	New	.	
	WEEK12/27NOV2013	NTL:3/NODE	LYING BETWEEN PORTAL VEIN AND IVC	CT	New	.	
	Summary:					.	SLD = 72, %CN = -11.11, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 27NOV2013
260-0003 /81/M/A7	SCREENING/27OCT2014	TL:1/LIVER	SEGMENT 2	CT		45	SLD = 45
	SCREENING/27OCT2014	NTL:1/LIVE	SEGMENT S5	CT		.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
260-0003 /81/M/A7	WEEK12/19JAN2015	TL:1/LIVER	SEGMENT 2	CT		52	
	WEEK12/19JAN2015	NTL:1/LIVE	SEGMENT S5	CT	Present	.	
	Summary:					.	SLD = 52, %CN = 15.56, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK24/09APR2015	TL:1/LIVER	SEGMENT 2	CT		49	
	WEEK24/09APR2015	NTL:1/LIVE	SEGMENT S5	CT	Present	.	
	Summary:					.	SLD = 49, %CN = 8.89, TL: SD, NTL: NotAssessed, OR: SD, PD confirmed: No

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
260-0003 /81/M/A7	WEEK36/03JUL2015	TL:1/LIVER	SEGMENT 2	CT		53	
	WEEK36/03JUL2015	NTL:1/LIVE	SEGMENT S5	CT	Present	.	
	Summary:					.	SLD = 53, %CN = 17.78, TL: SD, NTL: NotAssessed, OR: SD, PD confirmed: No
301-0005 /61/M/A2	SCREENING/08MAY2012	TL:1/LIVER	S2	CT		70	SLD = 70
	SCREENING/08MAY2012	NTL:1/LIVE	MULTIPLE IN BOTH HEPATIC LOBE	CT		.	
	WEEK12/09AUG2012	TL:1/LIVER	S2	CT		120	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
301-0005 /61/M/A2	WEEK12/09AUG2012	NTL:1/LIVE	MULTIPLE IN BOTH HEPATIC LOBE	CT	UP	.	
	Summary:					.	SLD = 120, %CN = 71.43, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 12AUG2012
301-0007 /55/F/A2	SCREENING/02JAN2013	TL:1/LIVER	SEGMENT4A	CT		71	
	SCREENING/02JAN2013	TL:2/LIVER	SEGMENT2	CT		32	
	SCREENING/02JAN2013	TL:3/SOFTT	OMENTUM	CT		19	
	SCREENING/02JAN2013	TL:4/SOFTT	OMENTUM	CT		16	SLD = 138

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Tumor Assessment Summary Listing
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Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
301-0007 /55/F/A2	SCREENING/02JAN2013	NTL:1/LUNG	BILATERAL LUNG MULTIPLE NODULE	CT		.	
301-0009 /55/M/A2	SCREENING/10JAN2013	TL:1/LIVER	S2-4	CT		95	SLD = 95
	SCREENING/10JAN2013	NTL:1/LUNG	L'T LUNG NODULE	CT		.	
	SCREENING/10JAN2013	NTL:2/BONE	R'T ISCHIUM	CT		.	
	SCREENING/10JAN2013	NTL:3/LIVE	BILATERAL LIVER MULTIPLE	CT		.	
	WEEK12/28MAR2013	TL:1/LIVER	S2-4	CT		76	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
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Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
301-0009 /55/M/A2	WEEK12/28MAR2013	NTL:1/LUNG	L'T LUNG NODULE	CT	UP	.	
	WEEK12/28MAR2013	NTL:2/BONE	R'T ISCHIUM		UP	.	
	WEEK12/28MAR2013	NTL:3/LIVE	BILATERAL LIVER MULTIPLE	CT	UP	.	
	WEEK12/28MAR2013	NTL:4/LIVE		CT	New	.	
	Summary:					.	SLD = 76, %CN = -20, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 28MAR2013
302-0002 /32/F/A2	SCREENING/03NOV2011	TL:1/LIVER	SEGMENT 4	CT		47	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
302-0002 /32/F/A2	SCREENING/03NOV2011	TL:2/LIVER	SEGMENT 3	CT		52	SLD = 99
	SCREENING/03NOV2011	NTL:1/LIVE	LIVER	CT		.	
	SCREENING/03NOV2011	NTL:2/LUNG	LUNG	CT		.	
302-0004 /57/M/A2	SCREENING/05JAN2012	TL:1/LIVER	SEGMENT4	CT		34	
	SCREENING/05JAN2012	TL:2/LIVER	SEGMENT5	CT		25	SLD = 59
	SCREENING/05JAN2012	NTL:1/LIVE	BOTH LOBES	CT		.	

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Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
302-0004 /57/M/A2	SCREENING/05JAN2012	NTL:2/GI	GASTRODUODENAL ARTERY	CT		.	
302-0007 /76/M/A2	SCREENING/08FEB2012	TL:1/LIVER	S5-6	CT		24	
	SCREENING/08FEB2012	TL:2/LIVER	S5	CT		18	SLD = 42
	SCREENING/08FEB2012	NTL:1/BONE	RIGHT 10TH RIB	CT		.	
	SCREENING/08FEB2012	NTL:2/BONE	L2 SPINAL	CT		.	
	SCREENING/08FEB2012	NTL:3/BONE	ILIAC	CT		.	

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Tumor Assessment Summary Listing
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Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
302-0007 /76/M/A2	WEEK12/03MAY2012	TL:1/LIVER	S5-6	CT		42	
	WEEK12/03MAY2012	TL:2/LIVER	S5	CT		19	
	WEEK12/03MAY2012	NTL:1/BONE	RIGHT 10TH RIB	CT	Present	.	
	WEEK12/03MAY2012	NTL:2/BONE	L2 SPINAL	CT	Present	.	
	WEEK12/03MAY2012	NTL:3/BONE	ILIAC	CT	Present	.	
	WEEK12/03MAY2012	NTL:4/BONE	T7	CT	New	.	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
302-0007 /76/M/A2	WEEK12/03MAY2012	NTL:5/BONE	T12	CT	New	.	
	Summary:					.	SLD = 61, %CN = 45.24, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 03MAY2012
302-0008 /37/M/A2	SCREENING/23FEB2012	TL:1/SOFTT	RIGHT PARACOLIC GUTTER	CT		85	SLD = 85
	SCREENING/23FEB2012	NTL:1/LIVE	ASCITES	CT		.	
	SCREENING/23FEB2012	NTL:2/LUNG	LEFT PLEURAL EFFUSION	CT		.	
	UNSCHEDULED/14MAY2012	TL:1/SOFTT	RIGHT PARACOLIC GUTTER	CT		135	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
302-0008 /37/M/A2	UNSCHEDULED/14MAY2012	NTL:1/LIVE	ASCITES	CT	Present	.	
	UNSCHEDULED/14MAY2012	NTL:2/LUNG	LEFT PLEURAL EFFUSION	CT	UP	.	
	Summary:					.	SLD = 135, %CN = 58.82, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 14MAY2012
302-0010 /45/M/A2	SCREENING/12APR2012	TL:1/LIVER	SEGEMENT 3-4	CT		45	
	SCREENING/12APR2012	TL:2/LIVER	SEGEMENT 4-5	CT		53	SLD = 98
	SCREENING/12APR2012	NTL:1/LUNG	RIGHT MIDDLE LUNG	CT		.	

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[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
302-0010 /45/M/A2	SCREENING/12APR2012	NTL:2/LUNG	LINGULAR SEGMENT OF LEFT UPPER LOBE	CT		.	
	WEEK12/05JUL2012	TL:1/LIVER	SEGEMENT 3-4	CT		53	
	WEEK12/05JUL2012	TL:2/LIVER	SEGEMENT 4-5	CT		83	
	WEEK12/05JUL2012	NTL:1/LUNG	RIGHT MIDDLE LUNG	CT	UP	.	
	WEEK12/05JUL2012	NTL:2/LUNG	LINGULAR SEGMENT OF LEFT UPPER LOBE	CT	UP	.	
	Summary:					.	SLD = 136, %CN = 38.78, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 05JUL2012

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
302-0011 /52/M/A2	SCREENING/02APR2012	TL:1/LIVER	SEGMENT 2	CT		27	
	SCREENING/02APR2012	TL:2/LIVER	SEGMENT 2	CT		27	
	SCREENING/02APR2012	TL:3/LUNG	RIGHT MIDDLE LUNG	CT		17	SLD = 71
	SCREENING/02APR2012	NTL:1/LIVE	ASCITES	CT		.	
302-0015 /60/M/A2	SCREENING/11APR2013	TL:1/NODES	LEFT LOWER NECK	CT		49	
	SCREENING/11APR2013	TL:2/NODES	PARATRACHEA	CT		34	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
302-0015 /60/M/A2	SCREENING/11APR2013	TL:3/NODES	RIGHT PARATRACHEA	CT		47	
	SCREENING/11APR2013	TL:4/LUNG	RIGHT LOWER LOBE	CT		55	
	SCREENING/11APR2013	TL:5/LUNG	LEFT LOWER LOBE	CT		42	SLD = 227
	WEEK12/08JUL2013	TL:1/NODES	LEFT LOWER NECK	CT		94	
	WEEK12/08JUL2013	TL:2/NODES	PARATRACHEA	CT		61	
	WEEK12/08JUL2013	TL:3/NODES	RIGHT PARATRACHEA	CT		69	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
302-0015 /60/M/A2	WEEK12/08JUL2013	TL:4/LUNG	RIGHT LOWER LOBE	CT		92	
	WEEK12/08JUL2013	TL:5/LUNG	LEFT LOWER LOBE	CT		48	
	Summary:					.	SLD = 364, %CN = 60.35, TL: PD, NTL: NotEvaluable, OR: PD, PD confirmed: Yes, 08JUL2013
302-0016 /60/M/A2	SCREENING/11APR2013	TL:1/LUNG	LEFT UPPER LOBE	CT		28	
	SCREENING/11APR2013	TL:2/LUNG	RIGHT MIDDLE LOBE	CT		33	
	SCREENING/11APR2013	TL:3/LIVER	RIGHT LOBE LIVER	CT		75	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
302-0016 /60/M/A2	SCREENING/11APR2013	TL:4/SOFTT	RIGHT ADRENAL	CT		55	SLD = 191
	SCREENING/11APR2013	NTL:1/LUNG	BILATERAL LUNG	CT		.	
	SCREENING/11APR2013	NTL:2/SOFT	INFERIOR VENA CAVA THROMBOSIS	CT		.	
	SCREENING/11APR2013	NTL:3/GI	ASCITES	CT		.	
	SCREENING/11APR2013	NTL:4/LIVE	RIGHT MIDDLE HEPATIC VEIN THROMBOSIS	CT		.	
	WEEK12/02JUL2013	TL:1/LUNG	LEFT UPPER LOBE	CT		26	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
302-0016 /60/M/A2	WEEK12/02JUL2013	TL:2/LUNG	RIGHT MIDDLE LOBE	CT		28	
	WEEK12/02JUL2013	TL:3/LIVER	RIGHT LOBE LIVER	CT		86	
	WEEK12/02JUL2013	TL:4/SOFTT	RIGHT ADRENAL	CT		83	
	WEEK12/02JUL2013	NTL:1/LUNG	BILATERAL LUNG	CT	UP	.	
	WEEK12/02JUL2013	NTL:2/SOFT	INFERIOR VENA CAVA THROMBOSIS	CT	UP	.	
	WEEK12/02JUL2013	NTL:3/GI	ASCITES	CT	Present	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
302-0016 /60/M/A2	WEEK12/02JUL2013	NTL:4/LIVE	RIGHT MIDDLE HEPATIC VEIN THROMBOSIS	CT	UP	.	
	WEEK12/02JUL2013	NTL:5/LUNG	BILATERAL LUNG	CT	New	.	
	Summary:					.	SLD = 223, %CN = 16.75, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 09JUL2013
302-0019 /52/M/A2	SCREENING/06MAY2013	TL:1/LUNG	LEFT LOWER LOBE	CT		37	
	SCREENING/06MAY2013	TL:2/LUNG	LEFT LOWER LOBE	CT		31	
	SCREENING/09MAY2013	TL:3/LIVER	SEGMENT 2-3	CT		32	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
302-0019 /52/M/A2	SCREENING/09MAY2013	TL:4/LIVER	SEGMENT 6	CT		31	SLD = 131
	WEEK12/30JUL2013	TL:1/LUNG	LEFT LOWER LOBE	CT		64	
	WEEK12/30JUL2013	TL:2/LUNG	LEFT LOWER LOBE	CT		38	
	WEEK12/30JUL2013	TL:3/LIVER	SEGMENT 2-3	CT		33	
	WEEK12/30JUL2013	TL:4/LIVER	SEGMENT 6	CT		37	
	WEEK12/30JUL2013	NTL:1/LUNG	BILATERAL LUNG	CT	New	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
302-0019 /52/M/A2	Summary:					.	SLD = 172, %CN = 31.3, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 05AUG2013
302-0022 /65/M/A2	SCREENING/18JUN2013	TL:1/LUNG	RIGHT LOWER LOBE	CT		34	
	SCREENING/18JUN2013	TL:2/LUNG	RIGHT LOWER LOBE	CT		29	SLD = 63
	UNSCHEDULED/18SEP2013	NTL:1/BRAI	FRONTAL AREA	MRI	New	.	
	Summary:					.	SLD = ., %CN = ., TL: NotAssessed, NTL: PD, OR: PD, PD confirmed: Yes, 23SEP2013
302-0023 /68/M/A2	SCREENING/09SEP2013	TL:1/LIVER	SEGMENT 8	CT		70	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
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Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
302-0023 /68/M/A2	SCREENING/09SEP2013	TL:2/LIVER	SEGMENT 2	CT		61	SLD = 131
302-0024 /66/F/A2	SCREENING/31AUG2013	NTL:1/LIVE	PORTAL VEIN THROMBOSIS	CT		.	
	SCREENING/18SEP2013	TL:1/LIVER	CUT MARGIN	CT		32	SLD = 32
	WEEK12/10DEC2013	TL:1/LIVER	CUT MARGIN	CT		39	
	WEEK12/10DEC2013	NTL:1/LIVE	PORTAL VEIN THROMBOSIS	CT	UP	.	
	WEEK12/10DEC2013	NTL:2/LIVE	CUT MARGIN	CT	New	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
302-0024 /66/F/A2	Summary:					.	SLD = 39, %CN = 21.88, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 10DEC2013
302-0025 /40/M/A2	SCREENING/17OCT2013	TL:1/LUNG	LEFT UPPER LOBE	CT		21	
	SCREENING/17OCT2013	TL:2/LUNG	RIGHT LOWER LOBE	CT		24	SLD = 45
302-0026 /49/M/A2	SCREENING/05NOV2013	TL:1/LIVER	SEGMENT6-7	CT		54	SLD = 54
	SCREENING/05NOV2013	NTL:1/LIVE	PROTAL VEIN THROMBOSIS	CT		.	
	WEEK12/28JAN2014	TL:1/LIVER	SEGMENT6-7	CT		52	

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[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
302-0026 /49/M/A2	WEEK12/28JAN2014	NTL:1/LIVE	PROTAL VEIN THROMBOSIS	CT	Present	.	
	Summary:					.	SLD = 52, %CN = -3.7, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK24/22APR2014	TL:1/LIVER	SEGMENT6-7	CT		62	
	WEEK24/22APR2014	NTL:1/LIVE	PROTAL VEIN THROMBOSIS	CT	Present	.	
	Summary:					.	SLD = 62, %CN = 19.23, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK36/15JUL2014	TL:1/LIVER	SEGMENT6-7	CT		71	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
302-0026 /49/M/A2	WEEK36/15JUL2014	NTL:1/LIVE	PROTAL VEIN THROMBOSIS	CT	UP	.	
	Summary:					.	SLD = 71, %CN = 36.54, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 15JUL2014
303-0001 /50/M/A2	SCREENING/27JAN2012	TL:1/LIVER	RIGHT SUPERIOPOSTERIOR ASPECT	CT		55	
	SCREENING/27JAN2012	TL:2/LIVER	RIGHT POSTERIOR LOBE	CT		29	
	SCREENING/27JAN2012	TL:3/LUNG	RIGHT LOW BASAL SEGMENT	CT		18	SLD = 102
	SCREENING/27JAN2012	NTL:1/LIVE	S1 SEGMENT	CT		.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
303-0001 /50/M/A2	SCREENING/27JAN2012	NTL:2/LIVE	MULTIPLE NODULES IN S2 SEGMENT	CT		.	
	SCREENING/27JAN2012	NTL:3/LUNG	MULTIPLE NODULES IN BOTH LUNG	CT		.	
	WEEK12/18APR2012	TL:1/LIVER	RIGHT SUPERIOPOSTERIOR ASPECT	CT		61	
	WEEK12/18APR2012	TL:2/LIVER	RIGHT POSTERIOR LOBE	CT		33	
	WEEK12/18APR2012	TL:3/LUNG	RIGHT LOW BASAL SEGMENT	CT		21	
	WEEK12/18APR2012	NTL:1/LIVE	S1 SEGMENT	CT	Present	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
303-0001 /50/M/A2	WEEK12/18APR2012	NTL:2/LIVE	MULTIPLE NODULES IN S2 SEGMENT	CT	UP	.	
	WEEK12/18APR2012	NTL:3/LUNG	MULTIPLE NODULES IN BOTH LUNG	CT	Present	.	
	WEEK12/18APR2012	NTL:4/LIVE	S2 SEGMENT	CT	New	.	
	Summary:					.	SLD = 115, %CN = 12.75, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 25APR2012
303-0003 /47/M/A2	SCREENING/19NOV2012	TL:1/LIVER	S2 SEGMENT	CT		40	
	SCREENING/19NOV2012	TL:2/LIVER	S3 SEGMENT	CT		17	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
303-0003 /47/M/A2	SCREENING/19NOV2012	TL:3/NODES	LYMPH NODE BETWEEN INFERIOR VENA CAVA AND PORTAL VEIN A	CT		28	
	SCREENING/19NOV2012	TL:4/NODES	LYMPH NODE BETWEEN INFERIOR VENA CAVA AND PORTAL VEIN B	CT		24	
	SCREENING/19NOV2012	TL:5/LUNG	RIGHT UPPER LOBE	CT		20	SLD = 129
	SCREENING/19NOV2012	NTL:1/LIVE	MULTIPLE NODULES IN LEFT LIVER LOBE	CT		.	
	SCREENING/19NOV2012	NTL:2/LUNG	MULTIPLE NODULES IN BILATERAL HEMILUNGS	CT		.	
	SCREENING/19NOV2012	NTL:3/NODE	LYMPH NODE BEHIND THE RIGHT PULMONARY VEIN	CT		.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
303-0003 /47/M/A2	WEEK12/16FEB2013	TL:1/LIVER	S2 SEGMENT	CT		43	
	WEEK12/16FEB2013	TL:2/LIVER	S3 SEGMENT	CT		12	
	WEEK12/16FEB2013	TL:3/NODES	LYMPH NODE BETWEEN INFERIOR VENA CAVA AND PORTAL VEIN A	CT		50	
	WEEK12/16FEB2013	TL:4/NODES	LYMPH NODE BETWEEN INFERIOR VENA CAVA AND PORTAL VEIN B	CT		29	
	WEEK12/16FEB2013	TL:5/LUNG	RIGHT UPPER LOBE	CT		28	
	WEEK12/16FEB2013	NTL:1/LIVE	MULTIPLE NODULES IN LEFT LIVER LOBE	CT	UP	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
303-0003 /47/M/A2	WEEK12/16FEB2013	NTL:2/LUNG	MULTIPLE NODULES IN BILATERAL HEMILUNGS	CT	UP	.	
	WEEK12/16FEB2013	NTL:3/NODE	LYMPH NODE BEHIND THE RIGHT PULMONARY VEIN	CT	UP	.	
	Summary:					.	SLD = 162, %CN = 25.58, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 20FEB2013
303-0004 /18/M/A2	SCREENING/29NOV2012	TL:1/LIVER	LATERAL SEGMENT OF LEFT LOBE IN LIVER	CT		76	
	SCREENING/29NOV2012	TL:2/LIVER	MEDIAL OF LEFT LOBE IN LIVER	CT		53	
	SCREENING/29NOV2012	TL:3/LUNG	RIGHT LOWER LUNG	CT		85	

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Tumor Assessment Summary Listing
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Treatment Group: ADI-PEG 20

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303-0004 /18/M/A2	SCREENING/29NOV2012	TL:4/NODES	LYMPH NODE IN RIGHT PARASPINAL	CT		36	SLD = 250
	SCREENING/29NOV2012	NTL:1/LIVE	S6 SEGMENT	CT		.	
	SCREENING/29NOV2012	NTL:2/LIVE	S4 SEGMENT	CT		.	
	SCREENING/29NOV2012	NTL:3/NODE	LYMPH NODE IN PARASPINAL	CT		.	
	SCREENING/29NOV2012	NTL:4/LUNG	MULTIPLE PULMONARY MASSES IN BOTH HEMILUNGS	CT		.	
	SCREENING/29NOV2012	NTL:5/LUNG	PLEURAL EFFUSION IN RIGHT POSTERIOR PLEURAL CAVITY	CT		.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
303-0004 /18/M/A2	WEEK12/23FEB2013	TL:1/LIVER	LATERAL SEGMENT OF LEFT LOBE IN LIVER	CT		53	
	WEEK12/23FEB2013	TL:2/LIVER	MEDIAL OF LEFT LOBE IN LIVER	CT		53	
	WEEK12/23FEB2013	TL:3/LUNG	RLL	CT		83	
	WEEK12/23FEB2013	TL:4/NODES	LYMPH NODE IN RIGHT PARASPINAL	CT		40	
	WEEK12/23FEB2013	NTL:1/LIVE	S6 SEGMENT	CT	UP	.	
	WEEK12/23FEB2013	NTL:2/LIVE	S4 SEGMENT	CT	UP	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
303-0004 /18/M/A2	WEEK12/23FEB2013	NTL:3/NODE	LYMPH NODE IN PARASPINAL	CT	UP	.	
	WEEK12/23FEB2013	NTL:4/LUNG	MULTIPLE PULMONARY MASSES IN BOTH HEMILUNGS	CT	UP	.	
	WEEK12/23FEB2013	NTL:5/LUNG	PLEURAL EFFUSION IN RIGHT POSTERIOR PLEURAL CAVITY	CT	Present	.	
	Summary:					.	SLD = 229, %CN = -8.4, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 27FEB2013
303-0006 /64/M/A2	SCREENING/01APR2013	TL:1/LIVER	SEGMENT 4	CT		38	
	SCREENING/01APR2013	TL:2/LIVER	SEGMENT 3	CT		19	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
303-0006 /64/M/A2	SCREENING/01APR2013	TL:3/LUNG	RIGHT PARA SPINAL IN LUNG	CT		24	
	SCREENING/01APR2013	TL:4/LUNG	RIGHT LOWER LOBE	CT		12	SLD = 93
	SCREENING/01APR2013	NTL:1/LIVE	MULTIPLE NODULES IN LIVER	CT		.	
	SCREENING/01APR2013	NTL:2/LUNG	MULTIPLE NODULES IN LUNG	CT		.	
	UNSCHEDULED/22MAY2013	TL:1/LIVER	SEGMENT 4	CT		50	
	UNSCHEDULED/22MAY2013	TL:2/LIVER	SEGMENT 3	CT		44	

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Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
303-0006 /64/M/A2	UNSCHEDULED/22MAY2013	TL:3/LUNG	RIGHT PARA SPINAL IN LUNG	CT		27	
	UNSCHEDULED/22MAY2013	TL:4/LUNG	RIGHT LOWER LOBE	CT		19	
	UNSCHEDULED/22MAY2013	NTL:1/LIVE	MULTIPLE NODULES IN LIVER	CT	Present	.	
	UNSCHEDULED/22MAY2013	NTL:2/LUNG	MULTIPLE NODULES IN LUNG	CT	UP	.	
	UNSCHEDULED/22MAY2013	NTL:3/ASCI	ASCITES	CT	New	.	
	Summary:					.	SLD = 140, %CN = 50.54, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 29MAY2013

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
303-0007 /50/M/A2	SCREENING/12JUL2013	TL:1/LIVER	SEGMENT 5	CT		47	
	SCREENING/12JUL2013	TL:2/LIVER	SEGMENT 6	CT		44	SLD = 91
	SCREENING/12JUL2013	NTL:1/LIVE	RIGHT MAIN PORTAL VEIN THROMBOSIS	CT		.	
	SCREENING/12JUL2013	NTL:2/LIVE	MULTIPLE NODULES IN LIVER	CT		.	
304-0001 /54/M/A2	SCREENING/30OCT2012	TL:1/LIVER	S8	CT		71	
	SCREENING/30OCT2012	TL:2/LIVER	S6	CT		42	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
304-0001 /54/M/A2	SCREENING/30OCT2012	TL:3/NODES	PORTAL HEPATIS REGION	CT		20	
	SCREENING/30OCT2012	TL:4/NODES	PARAAORTIC REGION	CT		23	SLD = 156
	SCREENING/30OCT2012	NTL:1/LIVE	OTHER TUMOR	CT		.	
	SCREENING/30OCT2012	NTL:2/NODE	OTHER LYMPH NODES METASTASIS	CT		.	
	UNSCHEDULED/13DEC2012	TL:1/LIVER	S8	CT		88	
	UNSCHEDULED/13DEC2012	TL:2/LIVER	S6	CT		57	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
304-0001 /54/M/A2	UNSCHEDULED/13DEC2012	TL:3/NODES	PORTAL HEPATIC REGION	CT		29	
	UNSCHEDULED/13DEC2012	TL:4/NODES	PARAAORTIC REGION	CT		30	
	UNSCHEDULED/13DEC2012	NTL:1/LIVE	OTHER TUMOR	CT	UP	.	
	UNSCHEDULED/13DEC2012	NTL:2/NODE	OTHER LYMPH NODES METASTASIS	CT	UP	.	
	UNSCHEDULED/13DEC2012	NTL:3/LIVE	LIVER LEVEL SET	CT	New	.	
	UNSCHEDULED/13DEC2012	NTL:4/LUNG	SMALL NODULE IN LEFT LOWER LUNG	CT	New	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
304-0001 /54/M/A2	Summary:					.	SLD = 204, %CN = 30.77, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 14DEC2012
304-0005 /58/M/A2	SCREENING/30MAY2013	TL:1/LIVER	SEGMENT 7	CT		19	
	SCREENING/30MAY2013	TL:2/LIVER	SEGMENT 6	CT		12	
	SCREENING/30MAY2013	TL:3/NODES	LEFT CAROTID SPACE OF LYMPH NODES	CT		33	
	SCREENING/30MAY2013	TL:4/NODES	LEFT AXILLARY OF LYMPH NODES	CT		35	SLD = 99
	SCREENING/30MAY2013	NTL:1/NODE	LEFT SUPRACLAVIAN LYMPH NODES	CT		.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
304-0005 /58/M/A2	SCREENING/30MAY2013	NTL:2/NODE	LEFT SUBCLAVIAN LYMPH NODES	CT		.	
	SCREENING/30MAY2013	NTL:3/NODE	RIGHT AXILLARY LYMPH NODES	CT		.	
	SCREENING/30MAY2013	NTL:4/NODE	RIGHT UPPER MEDIASTINUM LYMPH NODES	CT		.	
	SCREENING/30MAY2013	NTL:5/NODE	LEFT PARAESOPHAGUS LYMPH NODES	CT		.	
	UNSCHEDULED/28JUN2013	TL:1/LIVER	SEGMENT 7	CT		18	
	UNSCHEDULED/28JUN2013	TL:2/LIVER	SEGMENT 6	CT		12	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
304-0005 /58/M/A2	UNSCHEDULED/28JUN2013	TL:3/NODES	LEFT CAROTID SPACE LYMPH NODES	CT		30	
	UNSCHEDULED/28JUN2013	TL:4/NODES	LEFT AXILLARY LYMPH NODES	CT		47	
	UNSCHEDULED/28JUN2013	NTL:1/NODE	LEFT SUPRACLAVIAN LYMPH NODES	CT	Present	.	
	UNSCHEDULED/28JUN2013	NTL:2/NODE	LEFT SUBCLAVIAN LYMPH NODES	CT	Present	.	
	UNSCHEDULED/28JUN2013	NTL:3/NODE	RIGHT AXILLARY LYMPH NODES	CT	UP	.	
	UNSCHEDULED/28JUN2013	NTL:4/NODE	RIGHT UPPER MEDIASTINUM LYMPH NODE	CT	UP	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
304-0005 /58/M/A2	UNSCHEDULED/28JUN2013	NTL:5/NODE	LEFT PARAESOPHAGUS LYMPH NODES	CT	Present	.	
	UNSCHEDULED/28JUN2013	NTL:6/GI	TUMOR INVASION DUODENUM	CT	New	.	
	UNSCHEDULED/28JUN2013	NTL:7/BONE	BONE METASTASIS OF RIGHT 2ND RIBS	CT	New	.	
	UNSCHEDULED/28JUN2013	NTL:8/BONE	BONE METASTASIS OF RIGHT 8TH RIBS	CT	New	.	
	Summary:					.	SLD = 107, %CN = 8.08, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 29JUN2013
305-0002 /57/M/A2	SCREENING/13FEB2012	TL:1/LIVER	SEGMENT 4	CT		64	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
305-0002 /57/M/A2	SCREENING/13FEB2012	TL:2/LUNG	LEFT LOWER LUNG	CT		7	SLD = 71
	UNSCHEDULED/24FEB2012	NTL:1/BRAI	LEFT FRONAL BRAIN	MRI	New	.	
	UNSCHEDULED/24FEB2012	NTL:2/BRAI	RIGHT SUPERIOR FRONTAL SULCUS	MRI	New	.	
	Summary:					.	SLD = ., %CN = ., TL: NotEvaluable, NTL: PD, OR: PD, PD confirmed: Yes, 24FEB2012
305-0003 /50/M/A2	SCREENING/10FEB2012	TL:1/NODES	LUNG LYMPH NODE	CT		19	
	SCREENING/10FEB2012	TL:2/LIVER	SEGMENT 4	CT		54	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
305-0003 /50/M/A2	SCREENING/10FEB2012	TL:3/LUNG	RIGHT LOWER LOBE	CT		18	
	SCREENING/10FEB2012	TL:4/LUNG	RIGHT UPPER LOBE	CT		21	
	SCREENING/10FEB2012	TL:5/NODES	MEDIASTINUM	CT		21	SLD = 133
	WEEK12/11MAY2012	TL:1/NODES	LUNG LYMPH NODE	CT		20	
	WEEK12/11MAY2012	TL:2/LIVER	SEGMENT 4	CT		57	
	WEEK12/11MAY2012	TL:3/LUNG	RIGHT LOWER LOBE	CT		18	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
305-0003 /50/M/A2	WEEK12/11MAY2012	TL:4/LUNG	RIGHT UPPER LOBE	CT		18	
	WEEK12/11MAY2012	TL:5/NODES	MEDIASTINUM	CT		24	
	Summary:					.	SLD = 137, %CN = 3.01, TL: SD, NTL: NotAssessed, OR: SD, PD confirmed: No
	WEEK24/03AUG2012	TL:1/NODES	LUNG LYMPH NODE	CT		34	
	WEEK24/03AUG2012	TL:2/LIVER	SEGMENT 4	CT		64	
	WEEK24/03AUG2012	TL:3/LUNG	RIGHT LOWER LOBE	CT		16	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
305-0003 /50/M/A2	WEEK24/03AUG2012	TL:4/LUNG	RIGHT UPPER LOBE	CT		23	
	WEEK24/03AUG2012	TL:5/NODES	MEDIASTINUM	CT		30	
	Summary:					.	SLD = 167, %CN = 25.56, TL: PD, NTL: NotAssessed, OR: PD, PD confirmed: Yes, 03AUG2012
305-0005 /48/M/A2	SCREENING/16FEB2012	TL:1/LIVER	SEGMENT 8	CT		20	
	SCREENING/16FEB2012	TL:2/LIVER	SEGMENT 5	CT		18	
	SCREENING/16FEB2012	TL:3/NODES	PORTOCAVAL	CT		15	

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Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
305-0005 /48/M/A2	SCREENING/16FEB2012	TL:4/NODES	AORTOCAVAL	CT		14	SLD = 67
	SCREENING/16FEB2012	NTL:1/LIVE	LEFT LOBE TUMOR	CT		.	
	SCREENING/16FEB2012	NTL:10/LIV	LEFT PORTAL THROMBOSES	CT		.	
	SCREENING/16FEB2012	NTL:2/LIVE	RIGHT LOBE TUMOR	CT		.	
	SCREENING/16FEB2012	NTL:3/NODE	PARAAORTIC NODE	CT		.	
	SCREENING/16FEB2012	NTL:4/LIVE	RIGHT PORTAL THROMBOSES	CT		.	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
305-0005 /48/M/A2	SCREENING/16FEB2012	NTL:5/LIVE	PORTA TRANK THROMBOSES	CT		.	
	SCREENING/16FEB2012	NTL:6/NODE	REGIONAL	CT		.	
	SCREENING/16FEB2012	NTL:7/NODE	PARAAORTA	CT		.	
	SCREENING/16FEB2012	NTL:8/LUNG	LEFT LOBES TUMOR	CT		.	
	SCREENING/16FEB2012	NTL:9/LUNG	RIGHT LOBES TUMORS	CT		.	
305-0006 /65/M/A2	SCREENING/24FEB2012	TL:1/LUNG	RIGHT UPPER LOBE	CT		50	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
305-0006 /65/M/A2	SCREENING/24FEB2012	TL:2/LUNG	RIGHT UPPER LOBE	CT		63	
	SCREENING/24FEB2012	TL:3/LIVER	SEGMENT 6	CT		54	
	SCREENING/24FEB2012	TL:4/LIVER	SEGMENT 5	CT		51	SLD = 218
	SCREENING/24FEB2012	NTL:1/LIVE	SEGMENT 8	CT		.	
	WEEK12/30MAY2012	TL:1/LUNG	RIGHT UPPER LOBE	CT		55	
	WEEK12/30MAY2012	TL:2/LUNG	RIGHT UPPER LOBE	CT		55	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
305-0006 /65/M/A2	WEEK12/30MAY2012	TL:3/LIVER	SEGMENT 6	CT		54	
	WEEK12/30MAY2012	TL:4/LIVER	SEGMENT 5	CT		50	
	WEEK12/30MAY2012	NTL:1/LIVE	SEGMENT 8	CT	Present	.	
	Summary:					.	SLD = 214, %CN = -1.83, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK24/22AUG2012	TL:1/LUNG	RIGHT UPPER LOBE	CT		68	
	WEEK24/22AUG2012	TL:2/LUNG	RIGHT UPPER LOBE	CT		53	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
305-0006 /65/M/A2	WEEK24/22AUG2012	TL:3/LIVER	SEGMENT 6	CT		52	
	WEEK24/22AUG2012	TL:4/LIVER	SEGMENT 5	CT		48	
	WEEK24/22AUG2012	NTL:1/LIVE	SEGMENT 8	CT	UP	.	
	Summary:					.	SLD = 221, %CN = 3.27, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 22AUG2012
305-0009 /45/F/A2	SCREENING/28MAR2012	TL:1/LIVER	SEGMENT 4/5	CT		114	
	SCREENING/28MAR2012	TL:2/LIVER	SEGMENT 8	CT		28	SLD = 142

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[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
305-0009 /45/F/A2	WEEK12/04JUL2012	TL:1/LIVER	SEGMENT 4/5	CT		124	
	WEEK12/04JUL2012	TL:2/LIVER	SEGMENT 8	CT		27	
	Summary:					.	SLD = 151, %CN = 6.34, TL: SD, NTL: NotEvaluable, OR: SD, PD confirmed: No
	WEEK24/26SEP2012	TL:1/LIVER	SEGMENT 4/5	CT		122	
	WEEK24/26SEP2012	TL:2/LIVER	SEGMENT 8	CT		42	
	WEEK24/26SEP2012	NTL:1/LUNG	RIGHT MIDDLE LOBE	CT	New	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
305-0009 /45/F/A2	Summary:					.	SLD = 164, %CN = 15.49, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 26SEP2012
305-0010 /64/F/A2	SCREENING/17APR2012	TL:1/LIVER	SEGMENT 3	CT		20	SLD = 20
	SCREENING/17APR2012	NTL:1/LUNG	MULTIPLE RLL	CT		.	
	WEEK12/10JUL2012	TL:1/LIVER	SEGMENT 3	CT		26	
	WEEK12/10JUL2012	NTL:1/LUNG	MULTIPLE RLL	CT	Present	.	
	WEEK12/10JUL2012	NTL:2/LIVE	SEGMENT 3	CT	New	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
305-0010 /64/F/A2	Summary:					.	SLD = 26, %CN = 30, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 10JUL2012
305-0011 /68/M/A2	SCREENING/20APR2012	TL:1/LIVER	SEGMENT 7	CT		31	
	SCREENING/20APR2012	TL:2/LIVER	SEGMENT 6	CT		66	SLD = 97
	WEEK12/20JUL2012	TL:1/LIVER	SEGMENT 7	CT		37	
	WEEK12/20JUL2012	TL:2/LIVER	SEGMENT 6	CT		67	
	Summary:					.	SLD = 104, %CN = 7.22, TL: SD, NTL: NotAssessed, OR: SD, PD confirmed: No

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
305-0011 /68/M/A2	UNSCHEDULED/10AUG2012	TL:1/LIVER	SEGMENT 7	CT		38	
	UNSCHEDULED/10AUG2012	TL:2/LIVER	SEGMENT 6	CT		80	
	Summary:					.	SLD = 118, %CN = 21.65, TL: PD, NTL: NotAssessed, OR: PD, PD confirmed: Yes, 10AUG2012
305-0012 /62/F/A2	SCREENING/27APR2012	TL:1/LUNG	MULTIPLE RIGHT LOWER LOBE(RLL)	CT		32	
	SCREENING/27APR2012	TL:2/LUNG	RIGHT MIDDLE LOBE(RML)	CT		14	SLD = 46
	WEEK12/27JUL2012	TL:1/LUNG	MULTIPLE RIGHT LOWER LOBE(RLL)	CT		13	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
305-0012 /62/F/A2	WEEK12/27JUL2012	TL:2/LUNG	RIGHT MIDDLE LOBE(RML)	CT		12	
	Summary:					.	SLD = 25, %CN = -45.65, TL: PR, NTL: NotAssessed, OR: PR, PD confirmed: No
	UNSCHEDULED/07SEP2012	TL:1/LUNG	MULTIPLE RIGHT LOWER LOBE(RLL)	CT		12	
	UNSCHEDULED/07SEP2012	TL:2/LUNG	RIGHT MIDDLE LOBE(RML)	CT		11	
	Summary:					.	SLD = 23, %CN = 9.52, TL: PR, NTL: NotAssessed, OR: PR, PD confirmed: No
	WEEK24/19OCT2012	TL:1/LUNG	MULTIPLE RIGHT LOWER LOBE(RLL)	CT		12	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
305-0012 /62/F/A2	WEEK24/19OCT2012	TL:2/LUNG	RIGHT MIDDLE LOBE(RML)	CT		9	
	Summary:					.	SLD = 21, %CN = 0, TL: PR, NTL: NotAssessed, OR: PR, PD confirmed: No
	WEEK36/11JAN2013	TL:1/LUNG	MULTIPLE RIGHT LOWER LOBE(RLL)	CT		19	
	WEEK36/11JAN2013	TL:2/LUNG	RIGHT MIDDLE LOBE(RML)	CT		10	
	WEEK36/11JAN2013	NTL:1/LUNG	RIGHT MIDDLE LOBE(RML)	CT	New	.	
	Summary:					.	SLD = 29, %CN = 38.1, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 11JAN2013

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Tumor Assessment Summary Listing
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Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
305-0014 /61/F/A2	SCREENING/04JUL2012	TL:1/LUNG	RIGHT LOWER LOBE	CT		25	
	SCREENING/04JUL2012	TL:2/LUNG	RIGHT LOWER LOBE	CT		14	
	SCREENING/04JUL2012	TL:3/GI	ABDOMEN	CT		12	SLD = 51
	SCREENING/04JUL2012	NTL:1/LUNG	RIGHT LOBE TUMORS	CT		.	
	SCREENING/04JUL2012	NTL:2/LUNG	LEFT LOBE TUMORS	CT		.	
	WEEK12/21SEP2012	TL:1/LUNG	RIGHT LOWER LOBE	CT		30	

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Tumor Assessment Summary Listing
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Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
305-0014 /61/F/A2	WEEK12/21SEP2012	TL:2/LUNG	RIGHT LOWER LOBE	CT		17	
	WEEK12/21SEP2012	TL:3/GI	ABDOMEN	CT		4	
	WEEK12/21SEP2012	NTL:1/LUNG	RIGHT LOBE TUMORS	CT	UP	.	
	WEEK12/21SEP2012	NTL:2/LUNG	LEFT LOBE TUMORS	CT	UP	.	
	WEEK12/21SEP2012	NTL:3/NODE	MEDIASTINUM	CT	New	.	
	WEEK12/21SEP2012	NTL:4/LIVE	S8 TUMOR	CT	New	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
305-0014 /61/F/A2	Summary:					.	SLD = 51, %CN = 0, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 23SEP2012
305-0019 /35/M/A2	SCREENING/07SEP2012	TL:1/LIVER	SEGMENT 7	CT		28	
	SCREENING/07SEP2012	TL:2/LIVER	SEGMENT 5	CT		41	SLD = 69
	SCREENING/07SEP2012	NTL:1/LIVE	RIGHT LOBE TUMORS	CT		.	
	SCREENING/07SEP2012	NTL:2/LIVE	LEFT LOBE TUMORS	CT		.	
305-0023 /54/M/A2	SCREENING/02JAN2013	TL:1/LIVER	SEGMENT 8	CT		52	SLD = 52

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
305-0023 /54/M/A2	SCREENING/02JAN2013	NTL:1/LIVE	LEFT LOBE	CT		.	
	SCREENING/02JAN2013	NTL:2/LIVE	RIGHT LOBE	CT		.	
	SCREENING/02JAN2013	NTL:3/LUNG	RIGHT UPPER LOBE	CT		.	
	SCREENING/02JAN2013	NTL:4/LUNG	LEFT LOWER LOBE	CT		.	
	WEEK12/26MAR2013	TL:1/LIVER	SEGMENT 8	CT		112	
	WEEK12/26MAR2013	NTL:1/LIVE	LEFT LOBE	CT	Present	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
305-0023 /54/M/A2	WEEK12/26MAR2013	NTL:2/LIVE	RIGHT LOBE	CT	Present	.	
	WEEK12/26MAR2013	NTL:3/LUNG	RIGHT UPPER LOBE	CT	Present	.	
	WEEK12/26MAR2013	NTL:4/LUNG	LEFT LOWER LOBE	CT	Present	.	
	Summary:					.	SLD = 112, %CN = 115.38, TL: PD, NTL: IncompleteResponse/SD, OR: PD, PD confirmed: No
305-0025 /77/F/A2	SCREENING/08JAN2013	TL:1/LIVER	SEGMENT 6/7	CT		37	
	SCREENING/08JAN2013	TL:2/LIVER	SEGMENT 3	CT		13	SLD = 50

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
305-0025 /77/F/A2	SCREENING/08JAN2013	NTL:1/LUNG	RIGHT MIDDLE LOBE	CT		.	
	SCREENING/08JAN2013	NTL:2/LUNG	RIGHT LOWER LOBE	CT		.	
	WEEK12/16APR2013	TL:1/LIVER	SEGMENT 6/7	CT		64	
	WEEK12/16APR2013	TL:2/LIVER	SEGMENT 3	CT		31	
	WEEK12/16APR2013	NTL:1/LUNG	RIGHT MIDDLE LOBE	CT	Present	.	
	WEEK12/16APR2013	NTL:2/LUNG	RIGHT LOWER LOBE	CT	Present	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
305-0025 /77/F/A2	WEEK12/16APR2013	NTL:3/LUNG	RIGHT MIDDLE LOBE	CT	New	.	
	Summary:					.	SLD = 95, %CN = 90, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 16APR2013
305-0026 /45/M/A2	SCREENING/06FEB2013	TL:1/LIVER	SEGMENT 5	CT		59	
	SCREENING/06FEB2013	TL:2/LIVER	SEGMENT 2/4	CT		56	SLD = 115
	WEEK12/21MAY2013	TL:1/LIVER	SEGMENT 5	CT		67	
	WEEK12/21MAY2013	TL:2/LIVER	SEGMENT 2/4	CT		54	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
305-0026 /45/M/A2	Summary:					.	SLD = 121, %CN = 5.22, TL: SD, NTL: NotAssessed, OR: SD, PD confirmed: No
	WEEK24/13AUG2013	TL:1/LIVER	SEGMENT 5	CT		60	
	WEEK24/13AUG2013	TL:2/LIVER	SEGMENT 2/4	CT		66	
	Summary:					.	SLD = 126, %CN = 9.57, TL: SD, NTL: NotAssessed, OR: SD, PD confirmed: No
305-0028 /73/F/A2	SCREENING/27FEB2013	TL:1/LIVER	SEGMENT 4/8	CT		78	
	SCREENING/27FEB2013	TL:2/LIVER	SEGMENT 2	CT		35	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
305-0028 /73/F/A2	SCREENING/27FEB2013	TL:3/LUNG	RIGHT MIDDLE LOBE	CT		42	SLD = 155
	SCREENING/27FEB2013	NTL:1/LIVE	SEGMENT 2	CT		.	
	SCREENING/27FEB2013	NTL:2/LIVE	SEGMENT 6	CT		.	
	SCREENING/27FEB2013	NTL:3/LIVE	SEGMENT 7	CT		.	
	WEEK12/05JUN2013	TL:1/LIVER	SEGMENT 4/8	CT		78	
	WEEK12/05JUN2013	TL:2/LIVER	SEGMENT 2	CT		44	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
305-0028 /73/F/A2	WEEK12/05JUN2013	TL:3/LUNG	RIGHT MIDDLE LOBE	CT		48	
	WEEK12/05JUN2013	NTL:1/LIVE	SEGMENT 2	CT	Present	.	
	WEEK12/05JUN2013	NTL:2/LIVE	SEGMENT 6	CT	Present	.	
	WEEK12/05JUN2013	NTL:3/LIVE	SEGMENT 7	CT	Present	.	
	WEEK12/05JUN2013	NTL:4/PLEU	PLEURA EFFUSION	CT	New	.	
	WEEK12/05JUN2013	NTL:5/NODE	LYMPH NODES IN MEDIASTINAL	CT	New	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
305-0028 /73/F/A2	Summary:					.	SLD = 170, %CN = 9.68, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 05JUN2013
305-0030 /61/M/A2	SCREENING/28MAR2013	TL:1/LUNG	LEFT UPPER LOBE	CT		11	
	SCREENING/28MAR2013	TL:2/LUNG	LINGULA	CT		11	SLD = 22
	SCREENING/28MAR2013	NTL:1/LUNG	RIGHT LOBE	CT		.	
	SCREENING/28MAR2013	NTL:2/LUNG	LEFT LOBE	CT		.	
305-0031 /29/M/A2	SCREENING/29MAR2013	TL:1/LIVER	LEFT LOBE	CT		80	SLD = 80

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Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
305-0031 /29/M/A2	SCREENING/29MAR2013	NTL:1/LIVE	LEFT PORTAL VEIN THROMBOSE	CT		.	
	SCREENING/29MAR2013	NTL:2/NODE	REGIONAL NODAL METASTASES	CT		.	
	SCREENING/29MAR2013	NTL:3/NODE	PARAAORTIC NODAL METASTASES	CT		.	
	SCREENING/29MAR2013	NTL:4/NODE	AORTOCAVAL NODAL METASTASES	CT		.	
305-0034 /53/M/A2	SCREENING/28JUN2013	TL:1/LIVER	RIGHT LOBE POSTERIN MARGIN	CT		110	
	SCREENING/28JUN2013	TL:2/SOFTT	RIGHT ADRENAL	CT		53	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
305-0034 /53/M/A2	SCREENING/28JUN2013	TL:3/LUNG	RIGHT UPPER LOBE	CT		20	
	SCREENING/28JUN2013	TL:4/LUNG	RIGHT UPPER LOBE	CT		20	SLD = 203
	UNSCHEDULED/05AUG2013	TL:1/LIVER	RIGHT LOBE POSTERIN MARGIN	CT		111	
	UNSCHEDULED/05AUG2013	TL:2/SOFTT	RIGHT ADRENAL	CT		55	
	UNSCHEDULED/05AUG2013	TL:3/LUNG	RIGHT UPPER LOBE	CT		20	
	UNSCHEDULED/05AUG2013	TL:4/LUNG	RIGHT UPPER LOBE	CT		28	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
305-0034 /53/M/A2	UNSCHEDULED/05AUG2013	NTL:1/PLEU	RIGHT PLEURAL EFFUSION	CT	New	.	
	UNSCHEDULED/05AUG2013	NTL:2/LUNG	LEFT UPPER LOBE	CT	New	.	
	Summary:					.	SLD = 214, %CN = 5.42, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 05AUG2013
305-0036 /38/M/A2	SCREENING/30AUG2013	TL:1/LIVER	SEGMANT 2	CT		50	
	SCREENING/30AUG2013	TL:2/LIVER	SEGMANT 2	CT		53	SLD = 103
	SCREENING/30AUG2013	NTL:1/LIVE	LEFT LOBE TUMOR	CT		.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
305-0036 /38/M/A2	SCREENING/30AUG2013	NTL:10/NOD	RIGHT HILAR LYMPHADENOPATHY	CT		.	
	SCREENING/30AUG2013	NTL:2/LIVE	RIGHT LOBE TUMOR	CT		.	
	SCREENING/30AUG2013	NTL:3/LUNG	LEFT LOBE TUMOR	CT		.	
	SCREENING/30AUG2013	NTL:4/LUNG	RIGHT LOBE TUMOR	CT		.	
	SCREENING/30AUG2013	NTL:5/BONE	T-VERTEBRAE TUMOR	CT		.	
	SCREENING/30AUG2013	NTL:6/BONE	L-VERTEBRAE	CT		.	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
305-0036 /38/M/A2	SCREENING/30AUG2013	NTL:7/BONE	RIGHT SCAPULA	CT		.	
	SCREENING/30AUG2013	NTL:8/BONE	STERNUM	CT		.	
	SCREENING/30AUG2013	NTL:9/NODE	PARAORTA	CT		.	
	WEEK12/22NOV2013	TL:1/LIVER	SEGMENT 2	CT		50	
	WEEK12/22NOV2013	TL:2/LIVER	SEGMENT 2	CT		65	
	WEEK12/22NOV2013	NTL:/BONE	RIGHT ILIAC	CT	New	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
305-0036 /38/M/A2	WEEK12/22NOV2013	NTL:1/LIVE	LEFT LOBE TUMOR	CT	Present	.	
	WEEK12/22NOV2013	NTL:10/NOD	RIGHT HILAR LYMPHADENOPATHY	CT	Present	.	
	WEEK12/22NOV2013	NTL:11/BON	SACRUM	CT	New	.	
	WEEK12/22NOV2013	NTL:2/LIVE	RIGHT LOBE TUMOR	CT	Present	.	
	WEEK12/22NOV2013	NTL:3/LUNG	LEFT LOBE TUMOR	CT	Present	.	
	WEEK12/22NOV2013	NTL:4/LUNG	RIGHT LOBE TUMOR	CT	Present	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
305-0036 /38/M/A2	WEEK12/22NOV2013	NTL:5/BONE	T-VERTEBRAE TUMOR	CT	UP	.	
	WEEK12/22NOV2013	NTL:6/BONE	L-VERTEBRAE	CT	UP	.	
	WEEK12/22NOV2013	NTL:7/BONE	RIGHT SCAPULA	CT	UP	.	
	WEEK12/22NOV2013	NTL:8/BONE	STERNUM	CT	UP	.	
	WEEK12/22NOV2013	NTL:9/NODE	PARAORTA	CT	Present	.	
	Summary:					.	SLD = 115, %CN = 11.65, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 28NOV2013

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
305-0037 /50/M/A2	SCREENING/17OCT2013	TL:1/LIVER	SEGMENT 3	CT		26	
	SCREENING/17OCT2013	TL:2/LIVER	SEGMENT 3	CT		18	SLD = 44
	SCREENING/17OCT2013	NTL:1/LIVE	RIGHT LOBE TUMORS	CT		.	
	SCREENING/17OCT2013	NTL:2/LIVE	LEFT LOBE TUMORS	CT		.	
	SCREENING/17OCT2013	NTL:3/LIVE	RIGHT PORTAL VEIN THROMBOSES	CT		.	
	SCREENING/17OCT2013	NTL:4/LIVE	LEFT PORTAL VEIN THROMBOSES	CT		.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
305-0037 /50/M/A2	SCREENING/17OCT2013	NTL:5/LIVE	PORTAL TRUNK THROMBOSES	CT		.	
	SCREENING/17OCT2013	NTL:6/LUNG	RIGHT LUNG TUMORS	CT		.	
	SCREENING/17OCT2013	NTL:7/LUNG	LEFT LUNG TUMORS	CT		.	
	WEEK12/09JAN2014	TL:1/LIVER	SEGMENT 3	CT		26	
	WEEK12/09JAN2014	TL:2/LIVER	SEGMENT 3	CT		21	
	WEEK12/09JAN2014	NTL:1/LIVE	RIGHT LOBE TUMORS	CT	Present	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
305-0037 /50/M/A2	WEEK12/09JAN2014	NTL:2/LIVE	LEFT LOBE TUMORS	CT	Present	.	
	WEEK12/09JAN2014	NTL:3/LIVE	RIGHT PORTAL VEIN THROMBOSES	CT	Present	.	
	WEEK12/09JAN2014	NTL:4/LIVE	LEFT PORTAL VEIN THROMBOSES	CT	Present	.	
	WEEK12/09JAN2014	NTL:5/LIVE	PORTAL TRUNK THROMBOSES	CT	Present	.	
	WEEK12/09JAN2014	NTL:6/LUNG	RIGHT LUNG TUMORS	CT	Present	.	
	WEEK12/09JAN2014	NTL:7/LUNG	LEFT LUNG TUMORS	CT	Present	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
305-0037 /50/M/A2	Summary:					.	SLD = 47, %CN = 6.82, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
305-0039 /35/M/A2	SCREENING/22NOV2013	TL:1/LUNG	RIGHT UPPER LOBE	CT		14	
	SCREENING/22NOV2013	TL:2/LUNG	RIGHT LOWER LOBE	CT		34	SLD = 48
	SCREENING/22NOV2013	NTL:1/LIVE	LEFT LOBE TUMOR	CT		.	
	SCREENING/22NOV2013	NTL:10/PLE	RIGHT PLEURAL DFFUSION	CT		.	
	SCREENING/22NOV2013	NTL:2/LIVE	RIGHT LOBE TUMOR	CT		.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
305-0039 /35/M/A2	SCREENING/22NOV2013	NTL:3/LIVE	RIGHT PORTAL VEIN THROMBOSES	CT		.	
	SCREENING/22NOV2013	NTL:4/LUNG	LEFT LUNG TUMORS	CT		.	
	SCREENING/22NOV2013	NTL:5/LUNG	RIGHT LUNG TUMORS	CT		.	
	SCREENING/22NOV2013	NTL:6/NODE	LEFT HILAR	CT		.	
	SCREENING/22NOV2013	NTL:7/NODE	RIGHT HILAR	CT		.	
	SCREENING/22NOV2013	NTL:8/SOFT	RIGHT DIAPHRAGM TUMOR	CT		.	

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Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
305-0039 /35/M/A2	SCREENING/22NOV2013	NTL:9/ASCI		CT		.	
305-0040 /61/M/A2	SCREENING/11NOV2013	TL:1/LIVER	SEGMENT 8	CT		13	
	SCREENING/11NOV2013	TL:2/LIVER	SEGMENT 3	CT		16	SLD = 29
	SCREENING/11NOV2013	NTL:1/LIVE	RIGHT LOBE LIVER TUMOR	CT		.	
	SCREENING/11NOV2013	NTL:2/LIVE	RIGHT PORTAL VEIN THROMBOSIS	CT		.	
	SCREENING/11NOV2013	NTL:3/LIVE	LEFT PORTAL VEIN THROMBOSIS	CT		.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
305-0040 /61/M/A2	SCREENING/11NOV2013	NTL:4/LIVE	PORTAL TRUNK THROMBOSIS	CT		.	
305-0043 /70/M/A2	SCREENING/06JUN2014	TL:1/LIVER	SEGMENT 6	CT		21	
	SCREENING/06JUN2014	TL:2/LUNG	RIGHT UPPER LOBE	CT		17	
	SCREENING/06JUN2014	TL:3/LUNG	RIGHT MIDDLE LOBE	CT		19	SLD = 57
	SCREENING/06JUN2014	NTL:1/LIVE	RIGHT LOBE TUMORS	CT		.	
	SCREENING/06JUN2014	NTL:2/LUNG	RIGHT LOBE TUMORS	CT		.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
305-0043 /70/M/A2	SCREENING/06JUN2014	NTL:3/LUNG	LEFT LOBE TUMORS	CT		.	
	WEEK12/16SEP2014	TL:1/LIVER	SEGMENT 6	CT		34	
	WEEK12/16SEP2014	TL:2/LUNG	RIGHT UPPER LOBE	CT		16	
	WEEK12/16SEP2014	TL:3/LUNG	RIGHT MIDDLE LOBE	CT		27	
	WEEK12/16SEP2014	NTL:1/LIVE	RIGHT LOBE TUMORS	CT	Present	.	
	WEEK12/16SEP2014	NTL:2/LUNG	RIGHT LOBE TUMORS	CT	Present	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
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Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
305-0043 /70/M/A2	WEEK12/16SEP2014	NTL:3/LUNG	LEFT LOBE TUMORS	CT	Present	.	
	Summary:					.	SLD = 77, %CN = 35.09, TL: PD, NTL: IncompleteResponse/SD, OR: PD, PD confirmed: Yes, 26SEP2014
305-0044 /67/M/A2	SCREENING/24JUN2014	TL:1/LIVER	SEGMENT 2	CT		17	
	SCREENING/24JUN2014	TL:2/LUNG	RIGHT LOWER LOBE	CT		58	
	SCREENING/24JUN2014	TL:3/LUNG	LEFT LOWER LOBE	CT		47	SLD = 122
	SCREENING/24JUN2014	NTL:1/LIVE	LATERAL SEGMENT	CT		.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
305-0044 /67/M/A2	SCREENING/24JUN2014	NTL:2/LUNG	LEFT LOBE	CT		.	
	WEEK12/30SEP2014	TL:1/LIVER	SEGMENT 2	CT		27	
	WEEK12/30SEP2014	TL:2/LUNG	RIGHT LOWER LOBE	CT		75	
	WEEK12/30SEP2014	TL:3/LUNG	LEFT LOWER LOBE	CT		56	
	WEEK12/30SEP2014	NTL:1/LIVE	LATERAL SEGMENT	CT	Present	.	
	WEEK12/30SEP2014	NTL:2/LUNG	LEFT LOBE	CT	UP	.	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
305-0044 /67/M/A2	Summary:					.	SLD = 158, %CN = 29.51, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 07OCT2014
305-0045 /65/M/A2	SCREENING/06OCT2014	TL:1/LUNG	LEFT UPPER LOBE	CT		22	
	SCREENING/06OCT2014	TL:2/LIVER	SEGMENT 7	CT		109	SLD = 131
	SCREENING/06OCT2014	NTL:1/NODE	LYMPH NODE-HILAR	CT		.	
305-0047 /58/M/A2	SCREENING/24DEC2014	TL:1/LIVER	SEGMENT 1	CT		148	
	SCREENING/24DEC2014	TL:2/LIVER	SEGMENT 2	CT		48	SLD = 196

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
305-0047 /58/M/A2	SCREENING/24DEC2014	NTL:1/LIVE	SEGMENT 4	CT		.	
305-0048 /55/M/A2	SCREENING/13FEB2015	TL:1/LIVER	LATERAL SEGMENT	CT		17	
	SCREENING/13FEB2015	TL:2/LIVER	LATERAL SEGMENT	CT		14	SLD = 31
	SCREENING/13FEB2015	NTL:1/LIVE	LEFT LOBE	CT		.	
	SCREENING/13FEB2015	NTL:2/LIVE	RIGHT LOBE	CT		.	
	SCREENING/13FEB2015	NTL:3/LIVE	RIGHT PORTAL VEIN THROMBOSES	CT		.	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
305-0048 /55/M/A2	WEEK12/12MAY2015	TL:1/LIVER	LATERAL SEGMENT	CT		31	
	WEEK12/12MAY2015	TL:2/LIVER	LATERAL SEGMENT	CT		18	
	WEEK12/12MAY2015	NTL:1/LIVE	LEFT LOBE	CT	UP	.	
	WEEK12/12MAY2015	NTL:2/LIVE	RIGHT LOBE	CT	UP	.	
	WEEK12/12MAY2015	NTL:3/LIVE	RIGHT PORTAL VEIN THROMBOSES	CT	Present	.	
	WEEK12/12MAY2015	NTL:4/LIVE	SEGMENT 4	CT	New	.	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
305-0048 /55/M/A2	Summary:					.	SLD = 49, %CN = 58.06, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 13MAY2015
306-0001 /56/M/A2	SCREENING/13FEB2012	TL:1/LUNG	LEFT UPPER LOBE	CT		24	SLD = 24
	WEEK12/04MAY2012	TL:1/LUNG	LEFT UPPER LOBE	CT		32	
	Summary:					.	SLD = 32, %CN = 33.33, TL: PD, NTL: NotAssessed, OR: PD, PD confirmed: Yes, 08MAY2012
306-0002 /73/M/A2	SCREENING/09FEB2012	TL:1/LUNG	LEFT LINGULAR SEGMENT	CT		22	
	SCREENING/09FEB2012	TL:2/LUNG	RIGHT LOWER LOBE	CT		29	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
306-0002 /73/M/A2	SCREENING/09FEB2012	TL:3/LIVER	S2	CT		17	
	SCREENING/09FEB2012	TL:4/LIVER	S3	CT		27	SLD = 95
	SCREENING/09FEB2012	NTL:1/LUNG	RIGHT LOWER LOBE	CT		.	
	SCREENING/09FEB2012	NTL:2/LUNG	LEFT LOWER LOBE	CT		.	
	SCREENING/09FEB2012	NTL:3/LIVE	S2	CT		.	
	SCREENING/09FEB2012	NTL:4/LIVE	S3	CT		.	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
306-0002 /73/M/A2	WEEK12/02MAY2012	TL:1/LUNG	LEFT LINGULAR SEGMENT	CT		26	
	WEEK12/02MAY2012	TL:2/LUNG	RIGHT LOWER LOBE	CT		37	
	WEEK12/02MAY2012	TL:3/LIVER	S2	CT		19	
	WEEK12/02MAY2012	TL:4/LIVER	S3	CT		41	
	WEEK12/02MAY2012	NTL:1/LUNG	RIGHT LOWER LOBE	CT	Present	.	
	WEEK12/02MAY2012	NTL:2/LUNG	LEFT LOWER LOBE	CT	Present	.	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
306-0002 /73/M/A2	WEEK12/02MAY2012	NTL:3/LIVE	S2	CT	Present	.	
	WEEK12/02MAY2012	NTL:4/LIVE	S3	CT	Present	.	
	WEEK12/02MAY2012	NTL:5/NODE	RIGHT PARATRACHEAL REGION	CT	New	.	
	WEEK12/02MAY2012	NTL:6/GI	ASCITES	CT	New	.	
	Summary:					.	SLD = 123, %CN = 29.47, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 08MAY2012
306-0005 /69/F/A2	SCREENING/22FEB2012	TL:1/LIVER	S1	CT		12	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
306-0005 /69/F/A2	SCREENING/22FEB2012	TL:2/LIVER	S3	CT		12	
	SCREENING/22FEB2012	TL:3/LUNG	LEFT LING SEG	CT		10	
	SCREENING/22FEB2012	TL:4/LUNG	LEFT LING SEG	CT		10	SLD = 44
	SCREENING/22FEB2012	NTL:1/LIVE	S5	CT		.	
	UNSCHEDULED/25APR2012	TL:1/LIVER	S1	CT		27	
	UNSCHEDULED/25APR2012	TL:2/LIVER	S3	CT		22	

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[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
306-0005 /69/F/A2	UNSCHEDULED/25APR2012	TL:3/LUNG	LEFT LING SEG	CT		14	
	UNSCHEDULED/25APR2012	TL:4/LUNG	LEFT LING SEG	CT		17	
	UNSCHEDULED/25APR2012	NTL:1/LIVE	S5	CT	Present	.	
	UNSCHEDULED/25APR2012	NTL:2/LIVE	S7-8	CT	New	.	
	UNSCHEDULED/25APR2012	NTL:3/NODE	MEDIASTINAL	CT	New	.	
	UNSCHEDULED/25APR2012	NTL:4/LUNG	BILATERAL	CT	New	.	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
306-0005 /69/F/A2	UNSCHEDULED/25APR2012	NTL:5/GI	ASCITES	CT	New	.	
	Summary:					.	SLD = 80, %CN = 81.82, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 26APR2012
306-0006 /43/M/A2	SCREENING/22FEB2012	TL:1/LIVER	S8	CT		64	
	SCREENING/22FEB2012	TL:2/LIVER	S8	CT		88	SLD = 152
	SCREENING/22FEB2012	NTL:1/LIVE	RIGHT LOBE	CT		.	
	UNSCHEDULED/11APR2012	TL:1/LIVER	SEGMENT 8	CT		68	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
306-0006 /43/M/A2	UNSCHEDULED/11APR2012	TL:2/LIVER	SEGMENT 8	CT		98	
	UNSCHEDULED/11APR2012	NTL:1/LIVE	RIGHT LOBE	CT	Present	.	
	UNSCHEDULED/11APR2012	NTL:2/GI	ASCITES	CT	New	.	
	UNSCHEDULED/11APR2012	NTL:3/LIVE	BOTH LOBE	CT	New	.	
	Summary:					.	SLD = 166, %CN = 9.21, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 12APR2012
306-0007 /56/M/A2	SCREENING/09FEB2012	TL:1/LIVER	S7	CT		38	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
306-0007 /56/M/A2	SCREENING/09FEB2012	TL:2/LIVER	S3	CT		22	
	SCREENING/09FEB2012	TL:3/BONE	RIGHT ILIAC BONE	CT		25	SLD = 85
	UNSCHEDULED/23APR2012	NTL:1/BONE	MULTIPLE C-SPINE METASTASIS	MRI	New	.	
	Summary:					.	SLD = ., %CN = ., TL: NotEvaluable, NTL: PD, OR: PD, PD confirmed: Yes, 24APR2012
306-0008 /40/M/A2	SCREENING/07MAR2012	TL:1/LIVER	SEGMENT 3	CT		12	
	SCREENING/07MAR2012	TL:2/BONE	LEFT 9TH RIB	CT		78	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
306-0008 /40/M/A2	SCREENING/07MAR2012	TL:3/BONE	LEFT ILIACUS	CT		44	
	SCREENING/07MAR2012	TL:4/SOFTT	LEFT GLUTEAL	CT		93	
	SCREENING/07MAR2012	TL:5/LUNG	RIGHT LOWER LOBE	CT		10	SLD = 237
	SCREENING/07MAR2012	NTL:1/LUNG	BILATERAL PULMONARY	CT		.	
306-0011 /47/M/A2	SCREENING/07MAR2012	TL:1/LIVER	S6	CT		93	
	SCREENING/07MAR2012	TL:2/LIVER	S3	CT		20	

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[3] UP=Unequivocally Progressed
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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
306-0011 /47/M/A2	SCREENING/07MAR2012	TL:3/LUNG	RIGHT LOWER LOBE	CT		11	SLD = 124
	SCREENING/07MAR2012	NTL:1/LUNG	BILATERAL LUNG	CT		.	
	WEEK12/31MAY2012	TL:1/LIVER	S6	CT		150	
	WEEK12/31MAY2012	TL:2/LIVER	S3	CT		30	
	WEEK12/31MAY2012	TL:3/LUNG	RIGHT LOWER LOBE	CT		16	
	WEEK12/31MAY2012	NTL:1/LUNG	BILATERAL LUNG	CT	Present	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
306-0011 /47/M/A2	WEEK12/31MAY2012	NTL:2/NODE	SUBCARINAL LN	CT	New	.	
	WEEK12/31MAY2012	NTL:3/NODE	LEFT HILAR LN	CT	New	.	
	WEEK12/31MAY2012	NTL:4/LUNG	NUMEROUS NEW PULMONARY METASTATIC TUMORS IN BILATERAL LUNG.	CT	New	.	
	Summary:					.	SLD = 196, %CN = 58.06, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 04JUN2012
306-0012 /61/M/A2	SCREENING/29MAR2012	TL:1/LIVER	SEGMENT 7	CT		43	
	SCREENING/29MAR2012	TL:2/LIVER	SEGMENT 8	CT		43	SLD = 86

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[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
306-0012 /61/M/A2	WEEK12/19JUN2012	TL:1/LIVER	SEGMENT 7	CT		47	
	WEEK12/19JUN2012	TL:2/LIVER	SEGMENT 8	CT		42	
	Summary:					.	SLD = 89, %CN = 3.49, TL: SD, NTL: NotAssessed, OR: SD, PD confirmed: No
	WEEK24/11SEP2012	TL:1/LIVER	SEGMENT 7	CT		48	
	WEEK24/11SEP2012	TL:2/LIVER	SEGMENT 8	CT		40	
	Summary:					.	SLD = 88, %CN = 2.33, TL: SD, NTL: NotEvaluable, OR: SD, PD confirmed: No

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
306-0014 /47/M/A2	SCREENING/06APR2012	TL:1/LUNG	RIGHT LOWER LUNG	CT		16	
	SCREENING/06APR2012	TL:2/LUNG	RIGHT LOWER LUNG	CT		36	
	SCREENING/06APR2012	TL:3/LIVER	S2	CT		25	
	SCREENING/06APR2012	TL:4/LIVER	S3	CT		30	SLD = 107
306-0017 /49/M/A2	SCREENING/22JUN2012	TL:1/LIVER	S3	CT		74	
	SCREENING/22JUN2012	TL:2/LIVER	S3	CT		64	SLD = 138

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
306-0017 /49/M/A2	UNSCHEDULED/23AUG2012	TL:1/LIVER	S3	CT		94	
	UNSCHEDULED/23AUG2012	TL:2/LIVER	S3	CT		70	
	UNSCHEDULED/23AUG2012	NTL:1/LIVE	S8	CT	New	.	
	UNSCHEDULED/23AUG2012	NTL:2/LIVE	S7	CT	New	.	
	Summary:					.	SLD = 164, %CN = 18.84, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 31AUG2012
306-0019 /78/M/A2	SCREENING/08AUG2012	TL:1/LIVER	S8	CT		36	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
306-0019 /78/M/A2	SCREENING/08AUG2012	TL:2/LIVER	S2	CT		28	SLD = 64
	SCREENING/08AUG2012	NTL:1/NODE	RIGHT CLAVIAN	CT		.	
	SCREENING/08AUG2012	NTL:2/NODE	RIGHT TRACHEOBRONCHIAL	CT		.	
	WEEK12/01NOV2012	TL:1/LIVER	S8	CT		39	
	WEEK12/01NOV2012	TL:2/LIVER	S2	CT		30	
	WEEK12/01NOV2012	NTL:1/NODE	RIGHT CLAVIAN	CT	Present	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
306-0019 /78/M/A2	WEEK12/01NOV2012	NTL:2/NODE	RIGHT TRACHEOBRONCHIA L	CT	Present	.	
	WEEK12/01NOV2012	NTL:3/LIVE	MULTIPLE INFILTRATIVE HEPATOMA IN BOTH LOBES	CT	New	.	
	Summary:					.	SLD = 69, %CN = 7.81, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 05NOV2012
306-0020 /63/M/A2	SCREENING/27SEP2012	TL:1/LIVER	S8	CT		18	
	SCREENING/27SEP2012	TL:2/LIVER	S4	CT		12	SLD = 30
	SCREENING/27SEP2012	NTL:1/LIVE	S2	CT		.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
306-0020 /63/M/A2	SCREENING/27SEP2012	NTL:2/LIVE	S2	CT		.	
	SCREENING/27SEP2012	NTL:3/LIVE	S5	CT		.	
	WEEK12/20DEC2012	TL:1/LIVER	S8	CT		24	
	WEEK12/20DEC2012	TL:2/LIVER	S4	CT		16	
	WEEK12/20DEC2012	NTL:1/LIVE	S2	CT	Present	.	
	WEEK12/20DEC2012	NTL:2/LIVE	S2	CT	Present	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
306-0020 /63/M/A2	WEEK12/20DEC2012	NTL:3/LIVE	S5	CT	Present	.	
	WEEK12/20DEC2012	NTL:4/LIVE	S7	CT	New	.	
	Summary:					.	SLD = 40, %CN = 33.33, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 24DEC2012
306-0023 /68/M/A2	SCREENING/22NOV2012	TL:1/LIVER	SEGMENT 5	CT		33	
	SCREENING/22NOV2012	TL:2/LIVER	SEGMENT 6	CT		20	
	SCREENING/22NOV2012	TL:3/NODES	RIGHT CLAVICULAR	CT		15	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
306-0023 /68/M/A2	SCREENING/22NOV2012	TL:4/NODES	PORTOCAVAL	CT		18	SLD = 86
	UNSCHEDULED/03JAN2013	TL:1/LIVER	SEGMENT 5	CT		62	
	UNSCHEDULED/03JAN2013	TL:2/LIVER	SEGMENT 6	CT		19	
	UNSCHEDULED/03JAN2013	TL:3/NODES	RIGHT CLAVICULAR	CT		14	
	UNSCHEDULED/03JAN2013	TL:4/NODES	PORTOCAVAL	CT		18	
	UNSCHEDULED/03JAN2013	NTL:5/LIVE	S5	CT	New	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
306-0023 /68/M/A2	Summary:					.	SLD = 113, %CN = 31.4, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 08JAN2013
306-0026 /58/M/A2	SCREENING/01FEB2013	TL:1/LIVER	S4	CT		40	
	SCREENING/01FEB2013	TL:2/LIVER	S6	CT		29	
	SCREENING/01FEB2013	TL:3/GI	GALLBLADDER	CT		16	SLD = 85
	SCREENING/01FEB2013	NTL:1/LUNG	LEFT UPPER LOBE OF LUNG	CT		.	
	WEEK12/25APR2013	TL:1/LIVER	S4	CT		39	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
306-0026 /58/M/A2	WEEK12/25APR2013	TL:2/LIVER	S6	CT		29	
	WEEK12/25APR2013	TL:3/GI	GALLBLADDER	CT		26	
	WEEK12/25APR2013	NTL:1/LUNG	LEFT UPPER LOBE OF LUNG	CT	Present	.	
	Summary:					.	SLD = 94, %CN = 10.59, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK24/18JUL2013	TL:1/LIVER	S4	CT		26	
	WEEK24/18JUL2013	TL:2/LIVER	S6	CT		20	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
306-0026 /58/M/A2	WEEK24/18JUL2013	TL:3/GI	GALLBLADDER	CT		33	
	WEEK24/18JUL2013	NTL:1/LUNG	LEFT UPPER LOBE OF LUNG	CT	Absent	.	
	Summary:					.	SLD = 79, %CN = 0, TL: SD, NTL: CR, OR: SD, PD confirmed: No
	WEEK36/11OCT2013	TL:1/LIVER	S4	CT		33	
	WEEK36/11OCT2013	TL:2/LIVER	S6	CT		15	
	WEEK36/11OCT2013	TL:3/GI	GALLBLADDER	CT		49	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
306-0026 /58/M/A2	WEEK36/11OCT2013	NTL:1/LUNG	LEFT UPPER LOBE OF LUNG	CT	Absent	.	
	WEEK36/11OCT2013	NTL:2/GI	NEW THROMBOSIS IN MHV AND IVC.	CT	New	.	
	Summary:					.	SLD = 97, %CN = 22.78, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 17OCT2013
306-0027 /67/M/A2	SCREENING/18FEB2013	TL:1/LIVER	S4	CT		12	
	SCREENING/18FEB2013	TL:2/LIVER	S4	CT		42	SLD = 54
	SCREENING/18FEB2013	NTL:1/NODE	RIGHT THYROID CARTILAGE	CT		.	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
306-0027 /67/M/A2	SCREENING/18FEB2013	NTL:2/NODE	RIGHT HILAR LYMPH NODE	CT		.	
	UNSCHEDULED/25APR2013	TL:1/LIVER	S4	CT		11	
	UNSCHEDULED/25APR2013	TL:2/LIVER	S4	CT		40	
	UNSCHEDULED/25APR2013	NTL:1/NODE	RIGHT THYROID CRATILAGE	CT	Present	.	
	UNSCHEDULED/25APR2013	NTL:2/NODE	RIGHR HILAR LYMPH NODE	CT	Present	.	
	Summary:					.	SLD = 103, %CN = 101.96, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
306-0027 /67/M/A2	WEEK24/01AUG2013	TL:1/LIVER	S4	CT		11	
	WEEK24/01AUG2013	TL:2/LIVER	S4	CT		40	
	WEEK24/01AUG2013	NTL:1/NODE	RIGHT THYROID CARTILAGE	CT	Present	.	
	WEEK24/01AUG2013	NTL:2/NODE	RIGHT HILAR LYMPH NODE	CT	Present	.	
	Summary:					.	SLD = 51, %CN = 0, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	UNSCHEDULED/26SEP2013	TL:1/LIVER	S4	CT		11	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
306-0027 /67/M/A2	UNSCHEDULED/26SEP2013	TL:2/LIVER	S4	CT		41	
	UNSCHEDULED/26SEP2013	NTL:1/NODE	RIGHT THYROID CARTILAGE	CT	Present	.	
	UNSCHEDULED/26SEP2013	NTL:2/NODE	RIGHR HILAR LYMPH NODE	CT	Present	.	
	Summary:					.	SLD = 103, %CN = 101.96, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK36/24OCT2013	TL:1/LIVER	S4	CT		11	
	WEEK36/24OCT2013	TL:2/LIVER	S4	CT		41	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
306-0027 /67/M/A2	WEEK36/24OCT2013	NTL:1/NODE	RIGHT THYROID CARTILAGE	CT	Present	.	
	WEEK36/24OCT2013	NTL:2/NODE	RIGHT HILAR LYMPH NODE	CT	Present	.	
	Summary:					.	SLD = 52, %CN = 1.96, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK48/16JAN2014	TL:1/LIVER	S4	CT		14	
	WEEK48/16JAN2014	TL:2/LIVER	S4	CT		40	
	WEEK48/16JAN2014	NTL:1/NODE	RIGHT THYROID CARTILAGE	CT	Present	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
306-0027 /67/M/A2	WEEK48/16JAN2014	NTL:2/NODE	RIGHT HILAR LYMPH NODE	CT	Present	.	
	Summary:					.	SLD = 54, %CN = 5.88, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK60/10APR2014	TL:1/LIVER	S4	CT		20	
	WEEK60/10APR2014	TL:2/LIVER	S4	CT		40	
	WEEK60/10APR2014	NTL:1/NODE	RIGHT THYROID CARTILAGE	CT	Present	.	
	WEEK60/10APR2014	NTL:2/NODE	RIGHT HILAR LYMPH NODE	CT	Present	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
306-0027 /67/M/A2	Summary:					.	SLD = 60, %CN = 17.65, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK72/02JUL2014	TL:1/LIVER	S4	CT		27	
	WEEK72/02JUL2014	TL:2/LIVER	S4	CT		40	
	WEEK72/02JUL2014	NTL:1/NODE	RIGHT THYROID CARTILAGE	CT	Present	.	
	WEEK72/02JUL2014	NTL:2/NODE	RIGHT HILAR LYMPH NODE	CT	Present	.	
	Summary:					.	SLD = 67, %CN = 31.37, TL: PD, NTL: IncompleteResponse/SD, OR: PD, PD confirmed: Yes, 09JUL2014

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
306-0030 /63/M/A2	SCREENING/18APR2013	TL:1/LIVER	S7-8	CT		47	
	SCREENING/18APR2013	TL:2/LIVER	S2	CT		36	SLD = 83
	SCREENING/18APR2013	NTL:1/NODE	RIGHT AXILLAR	CT		.	
	SCREENING/18APR2013	NTL:2/NODE	PORTOCAVAL	CT		.	
	SCREENING/18APR2013	NTL:3/BONE	RIGHT 3RD RIB, T12 AND L4	CT		.	
306-0031 /40/M/A2	SCREENING/09MAY2013	TL:1/LIVER	S4	CT		56	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
306-0031 /40/M/A2	SCREENING/09MAY2013	TL:2/LIVER	S4-5-6	CT		131	SLD = 187
	SCREENING/09MAY2013	NTL:1/LIVE	S4	CT		.	
	SCREENING/09MAY2013	NTL:2/LIVE	RIGHT LOBE	CT		.	
	UNSCHEDULED/18JUL2013	TL:1/LIVER	S4	CT		61	
	UNSCHEDULED/18JUL2013	TL:2/LIVER	S4-5-6	CT		136	
	UNSCHEDULED/18JUL2013	NTL:1/LIVE	S4	CT	Present	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
306-0031 /40/M/A2	UNSCHEDULED/18JUL2013	NTL:2/LUNG	RIGHT UPPER LOBE	CT	New	.	
	UNSCHEDULED/18JUL2013	NTL:3/LUNG	RIGHT MIDDLE LOBE	CT	New	.	
	UNSCHEDULED/18JUL2013	NTL:4/LIVE	RIGHT LOBE	CT	Present	.	
	Summary:					.	SLD = 197, %CN = 5.35, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 24JUL2013
306-0034 /65/M/A2	SCREENING/27JUN2013	TL:1/BONE	T8	CT		51	
	SCREENING/27JUN2013	TL:2/BONE	T12	CT		44	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
306-0034 /65/M/A2	SCREENING/27JUN2013	TL:3/LIVER	S6-7	CT		94	
	SCREENING/27JUN2013	TL:4/LIVER	S6	CT		67	SLD = 256
	SCREENING/27JUN2013	NTL:1/LUNG	RIGHT LOWER LOBE	CT		.	
	SCREENING/27JUN2013	NTL:2/LUNG	LEFT LOWER LOBE	CT		.	
	UNSCHEDULED/25JUL2013	NTL:3/BONE	T-L SPINE	MRI	New	.	
	Summary:					.	SLD = ., %CN = ., TL: NotAssessed, NTL: PD, OR: PD, PD confirmed: Yes, 01AUG2013

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
306-0035 /48/M/A2	SCREENING/04JUL2013	TL:1/LIVER	S4	CT		33	
	SCREENING/04JUL2013	TL:2/LIVER	S2	CT		28	
	SCREENING/04JUL2013	TL:3/NODES	SUBCARINAL LYMPH NODE	CT		30	
	SCREENING/04JUL2013	TL:4/NODES	RETROPERITONEAL LYMPH NODE	CT		22	SLD = 113
	UNSCHEDULED/22AUG2013	TL:1/LIVER	S4	CT		41	
	UNSCHEDULED/22AUG2013	TL:2/LIVER	S2	CT		32	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
306-0035 /48/M/A2	UNSCHEDULED/22AUG2013	TL:3/NODES	SUBCARINAL LYMPH NODE	CT		33	
	UNSCHEDULED/22AUG2013	TL:4/NODES	RETROPERITONEAL LYMPH NODE	CT		35	
	UNSCHEDULED/22AUG2013	NTL:1/LUNG	BILATERAL PULMONARY METASTASIS	CT	New	.	
	UNSCHEDULED/22AUG2013	NTL:2/NODE	NECK	CT	New	.	
	UNSCHEDULED/22AUG2013	NTL:3/NODE	RETROPERITONEAL	CT	New	.	
	Summary:					.	SLD = 141, %CN = 24.78, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 26AUG2013

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
306-0036 /73/M/A2	SCREENING/04JUL2013	TL:1/LIVER	S8	CT		23	
	SCREENING/04JUL2013	TL:2/LIVER	S8	CT		18	
	SCREENING/04JUL2013	TL:3/NODES	CENTRAL SUBPHRENIC	CT		52	SLD = 93
	UNSCHEDULED/09SEP2013	NTL:1/ASCI	RIGHT INGUINAL	CT	New	.	
	Summary:					.	SLD = ., %CN = ., TL: NotAssessed, NTL: PD, OR: PD, PD confirmed: Yes, 24SEP2014
306-0038 /66/M/A2	SCREENING/15AUG2013	TL:1/LUNG	RIGHT UPPER LOBE	CT		22	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
306-0038 /66/M/A2	SCREENING/15AUG2013	TL:2/LUNG	RIGHT LOWER LOBE	CT		28	SLD = 50
	SCREENING/15AUG2013	NTL:1/LUNG	MORE THAN 10 PULMONARY METASTASIS	CT		.	
	WEEK12/31OCT2013	TL:1/LUNG	RIGHT UPPER LOBE	CT		37	
	WEEK12/31OCT2013	TL:2/LUNG	RIGHT LOWER LOBE	CT		37	
	WEEK12/31OCT2013	NTL:1/LUNG	MORE THAN 10 PULMONARY METASTASIS	CT	Present	.	
	WEEK12/31OCT2013	NTL:2/LUNG	MULTIPLE NEW PULMONARY METASTASIS, NEW MULTIPLE MEDIASTINAL METASTASIS LYMPH NODES	CT	New	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
306-0038 /66/M/A2	Summary:					.	SLD = 74, %CN = 48, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 06NOV2013
306-0039 /62/M/A2	SCREENING/16AUG2013	TL:1/LUNG	LEFT UPPER LUNG	CT		30	
	SCREENING/16AUG2013	TL:2/LUNG	LEFT LOWER LUNG	CT		44	
	SCREENING/16AUG2013	TL:3/NODES	RIGHT PARATRACHEAL LYMPH NODES	CT		92	
	SCREENING/16AUG2013	TL:4/NODES	LEFT PREVASCULAR LYMPH NODES	CT		77	
	SCREENING/16AUG2013	TL:5/SOFTT	RIGHT GLUTEAL MUSCLE	CT		31	SLD = 274

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
306-0039 /62/M/A2	SCREENING/16AUG2013	NTL:1/NODE	MULTIPLE PULMONARY AND MEDIASTINAL LYMPH NODES METASTASIS	CT		.	
	WEEK12/31OCT2013	TL:1/LUNG	LEFT UPPER LUNG	CT		28	
	WEEK12/31OCT2013	TL:2/LUNG	LEFT LOWER LUNG	CT		49	
	WEEK12/31OCT2013	TL:3/NODES	RIGHT PARATRACHEAL LYMPH NODES	CT		97	
	WEEK12/31OCT2013	TL:4/NODES	LEFT PREVASCULAR LYMPH NODES	CT		86	
	WEEK12/31OCT2013	TL:5/SOFTT	RIGHT GLUTEAL MUSCLE	CT		39	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
306-0039 /62/M/A2	WEEK12/31OCT2013	NTL:1/NODE	MULTIPLE PULMONARY AND MEDIASTINAL LYMPH NODES METASTASIS	CT	Present	.	
	WEEK12/31OCT2013	NTL:2/BONE	BONY PATHOLOGY OF LEFT 7TH, 11TH AND 12TH RIBS.	CT	New	.	
	Summary:					.	SLD = 299, %CN = 9.12, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 05NOV2013
306-0040 /44/F/A2	SCREENING/20SEP2013	TL:1/SOFTT	PELVIS	CT		183	
	SCREENING/20SEP2013	TL:2/SOFTT	LEFT MESENTERY	CT		21	
	SCREENING/20SEP2013	TL:3/SOFTT	LEFT POST PELVIS	CT		23	SLD = 227

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
306-0040 /44/F/A2	SCREENING/20SEP2013	NTL:1/SOFT	PERITONEAL CARCINOMATOSIS	CT		.	
	UNSCHEDULED/14NOV2013	TL:1/SOFTT	PELVIS	CT		170	
	UNSCHEDULED/14NOV2013	TL:2/SOFTT	LEFT MESENTERY	CT		40	
	UNSCHEDULED/14NOV2013	TL:3/SOFTT	LEFT POST PELVIS	CT		22	
	UNSCHEDULED/14NOV2013	NTL:1/SOFT	PERITONEAL CARCINOMATOSIS	CT	Present	.	
	Summary:					.	SLD = 232, %CN = 2.2, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No

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Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
306-0040 /44/F/A2	WEEK12/12DEC2013	TL:1/SOFTT	PELVIS	CT		174	
	WEEK12/12DEC2013	TL:2/SOFTT	LEFT MESENTERY	CT		39	
	WEEK12/12DEC2013	TL:3/SOFTT	LEFT POST PELVIS	CT		23	
	WEEK12/12DEC2013	NTL:1/SOFT	PERITONEAL CARCINOMATOSIS	CT	Present	.	
	Summary:					.	SLD = 236, %CN = 3.96, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK24/06MAR2014	TL:1/SOFTT	PELVIS	CT		192	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
306-0040 /44/F/A2	WEEK24/06MAR2014	TL:2/SOFTT	LEFT MESENTERY	CT		65	
	WEEK24/06MAR2014	TL:3/SOFTT	LEFT POST PELVIS	CT		19	
	WEEK24/06MAR2014	NTL:1/SOFT	PERITONEAL CARCINOMATOSIS	CT	UP	.	
	WEEK24/06MAR2014	NTL:2/LIVE	LEFT LATERAL SEGMENT OF LIVER	CT	New	.	
	Summary:					.	SLD = 276, %CN = 21.59, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 11MAR2014
306-0041 /62/M/A2	SCREENING/24OCT2013	TL:1/NODES	RETROCAVAL	CT		15	

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Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
306-0041 /62/M/A2	SCREENING/24OCT2013	TL:2/NODES	LEFT PARA-AORTIC	CT		16	SLD = 31
	SCREENING/24OCT2013	NTL:1/NODE	LEFT SUPRACLAVICULAR	CT		.	
	SCREENING/24OCT2013	NTL:2/NODE	LEFT AXILLARY	CT		.	
	WEEK12/16JAN2014	TL:1/NODES	RETROCAVAL	CT		15	
	WEEK12/16JAN2014	TL:2/NODES	LEFT PARA-AORTIC	CT		15	
	WEEK12/16JAN2014	NTL:1/NODE	LEFT SUPRACLAVICULAR	CT	Present	.	

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Tumor Assessment Summary Listing
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Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
306-0041 /62/M/A2	WEEK12/16JAN2014	NTL:2/NODE	LEFT AXILLARY	CT	Present	.	
	Summary:					.	SLD = 30, %CN = -3.23, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	UNSCHEDULED/21FEB2014	NTL:1/NODE	LEFT SUPRACLAVICULAR	CT	UP	.	
	UNSCHEDULED/21FEB2014	NTL:2/NODE	LEFT AXILLARY	CT	UP	.	
	UNSCHEDULED/21FEB2014	NTL:3/SOFT	MULTIPLE SUBCUTANEOUS NODULES IN THE LEFT CHEST WALL	CT	New	.	
	Summary:					.	SLD = ., %CN = ., TL: NotAssessed, NTL: PD, OR: PD, PD confirmed: Yes, 24FEB2014

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Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
306-0043 /56/M/A2	SCREENING/13MAY2014	TL:1/LUNG	RIGHT LOWER LOBE	CT		10	
	SCREENING/13MAY2014	TL:2/NODES	HEPATODUODENAL LIGAMENT	CT		45	
	SCREENING/13MAY2014	TL:3/NODES	LEFT PERIAORTA	CT		26	
	SCREENING/13MAY2014	TL:4/LIVER	SEGMENT 6	CT		41	SLD = 122
	SCREENING/13MAY2014	NTL:1/LIVE	SEGMENT 7-8 (CONFLUENT MASS)	CT		.	
	WEEK12/04AUG2014	TL:1/LUNG	RIGHT LOWER LOBE	CT		10	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
306-0043 /56/M/A2	WEEK12/04AUG2014	TL:2/NODES	HEPATODUODENAL LIGAMENT	CT		50	
	WEEK12/04AUG2014	TL:3/NODES	LEFT PERIAORTA	CT		39	
	WEEK12/04AUG2014	TL:4/LIVER	SEGMENT 6	CT		56	
	WEEK12/04AUG2014	NTL:1/LIVE	SEGMENT 7-8 (CONFLUENT MASS)	CT	UP	.	
	WEEK12/04AUG2014	NTL:2/LUNG	MULTIPLE LUNG NODULES	CT	New	.	
	WEEK12/04AUG2014	NTL:3/LIVE	MULTIPLE LIVER TUMOR	CT	New	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
306-0043 /56/M/A2	WEEK12/04AUG2014	NTL:4/NODE	ENLARGED MEDIASTINAL	CT	New	.	
	WEEK12/04AUG2014	NTL:5/NODE	RETROPERITONEAL LYMPHONODE	CT	New	.	
	Summary:					.	SLD = 155, %CN = 27.05, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 11AUG2014
307-0002 /61/M/A2	SCREENING/31OCT2011	TL:1/LIVER	HCC, S2	CT		34	
	SCREENING/31OCT2011	TL:2/LIVER	HCC, S4	CT		21	SLD = 55
	SCREENING/31OCT2011	NTL:1/LIVE	HCC, S8, S/P TREATMENT	CT		.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
307-0002 /61/M/A2	SCREENING/31OCT2011	NTL:2/LUNG	LUNG METASTASIS, RUL	CT		.	
	SCREENING/31OCT2011	NTL:3/LIVE	PORTAL VEIN THROMBOSIS, MAIN AND BILATERAL	CT		.	
	SCREENING/31OCT2011	NTL:4/LIVE	HEPATIC VEIN THROMBOSIS, LEFT	CT		.	
	WEEK12/20JAN2012	TL:1/LIVER	HCC, S2	CT		27	
	WEEK12/20JAN2012	TL:2/LIVER	HCC, S4	CT		21	
	WEEK12/20JAN2012	NTL:1/LIVE	HCC, S8, S/P TREATMENT	CT	Present	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
307-0002 /61/M/A2	WEEK12/20JAN2012	NTL:2/LUNG	LUNG METASTASIS, RUL	CT	UP	.	
	WEEK12/20JAN2012	NTL:3/LIVE	PORTAL VEIN THROMBOSIS, MAIN AND BILATERAL	CT	Present	.	
	WEEK12/20JAN2012	NTL:4/LIVE	HEPATIC VEIN THROMBOSIS, LEFT	CT	Present	.	
	WEEK12/20JAN2012	NTL:5/LUNG	LUNG METASTASIS, LUL	CT	New	.	
	Summary:					.	SLD = 48, %CN = -12.73, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 20JAN2012
307-0003 /68/M/A2	SCREENING/04NOV2011	TL:1/LIVER	HCC, S5	CT		38	SLD = 38

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
307-0003 /68/M/A2	SCREENING/04NOV2011	NTL:1/LIVE	HCC, BOTH LOBES	CT		.	
	WEEK12/31JAN2012	TL:1/LIVER	HCC, S5	CT		37	
	WEEK12/31JAN2012	NTL:1/LIVE	HCC, BOTH LOBES	CT	Present	.	
	Summary:					.	SLD = 37, %CN = -2.63, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK24/16APR2012	TL:1/LIVER	HCC, S5	CT		32	
	WEEK24/16APR2012	NTL:1/LIVE	HCC, BOTH LOBES	CT	Present	.	

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[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
307-0003 /68/M/A2	Summary:					.	SLD = 32, %CN = 6.67, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK36/10JUL2012	TL:1/LIVER	S5	CT		30	
	WEEK36/10JUL2012	NTL:1/LIVE	HCC, BOTH LOBES	CT	Present	.	
	Summary:					.	SLD = 30, %CN = 0, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
307-0004 /60/M/A2	SCREENING/04NOV2011	TL:1/LUNG	LUNG METASTASIS, LINGUAL LOBE	CT		22	
	SCREENING/04NOV2011	TL:2/LUNG	LUNG METASTASIS, LEFT LOWER LOBE	CT		13	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
307-0004 /60/M/A2	SCREENING/04NOV2011	TL:3/NODES	LUMPH NODES, ANTERIOR MEDIASTINUM	CT		15	
	SCREENING/04NOV2011	TL:4/SOFTT	METASTASIS, LEFT INFRASPINATUS MUSCLE	CT		73	SLD = 123
	SCREENING/04NOV2011	NTL:1/LUNG	LUNG METASTASIS, BOTH LUNG	CT		.	
	SCREENING/04NOV2011	NTL:2/ASCI		CT		.	
	UNSCHEDULED/19JAN2012	NTL:3/BONE	T4 BONY METASTASIS	MRI	New	.	
	Summary:					.	SLD = ., %CN = ., TL: NotAssessed, NTL: PD, OR: PD, PD confirmed: Yes, 27JAN2012

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
307-0008 /58/M/A2	SCREENING/28NOV2011	TL:1/LUNG	RIGHT MIDDLE LOBE	CT		32	
	SCREENING/28NOV2011	TL:2/LUNG	LEFT LOWER LOBE	CT		22	SLD = 54
	SCREENING/28NOV2011	NTL:1/LIVE	POST SURGICAL TREATMENT	CT		.	
	SCREENING/28NOV2011	NTL:2/SOFT	PERITONEAL CARCINOMATOSIS	CT		.	
	WEEK12/08MAR2012	TL:1/LUNG	RIGHT MIDDLE LOBE	CT		40	
	WEEK12/08MAR2012	TL:2/LUNG	LEFT LOWER LOBE	CT		20	

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Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
307-0008 /58/M/A2	WEEK12/08MAR2012	NTL:1/LIVE	POST SURGICAL TREATMENT	CT	Present	.	
	WEEK12/08MAR2012	NTL:2/SOFT	PERITONEAL CARCINOMATOSIS	CT	Present	.	
	WEEK12/08MAR2012	NTL:3/LUNG	BOTH LUNGS	CT	New	.	
	Summary:					.	SLD = 60, %CN = 11.11, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 12MAR2012
307-0011 /75/M/A2	SCREENING/03FEB2012	TL:1/LIVER	HCC, S7-8	CT		155	
	SCREENING/03FEB2012	TL:2/LIVER	HCC, S6-7	CT		107	SLD = 262

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
307-0011 /75/M/A2	SCREENING/03FEB2012	NTL:1/LIVE	PORTAL VEIN THROMBOSIS, RIGHT	CT		.	
	SCREENING/03FEB2012	NTL:2/LIVE	PORTAL VEIN THROMBOSIS, LEFT	CT		.	
	SCREENING/03FEB2012	NTL:3/ASCI		CT		.	
307-0014 /61/M/A2	SCREENING/20JAN2012	TL:1/LIVER	SEGMENT 7-8	CT		29	
	SCREENING/20JAN2012	TL:2/NODES	LOWER PARATRACHEAL	CT		18	SLD = 47
	SCREENING/20JAN2012	NTL:1/LIVE	BOTH LOBES	CT		.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
307-0014 /61/M/A2	SCREENING/20JAN2012	NTL:2/NODE	PARA-AORTIC	CT		.	
	WEEK12/08MAY2012	TL:1/LIVER	SEGMENT 7-8	CT		33	
	WEEK12/08MAY2012	TL:2/NODES	LOWER PARATRACHEAL	CT		18	
	WEEK12/08MAY2012	NTL:1/LIVE	BOTH LOBES	CT	Present	.	
	WEEK12/08MAY2012	NTL:2/NODE	PARA-AORTIC	CT	Present	.	
	Summary:					.	SLD = 51, %CN = 8.51, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No

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Listing 16.2.6.2
Tumor Assessment Summary Listing
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Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
307-0014 /61/M/A2	WEEK24/26JUL2012	TL:1/LIVER	SEGMENT 7-8	CT		41	
	WEEK24/26JUL2012	TL:2/NODES	LOWER PARATRACHEAL	CT		18	
	WEEK24/26JUL2012	NTL:1/LIVE	BOTH LOBES	CT	Present	.	
	WEEK24/26JUL2012	NTL:2/NODE	PARA-AORTIC	CT	Present	.	
	WEEK24/26JUL2012	NTL:3/LIVE	SEGMENT 6	CT	New	.	
	Summary:					.	SLD = 59, %CN = 25.53, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 28JUL2012

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
307-0018 /70/M/A2	SCREENING/11JUN2012	TL:1/LIVER	SEGMENT 8	CT		34	
	SCREENING/11JUN2012	TL:2/LIVER	SEGMENT 6	CT		31	SLD = 65
	SCREENING/11JUN2012	NTL:1/LIVE	BOTH LOBES	CT		.	
	SCREENING/11JUN2012	NTL:2/NODE	LYMPH NODE, PERI-PANCREATIC	CT		.	
	WEEK12/30AUG2012	TL:1/LIVER	SEGMENT 8	CT		34	
	WEEK12/30AUG2012	TL:2/LIVER	SEGMENT 6	CT		33	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
307-0018 /70/M/A2	WEEK12/30AUG2012	NTL:1/LIVE	BOTH LOBES	CT	Present	.	
	WEEK12/30AUG2012	NTL:2/NODE	LYMPH NODE, PERI-PANCREATIC	CT	Present	.	
	Summary:					.	SLD = 67, %CN = 3.08, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK24/22NOV2012	TL:1/LIVER	SEGMENT 8	CT		36	
	WEEK24/22NOV2012	TL:2/LIVER	SEGMENT 6	CT		33	
	WEEK24/22NOV2012	NTL:1/LIVE	BOTH LOBES	CT	Present	.	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
307-0018 /70/M/A2	WEEK24/22NOV2012	NTL:2/NODE	LYMPH NODE, PERI-PANCREATIC	CT	Present	.	
	Summary:					.	SLD = 69, %CN = 6.15, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK36/14FEB2013	TL:1/LIVER	SEGMENT 8	CT		37	
	WEEK36/14FEB2013	TL:2/LIVER	SEGMENT 6	CT		37	
	WEEK36/14FEB2013	NTL:1/LIVE	BOTH LOBES	CT	Present	.	
	WEEK36/14FEB2013	NTL:2/NODE	LYMPH NODE, PERI-PANCREATIC	CT	Present	.	

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[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
307-0018 /70/M/A2	Summary:					.	SLD = 74, %CN = 13.85, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK48/09MAY2013	TL:1/LIVER	SEGMENT 8	CT		43	
	WEEK48/09MAY2013	TL:2/LIVER	SEGMENT 6	CT		38	
	WEEK48/09MAY2013	NTL:1/LIVE	BOTH LOBES	CT	Present	.	
	WEEK48/09MAY2013	NTL:2/NODE	LYMPH NODE, PERI-PANCREATIC	CT	Present	.	
	Summary:					.	SLD = 81, %CN = 24.62, TL: PD, NTL: IncompleteResponse/SD, OR: PD, PD confirmed: Yes, 16MAY2013

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
307-0020 /68/F/A2	SCREENING/07AUG2012	TL:1/LIVER	SEGMENT 2-4	CT		31	
	SCREENING/07AUG2012	TL:2/LIVER	SEGMENT 4-8	CT		32	
	SCREENING/07AUG2012	TL:3/LUNG	RIGHT UPPER LOBE	CT		32	
	SCREENING/07AUG2012	TL:4/LUNG	RIGHT LOWER LOBE	CT		36	SLD = 131
	SCREENING/07AUG2012	NTL:1/LIVE	BOTH LOBES	CT		.	
	SCREENING/07AUG2012	NTL:2/LUNG	BOTH LUNGS	CT		.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
307-0020 /68/F/A2	WEEK12/30OCT2012	TL:1/LIVER	SEGMENT 2-4	CT		46	
	WEEK12/30OCT2012	TL:2/LIVER	SEGMENT 4-8	CT		48	
	WEEK12/30OCT2012	TL:3/LUNG	RIGHT UPPER LOBE	CT		39	
	WEEK12/30OCT2012	TL:4/LUNG	RIGHT LOWER LOBE	CT		47	
	WEEK12/30OCT2012	NTL:1/LIVE	BOTH LOBES	CT	UP	.	
	WEEK12/30OCT2012	NTL:2/LUNG	BOTH LUNGS	CT	UP	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
307-0020 /68/F/A2	WEEK12/30OCT2012	NTL:3/ASCI		CT	New	.	
	Summary:					.	SLD = 180, %CN = 37.4, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 31OCT2012
307-0022 /59/M/A2	SCREENING/21NOV2012	TL:1/SOFTT	RIGHT SUBPHRENIC	CT		28	
	SCREENING/21NOV2012	TL:2/SOFTT	RIGHT 9TH INTERCOSTAL	CT		31	
	SCREENING/21NOV2012	TL:3/SOFTT	RIGHT 7TH INTERCOSTAL	CT		30	
	SCREENING/21NOV2012	TL:4/NODES	LEFT MESENTERIC	CT		72	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
307-0022 /59/M/A2	SCREENING/21NOV2012	TL:5/NODES	INFERIOR MESENTERIC	CT		88	SLD = 249
	SCREENING/21NOV2012	NTL:1/LIVE	SEGMENT 4	CT		.	
	SCREENING/21NOV2012	NTL:2/SOFT	METASTASES, RIGHT SUBPHRENIC	CT		.	
	SCREENING/21NOV2012	NTL:3/LUNG	LUNG METASTASES, BOTH LUNGS	CT		.	
	SCREENING/21NOV2012	NTL:4/NODE	LYMPH NODE, RIGHT EXTERNAL ILIAC	CT		.	
	SCREENING/21NOV2012	NTL:5/ASCI		CT		.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
307-0022 /59/M/A2	WEEK12/14FEB2013	TL:1/SOFTT	RIGHT SUBPHRENIC	CT		45	
	WEEK12/14FEB2013	TL:2/SOFTT	RIGHT 9TH INTERCOSTAL	CT		23	
	WEEK12/14FEB2013	TL:3/SOFTT	RIGHT 7TH INTERCOSTAL	CT		30	
	WEEK12/14FEB2013	TL:4/NODES	LEFT MESENTERIC	CT		80	
	WEEK12/14FEB2013	TL:5/NODES	INFERIOR MESENTERIC	CT		100	
	WEEK12/14FEB2013	NTL:1/LIVE	SEGMENT 4	CT	Present	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
307-0022 /59/M/A2	WEEK12/14FEB2013	NTL:2/SOFT	METASTASES, RIGHT SUBPHRENIC	CT	Present	.	
	WEEK12/14FEB2013	NTL:3/LUNG	LUNG METASTASES, BOTH LUNGS	CT	Present	.	
	WEEK12/14FEB2013	NTL:4/NODE	LYMPH NODE, RIGHT EXTERNAL ILIAC	CT	Present	.	
	WEEK12/14FEB2013	NTL:5/ASCI		CT	Present	.	
	WEEK12/14FEB2013	NTL:6/LUNG	LUNG METASTASES, BOTH LUNGS	CT	New	.	
	Summary:					.	SLD = 278, %CN = 11.65, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 18FEB2013

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
307-0025 /68/M/A2	SCREENING/10DEC2012	TL:1/LIVER	SEGMENT 4-8	CT		19	
	SCREENING/10DEC2012	TL:2/LIVER	SEGMENT 5-6	CT		21	SLD = 40
	SCREENING/10DEC2012	NTL:1/LIVE	HCC, BOTH LOBE	CT		.	
	SCREENING/10DEC2012	NTL:2/NODE	LYMPH NODE, PERI-GASTRIC	CT		.	
	SCREENING/10DEC2012	NTL:3/NODE	LYMPH NODE, HEPATO-DUODENAL	CT		.	
	WEEK12/07MAR2013	TL:1/LIVER	SEGMENT 4-8	CT		17	

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[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
307-0025 /68/M/A2	WEEK12/07MAR2013	TL:2/LIVER	SEGMENT 5-6	CT		21	
	WEEK12/07MAR2013	NTL:1/LIVE	HCC, BOTH LOBE	CT	Present	.	
	WEEK12/07MAR2013	NTL:2/NODE	LYMPH NODE, PERI-GASTRIC	CT	Present	.	
	WEEK12/07MAR2013	NTL:3/NODE	LYMPH NODE, HEPATO-DUODENAL	CT	Present	.	
	Summary:					.	SLD = 38, %CN = -5, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK24/30MAY2013	TL:1/LIVER	SEGMENT 4-8	CT		21	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
307-0025 /68/M/A2	WEEK24/30MAY2013	TL:2/LIVER	SEGMENT 5-6	CT		25	
	WEEK24/30MAY2013	NTL:1/LIVE	HCC, BOTH LOBE	CT	UP	.	
	WEEK24/30MAY2013	NTL:2/NODE	LYMPH NODE, PERI-GASTRIC	CT	Present	.	
	WEEK24/30MAY2013	NTL:3/NODE	LYMPH NODE, HEPATO-DUODENAL	CT	Present	.	
	WEEK24/30MAY2013	NTL:4/ASCI		CT	New	.	
	Summary:					.	SLD = 46, %CN = 21.05, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 03JUN2013

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
307-0026 /65/M/A2	SCREENING/12DEC2012	TL:1/LIVER	SEGMENT 2	CT		43	
	SCREENING/12DEC2012	TL:2/LIVER	SEGMENT 2-3	CT		76	SLD = 119
	SCREENING/12DEC2012	NTL:1/LIVE	BOTH LOBE	CT		.	
	WEEK12/12MAR2013	TL:1/LIVER	SEGMENT 2	CT		45	
	WEEK12/12MAR2013	TL:2/LIVER	SEGMENT 2-3	CT		79	
	WEEK12/12MAR2013	NTL:1/LIVE	BOTH LOBE	CT	Present	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
307-0026 /65/M/A2	Summary:					.	SLD = 124, %CN = 4.2, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK24/04JUN2013	TL:1/LIVER	SEGMENT 2	CT		52	
	WEEK24/04JUN2013	TL:2/LIVER	SEGMENT 2-3	CT		97	
	WEEK24/04JUN2013	NTL:1/LIVE	BOTH LOBE	CT	Present	.	
	Summary:					.	SLD = 149, %CN = 25.21, TL: PD, NTL: IncompleteResponse/SD, OR: PD, PD confirmed: Yes, 05JUN2013
307-0030 /53/M/A2	SCREENING/01MAR2013	TL:1/LIVER	SEGMENT 3	CT		22	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
307-0030 /53/M/A2	SCREENING/01MAR2013	TL:2/LIVER	SEGMENT 3	CT		33	
	SCREENING/01MAR2013	TL:3/LUNG	RIGHR MIDDLE LOBE	CT		21	
	SCREENING/01MAR2013	TL:4/LUNG	LEFT LOWER LUNG	CT		27	SLD = 103
	SCREENING/01MAR2013	NTL:1/LIVE	RIGHT LOBE	CT		.	
	SCREENING/01MAR2013	NTL:2/LIVE	PORTAL VEIN THROMBOSIS, RIGHT INFERIOR	CT		.	
	SCREENING/01MAR2013	NTL:3/LUNG	BOTH LUNGS	CT		.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
307-0030 /53/M/A2	SCREENING/01MAR2013	NTL:4/ASCI		CT		.	
	UNSCHEDULED/13MAY2013	TL:1/LIVER	SEGMENT 3	CT		33	
	UNSCHEDULED/13MAY2013	TL:2/LIVER	SEGMENT 3	CT		37	
	UNSCHEDULED/13MAY2013	TL:3/LUNG	RIGHT MIDDLE LOBE	CT		24	
	UNSCHEDULED/13MAY2013	TL:4/LUNG	LEFT LOWER LOBE	CT		42	
	UNSCHEDULED/13MAY2013	NTL:1/LIVE	RIGHT LOBE	CT	Present	.	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
307-0030 /53/M/A2	UNSCHEDULED/13MAY2013	NTL:2/LIVE	PORTAL VEIN THROMBOSIS, RIGHT INFERIOR	CT	UP	.	
	UNSCHEDULED/13MAY2013	NTL:3/LUNG	BOTH LUNGS	CT	UP	.	
	UNSCHEDULED/13MAY2013	NTL:4/ASCI		CT	Present	.	
	Summary:					.	SLD = 136, %CN = 32.04, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 14MAY2013
307-0031 /60/M/A2	SCREENING/04MAR2013	TL:1/LIVER	SEGMENT 7-8	CT		34	
	SCREENING/04MAR2013	TL:2/LIVER	SEGMENT 6	CT		20	SLD = 54

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
307-0031 /60/M/A2	SCREENING/04MAR2013	NTL:1/LIVE	RIGHT LOBE, S/P TREATMENT	CT		.	
	SCREENING/04MAR2013	NTL:2/LIVE	RIGHT LOBE	CT		.	
	WEEK12/30MAY2013	TL:1/LIVER	SEGMENT 7-8	CT		37	
	WEEK12/30MAY2013	TL:2/LIVER	SEGMENT 6	CT		21	
	WEEK12/30MAY2013	NTL:1/LIVE	RIGHT LOBE, S/P TREATMENT	CT	Present	.	
	WEEK12/30MAY2013	NTL:2/LIVE	RIGHT LOBE	CT	Present	.	

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[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
307-0031 /60/M/A2	Summary:					.	SLD = 58, %CN = 7.41, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK24/22AUG2013	TL:1/LIVER	SEGMENT 7-8	CT		45	
	WEEK24/22AUG2013	TL:2/LIVER	SEGMENT 6	CT		17	
	WEEK24/22AUG2013	NTL:1/LIVE	RIGHT LOBE, S/P TREATMENT	CT	Present	.	
	WEEK24/22AUG2013	NTL:2/LIVE	RIGHT LOBE	CT	Present	.	
	Summary:					.	SLD = 62, %CN = 14.81, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
307-0031 /60/M/A2	WEEK36/14NOV2013	TL:1/LIVER	SEGMENT 7-8	CT		45	
	WEEK36/14NOV2013	TL:2/LIVER	SEGMENT 6	CT		18	
	WEEK36/14NOV2013	NTL:1/LIVE	RIGHT LOBE, S/P TREATMENT	CT	Present	.	
	WEEK36/14NOV2013	NTL:2/LIVE	RIGHT LOBE	CT	Present	.	
	WEEK36/14NOV2013	NTL:3/LIVE	PORTAL VEIN THROMBOSIS, MAIN AND BILATERAL	CT	New	.	
	WEEK36/14NOV2013	NTL:4/GI	SMV THROMBOSIS	CT	New	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
307-0031 /60/M/A2	WEEK36/14NOV2013	NTL:5/LUNG	BILATERAL PLEURAL EFFUSION	CT	New	.	
	Summary:					.	SLD = 63, %CN = 16.67, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 18NOV2013
307-0032 /74/F/A2	SCREENING/10APR2013	TL:1/LIVER	SEGMENT 4-8	CT		89	
	SCREENING/10APR2013	TL:2/LIVER	SEGMENT 5-8	CT		72	SLD = 161
	SCREENING/10APR2013	NTL:1/LIVE	SEGMENT 1 AND RIGHT LOBE	CT		.	
	SCREENING/10APR2013	NTL:2/LUNG	BOTH LUNGS	CT		.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
307-0032 /74/F/A2	SCREENING/10APR2013	NTL:3/ASCI	ASCITES, MODERATE	CT		.	
307-0037 /61/M/A2	SCREENING/30SEP2013	TL:1/LIVER	SEGMENT 7	CT		38	
	SCREENING/30SEP2013	TL:2/LIVER	SEGMENT 7	CT		41	SLD = 79
	SCREENING/30SEP2013	NTL:1/LIVE	RIGHT LOBE	CT		.	
	SCREENING/30SEP2013	NTL:2/LUNG	BOTH LUNGS	CT		.	
307-0039 /51/M/A2	SCREENING/31OCT2013	TL:1/LUNG	LEFT LOWER LUNG	CT		19	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
307-0039 /51/M/A2	SCREENING/31OCT2013	TL:2/LUNG	RIGHT MIDDLE LUNG	CT		25	SLD = 44
	SCREENING/31OCT2013	NTL:1/LUNG	BOTH LUNGS	CT		.	
	WEEK12/21JAN2014	TL:1/LUNG	LEFT LOWER LUNG	CT		29	
	WEEK12/21JAN2014	TL:2/LUNG	RIGHT MIDDLE LUNG	CT		29	
	WEEK12/21JAN2014	NTL:1/LUNG	BOTH LUNGS	CT	Present	.	
	Summary:					.	SLD = 58, %CN = 31.82, TL: PD, NTL: IncompleteResponse/SD, OR: PD, PD confirmed: Yes, 24JAN2014

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
307-0040 /65/M/A2	SCREENING/22MAY2014	TL:1/LUNG	R5GHT MIDDLE LUNG	CT		21	
	SCREENING/22MAY2014	TL:2/GI	LEFT ADRENAL	CT		22	
	SCREENING/22MAY2014	TL:3/NODES	SUBCARINAL	CT		29	SLD = 72
	SCREENING/22MAY2014	NTL:1/LIVE	SEGMENT 4	CT		.	
	SCREENING/22MAY2014	NTL:2/LUNG	RIGHT MIDDLE LUNG	CT		.	
	SCREENING/22MAY2014	NTL:3/LUNG	RIGHT LOWER LUNG	CT		.	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
307-0043 /54/M/A2	SCREENING/20JUN2014	TL:1/LIVER	SEGMENT 2	CT		58	
	SCREENING/20JUN2014	TL:2/LIVER	SEGMENT 2-3	CT		67	
	SCREENING/20JUN2014	TL:3/NODES	AORTO-CAVAL	CT		14	
	SCREENING/20JUN2014	TL:4/BONE	RIGHT 6TH RIB	CT		90	SLD = 229
	SCREENING/20JUN2014	NTL:1/LIVE	LEFT LOBE	CT		.	
	WEEK12/09SEP2014	TL:1/LIVER	SEGMENT 2	CT		67	

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[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
307-0043 /54/M/A2	WEEK12/09SEP2014	TL:2/LIVER	SEGMENT 2-3	CT		72	
	WEEK12/09SEP2014	TL:3/NODES	AORTO-CAVAL	CT		11	
	WEEK12/09SEP2014	TL:4/BONE	RIGHT 6TH RIB	CT		123	
	WEEK12/09SEP2014	NTL:1/LIVE	LEFT LOBE	CT	Present	.	
	Summary:					.	SLD = 273, %CN = 19.21, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
307-0044 /53/M/A2	SCREENING/23JUN2014	TL:1/LIVER	SEGMENT 7	CT		15	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
307-0044 /53/M/A2	SCREENING/23JUN2014	TL:2/LIVER	SEGMENT 5	CT		16	
	SCREENING/23JUN2014	TL:3/LUNG	LEFT UPPER LUNG	CT		23	
	SCREENING/23JUN2014	TL:4/LUNG	RIGHT LOWER LUNG	CT		23	SLD = 77
	SCREENING/23JUN2014	NTL:1/LIVE	POST TREATMENT, RIGHT LOBE	CT		.	
	SCREENING/23JUN2014	NTL:2/LUNG	BOTH LUNGS	CT		.	
	SCREENING/23JUN2014	NTL:3/PLEU	LEFT PLEURAL SEEDING	CT		.	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
307-0044 /53/M/A2	SCREENING/23JUN2014	NTL:4/BONE	LEFT 6TH RIB	CT		.	
	SCREENING/23JUN2014	NTL:5/BONE	THORACOLUMBAR VERTEBRAE	CT		.	
307-0045 /48/M/A2	SCREENING/30JUN2014	TL:1/LUNG	RIGHT LOWER LUNG	CT		14	
	SCREENING/30JUN2014	TL:2/LUNG	LEFT LOWER LUNG	CT		12	SLD = 26
	SCREENING/30JUN2014	NTL:1/LUNG	BOTH LUNGS	CT		.	
	SCREENING/30JUN2014	NTL:2/ASCI		CT		.	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
307-0045 /48/M/A2	WEEK12/22SEP2014	TL:1/LUNG	RIGHT LOWER LUNG	CT		18	
	WEEK12/22SEP2014	TL:2/LUNG	LEFT LOWER LUNG	CT		17	
	WEEK12/22SEP2014	NTL:1/LUNG	BOTH LUNGS	CT	Present	.	
	WEEK12/22SEP2014	NTL:2/ASCI		CT	Present	.	
	Summary:					.	SLD = 35, %CN = 34.62, TL: PD, NTL: IncompleteResponse/SD, OR: PD, PD confirmed: Yes, 22SEP2014
307-0046 /46/M/A2	SCREENING/30JUN2014	TL:1/LIVER	SEGMENT 2	CT		16	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
307-0046 /46/M/A2	SCREENING/30JUN2014	TL:2/GU	RIGHT ADRENAL METASTASIS	CT		38	SLD = 54
	SCREENING/30JUN2014	NTL:1/LIVE	BOTH LOBES	CT		.	
308-0003 /54/M/A2	SCREENING/24JAN2013	TL:1/GI	PERITONEUM	CT		30	
	SCREENING/24JAN2013	TL:2/NODES	RIGHT SUBPHRENIC	CT		29	SLD = 59
	SCREENING/24JAN2013	NTL:1/GI	PERITONEUM TUMORS	CT		.	
	WEEK12/18APR2013	TL:1/GI	PERITONEUM	CT		31	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
308-0003 /54/M/A2	WEEK12/18APR2013	TL:2/NODES	RIGHT SUBPHRENIC	CT		28	
	WEEK12/18APR2013	NTL:1/GI	PERITONEUM TUMORS	CT	Present	.	
	Summary:					.	SLD = 59, %CN = 0, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK24/11JUL2013	TL:1/GI	PERITONEUM	CT		30	
	WEEK24/11JUL2013	TL:2/NODES	RIGHT SUBPHRENIC	CT		32	
	WEEK24/11JUL2013	NTL:1/GI	PERITONEUM TUMORS	CT	Present	.	

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[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
308-0003 /54/M/A2	Summary:					.	SLD = 62, %CN = 5.08, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK36/03OCT2013	TL:1/GI	PERITONEUM	CT		36	
	WEEK36/03OCT2013	TL:2/NODES	RIGHT SUBPHRENIC	CT		65	
	WEEK36/03OCT2013	NTL:1/GI	PERITONEUM TUMORS	CT	UP	.	
	Summary:					.	SLD = 101, %CN = 71.19, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 15OCT2013
308-0005 /68/F/A2	SCREENING/25APR2013	TL:1/LIVER	S7	CT		41	

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[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
308-0005 /68/F/A2	SCREENING/25APR2013	TL:2/LIVER	S4	CT		39	SLD = 80
	SCREENING/25APR2013	NTL:1/LIVE	BILATERAL LOBE	CT		.	
	WEEK12/18JUL2013	TL:1/LIVER	S7	CT		70	
	WEEK12/18JUL2013	TL:2/LIVER	S4	CT		43	
	WEEK12/18JUL2013	NTL:1/LIVE	BILATERAL LOBE	CT	Present	.	
	WEEK12/18JUL2013	NTL:2/LUNG	RIGHT MIDDLE	CT	New	.	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
308-0005 /68/F/A2	WEEK12/18JUL2013	NTL:3/LUNG	LEFT LINGULAR	CT	New	.	
	WEEK12/18JUL2013	NTL:4/LUNG	BILATERAL LOWER LOBE	CT	New	.	
	Summary:					.	SLD = 113, %CN = 41.25, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 18JUL2013
309-0001 /46/M/A2	SCREENING/04JUN2012	TL:1/LIVER	SEGMENT 2	CT		64	
	SCREENING/04JUN2012	TL:2/LIVER	SEGMENT 8	CT		46	
	SCREENING/04JUN2012	TL:3/LUNG	RIGHT LUNG	CT		49	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
309-0001 /46/M/A2	SCREENING/04JUN2012	TL:4/LUNG	RIGHT LOWER LOBE	CT		25	
	SCREENING/04JUN2012	TL:5/NODES	MEDIASTINUM	CT		15	SLD = 199
	SCREENING/04JUN2012	NTL:1/LIVE	MULTIPLE IN LIVER	CT		.	
	SCREENING/04JUN2012	NTL:2/LUNG	MULTIPLE IN LUNG	CT		.	
	WEEK12/21AUG2012	TL:1/LIVER	SEGMENT 2	CT		73	
	WEEK12/21AUG2012	TL:2/LIVER	SEGMENT 8	CT		58	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
309-0001 /46/M/A2	WEEK12/21AUG2012	TL:3/LUNG	RIGHT LUNG	CT		53	
	WEEK12/21AUG2012	TL:4/LUNG	RIGHT LOWER LOBE	CT		24	
	WEEK12/21AUG2012	TL:5/NODES	MEDIASTINUM	CT		12	
	WEEK12/21AUG2012	NTL:1/LIVE	MULTIPLE IN LIVER	CT	Present	.	
	WEEK12/21AUG2012	NTL:2/LUNG	MULTIPLE IN LUNG	CT	UP	.	
	WEEK12/21AUG2012	NTL:3/LIVE	SEGMENT 8	CT	New	.	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
309-0001 /46/M/A2	Summary:					.	SLD = 220, %CN = 10.55, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 27AUG2012
309-0002 /56/M/A2	SCREENING/11JUN2012	TL:1/LIVER	RIGHT HEPATIC LOBE	CT		131	
	SCREENING/11JUN2012	TL:2/LIVER	LEFT HEPATIC LOBE	CT		83	
	SCREENING/11JUN2012	TL:3/SPLEE	SPLEEN	CT		50	
	SCREENING/11JUN2012	TL:4/GU	LEFT ADRENAL	CT		49	
	SCREENING/11JUN2012	TL:5/NODES	LYMPH NODE	CT		16	SLD = 329

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
309-0002 /56/M/A2	SCREENING/11JUN2012	NTL:1/LIVE	MULTIPLE NODULES IN LIVER	CT		.	
	UNSCHEDULED/21JUN2012	NTL:2/BONE	STERNUM	Oth	New	.	
	Summary:					.	SLD = ., %CN = ., TL: NotAssessed, NTL: PD, OR: PD, PD confirmed: Yes, 27JUN2012
309-0003 /52/F/A2	SCREENING/14JUN2012	TL:1/LIVER	SEGMENT 4	CT		78	
	SCREENING/14JUN2012	TL:2/LIVER	SEGMENT 6	CT		38	SLD = 116
	SCREENING/14JUN2012	NTL:1/LIVE	MULTIPLE NODULES IN LIVER	CT		.	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
309-0003 /52/F/A2	WEEK12/29AUG2012	TL:1/LIVER	SEGMENT 4	CT		103	
	WEEK12/29AUG2012	TL:2/LIVER	SEGMENT 6	CT		47	
	WEEK12/29AUG2012	NTL:1/LIVE	MULTIPLE NODULES IN LIVER	CT	UP	.	
	WEEK12/29AUG2012	NTL:2/LUNG	TWO LUNG NODULES	CT	New	.	
	Summary:					.	SLD = 150, %CN = 29.31, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 05SEP2012
309-0004 /55/M/A2	SCREENING/19JUN2012	TL:1/NODES	LYMPH NODE	CT		64	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
309-0004 /55/M/A2	SCREENING/19JUN2012	TL:2/NODES	NECK LYMPH NODE	CT		40	
	SCREENING/19JUN2012	TL:3/GU	RENAL HILUM	CT		54	SLD = 158
	SCREENING/19JUN2012	NTL:1/NODE	LYMPH NODES	CT		.	
	SCREENING/19JUN2012	NTL:2/LUNG	LUNG	CT		.	
309-0008 /38/M/A2	SCREENING/08FEB2013	TL:1/LIVER	LEFT HEPATIC LOBE	CT		161	
	SCREENING/08FEB2013	TL:2/NODES	LYMPH NODES	CT		20	SLD = 181

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
309-0008 /38/M/A2	WEEK12/02MAY2013	TL:1/LIVER	LEFT HEPATIC LOBE	CT		163	
	WEEK12/02MAY2013	TL:2/NODES	LYMPH NODES	CT		19	
	WEEK12/02MAY2013	NTL:1/NODE	LYMPH NODES	CT	New	.	
	Summary:					.	SLD = 182, %CN = 0.55, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 09MAY2013
309-0010 /47/M/A2	SCREENING/14MAR2013	TL:1/LIVER	SEGMENT 6	CT		41	
	SCREENING/14MAR2013	TL:2/LIVER	SEGMENT 5	CT		12	SLD = 53

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
309-0010 /47/M/A2	SCREENING/14MAR2013	NTL:1/LIVE	SMALL NODULES	CT		.	
	SCREENING/14MAR2013	NTL:2/LIVE	PORTAL VEIN THROMBOSIS	CT		.	
	WEEK12/03JUN2013	TL:1/LIVER	SEGMENT 6	CT		33	
	WEEK12/03JUN2013	TL:2/LIVER	SEGMENT 5	CT		9	
	WEEK12/03JUN2013	NTL:1/LIVE	SMALL NODULES	CT	Present	.	
	WEEK12/03JUN2013	NTL:2/LIVE	PORTAL VEIN THROMBOSIS	CT	Present	.	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
309-0010 /47/M/A2	Summary:					.	SLD = 42, %CN = -20.75, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK24/26AUG2013	TL:1/LIVER	SEGMENT 6	CT		29	
	WEEK24/26AUG2013	TL:2/LIVER	SEGMENT 5	CT		8	
	WEEK24/26AUG2013	NTL:1/LIVE	SMALL NODULES	CT	Present	.	
	WEEK24/26AUG2013	NTL:2/LIVE	PORTAL VEIN THROMBOSIS	CT	Present	.	
	Summary:					.	SLD = 37, %CN = 60.87, TL: PR, NTL: IncompleteResponse/SD, OR: PR, PD confirmed: No

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
309-0010 /47/M/A2	WEEK36/20NOV2013	TL:1/LIVER	SEGMENT 6	CT		24	
	WEEK36/20NOV2013	TL:2/LIVER	SEGMENT 5	CT		5	
	WEEK36/20NOV2013	NTL:1/LIVE	SMALL NODULES	CT	Present	.	
	WEEK36/20NOV2013	NTL:2/LIVE	PORTAL VEIN THROMBOSIS	CT	Present	.	
	Summary:					.	SLD = 29, %CN = 26.09, TL: PR, NTL: IncompleteResponse/SD, OR: PR, PD confirmed: No
	WEEK48/10FEB2014	TL:1/LIVER	SEGMENT 6	CT		22	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
309-0010 /47/M/A2	WEEK48/10FEB2014	TL:2/LIVER	SEGMENT 5	CT		5	
	WEEK48/10FEB2014	NTL:1/LIVE	SMALL NODULES	CT	Present	.	
	WEEK48/10FEB2014	NTL:2/LIVE	PORTAL VEIN THROMBOSIS	CT	Present	.	
	Summary:					.	SLD = 27, %CN = 17.39, TL: PR, NTL: IncompleteResponse/SD, OR: PR, PD confirmed: No
	WEEK60/05MAY2014	TL:1/LIVER	SEGMENT 6	CT		20	
	WEEK60/05MAY2014	TL:2/LIVER	SEGMENT 5	CT		5	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
309-0010 /47/M/A2	WEEK60/05MAY2014	NTL:1/LIVE	SMALL NODULES	CT	Present	.	
	WEEK60/05MAY2014	NTL:2/LIVE	PORTAL VEIN THROMBOSIS	CT	Present	.	
	Summary:					.	SLD = 25, %CN = 8.7, TL: PR, NTL: IncompleteResponse/SD, OR: PR, PD confirmed: No
	WEEK72/28JUL2014	TL:1/LIVER	SEGMENT 6	CT		20	
	WEEK72/28JUL2014	TL:2/LIVER	SEGMENT 5	CT		5	
	WEEK72/28JUL2014	NTL:1/LIVE	SMALL NODULES	CT	Present	.	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
309-0010 /47/M/A2	WEEK72/28JUL2014	NTL:2/LIVE	PORTAL VEIN THROMBOSIS	CT	Present	.	
	Summary:					.	SLD = 25, %CN = 8.7, TL: PR, NTL: IncompleteResponse/SD, OR: PR, PD confirmed: No
	WEEK84/20OCT2014	TL:1/LIVER	SEGMENT 6	CT		18	
	WEEK84/20OCT2014	TL:2/LIVER	SEGMENT 5	CT		5	
	WEEK84/20OCT2014	NTL:1/LIVE	SMALL NODULES	CT	Present	.	
	WEEK84/20OCT2014	NTL:2/LIVE	PORTAL VEIN THROMBOSIS	CT	Present	.	

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[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
309-0010 /47/M/A2	WEEK84/20OCT2014	NTL:3/GU	RIGHT ADRENAL GLAND	CT	New	.	
	WEEK84/20OCT2014	NTL:4/LIVE	SEGMENT 6	CT	New	.	
	Summary:					.	SLD = 23, %CN = 0, TL: PR, NTL: PD, OR: PD, PD confirmed: Yes, 27OCT2014
309-0011 /59/M/A2	SCREENING/28MAR2013	TL:1/LIVER	SEGMENT 3	CT		70	
	SCREENING/28MAR2013	TL:2/LIVER	SEGMENT 6	CT		72	
	SCREENING/28MAR2013	TL:3/BONE	STERNUM	CT		42	

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[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
309-0011 /59/M/A2	SCREENING/28MAR2013	TL:4/BONE	LEFT 5TH RIB	CT		31	SLD = 215
	SCREENING/28MAR2013	NTL:1/LIVE		CT		.	
	SCREENING/28MAR2013	NTL:2/LUNG		CT		.	
	WEEK12/17JUN2013	TL:1/LIVER	SEGMENT 3	CT		67	
	WEEK12/17JUN2013	TL:2/LIVER	SEGMENT 6	CT		118	
	WEEK12/17JUN2013	TL:3/BONE	STERNUM	CT		68	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
309-0011 /59/M/A2	WEEK12/17JUN2013	TL:4/BONE	LEFT 5TH RIB	CT		55	
	WEEK12/17JUN2013	NTL:1/LIVE		CT	UP	.	
	WEEK12/17JUN2013	NTL:2/LUNG		CT	UP	.	
	WEEK12/17JUN2013	NTL:3/LIVE	LATERAL SEGMENT	CT	New	.	
	Summary:					.	SLD = 308, %CN = 43.26, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 24JUN2013
309-0012 /82/M/A2	SCREENING/13MAY2013	TL:1/LIVER	SEGMENT5-8	CT		29	

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[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
309-0012 /82/M/A2	SCREENING/13MAY2013	TL:2/LIVER	SEGMENT 1	CT		17	
	SCREENING/13MAY2013	TL:3/GU	LEFT ADRENAL VEIN	CT		72	
	SCREENING/13MAY2013	TL:4/GU	LEFT RENAL VEIN	CT		70	SLD = 188
	SCREENING/13MAY2013	NTL:1/LIVE	LIVER	CT		.	
	SCREENING/13MAY2013	NTL:2/GU	ADRENAL VEIN	CT		.	
	WEEK12/01AUG2013	TL:1/LIVER	SEGMENT5-8	CT		31	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
309-0012 /82/M/A2	WEEK12/01AUG2013	TL:2/LIVER	SEGMENT 1	CT		22	
	WEEK12/01AUG2013	TL:3/GU	LEFT ADRENAL VEIN	CT		79	
	WEEK12/01AUG2013	TL:4/GU	LEFT RENAL VEIN	CT		106	
	WEEK12/01AUG2013	NTL:1/LIVE	LIVER	CT	UP	.	
	WEEK12/01AUG2013	NTL:2/GU	ADRENAL VEIN	CT	UP	.	
	WEEK12/01AUG2013	NTL:3/LUNG	LEFT LOWER LOBE	CT	New	.	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
309-0012 /82/M/A2	WEEK12/01AUG2013	NTL:4/LIVE	SEGMENT 4	CT	New	.	
	WEEK12/01AUG2013	NTL:5/LIVE	SEGMENT 6-7	CT	New	.	
	Summary:					.	SLD = 238, %CN = 26.6, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 08AUG2013
309-0015 /62/M/A2	SCREENING/18JUN2013	TL:1/LIVER	RIGHT LOBE	CT		97	SLD = 97
	SCREENING/18JUN2013	NTL:1/LIVE	PORTAL VEIN	CT		.	
	SCREENING/18JUN2013	NTL:2/NODE	LYMPH NODE	CT		.	

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[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
309-0015 /62/M/A2	WEEK12/02SEP2013	TL:1/LIVER	RIGHT LOBE	CT		103	
	WEEK12/02SEP2013	NTL:1/LIVE	PORTAL VEIN	CT	UP	.	
	WEEK12/02SEP2013	NTL:2/NODE	LYMPH NODE	CT	Present	.	
	WEEK12/02SEP2013	NTL:3/LIVE	GALLBLADDER	CT	New	.	
	Summary:					.	SLD = 103, %CN = 6.19, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 09SEP2013
309-0016 /72/F/A2	SCREENING/12AUG2013	TL:1/LIVER	SEGMENT 5	CT		44	

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[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
309-0016 /72/F/A2	SCREENING/12AUG2013	TL:2/LIVER	SEGMENT 6	CT		31	
	SCREENING/12AUG2013	TL:3/NODES	CELIAC LYMPH NODE	CT		23	
	SCREENING/12AUG2013	TL:4/NODES	SUBCARINA LYMPH NODE	CT		15	SLD = 113
	SCREENING/12AUG2013	NTL:1/LIVE	LIVER	CT		.	
	WEEK12/14NOV2013	TL:1/LIVER	SEGMENT 5	CT		53	
	WEEK12/14NOV2013	TL:2/LIVER	SEGMENT 6	CT		34	

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[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
309-0016 /72/F/A2	WEEK12/14NOV2013	TL:3/NODES	CELIAC LYMPH NODE	CT		35	
	WEEK12/14NOV2013	TL:4/NODES	SUBCARINA LYMPH NODE	CT		22	
	WEEK12/14NOV2013	NTL:1/LIVE	LIVER	CT	UP	.	
	WEEK12/14NOV2013	NTL:2/NODE	PARAAORTIC LYMPH NODE	CT	New	.	
	Summary:					.	SLD = 144, %CN = 27.43, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 21NOV2013
309-0017 /73/F/A2	SCREENING/20NOV2013	TL:1/LIVER	SEGMENT OF 6-7	CT		53	

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[3] UP=Unequivocally Progressed
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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
309-0017 /73/F/A2	SCREENING/20NOV2013	TL:2/LIVER	SEGMENT OF 5-6	CT		34	SLD = 87
	WEEK12/10FEB2014	TL:1/LIVER	SEGMENT OF 6-7	CT		53	
	WEEK12/10FEB2014	TL:2/LIVER	SEGMENT OF 5-6	CT		65	
	Summary:					.	SLD = 118, %CN = 35.63, TL: PD, NTL: NotAssessed, OR: PD, PD confirmed: Yes, 17FEB2014
309-0018 /82/M/A2	SCREENING/03JUN2014	TL:1/LIVER	RIGHT LOBE	CT		154	
	SCREENING/03JUN2014	TL:2/LIVER	SEGMENT 6	CT		20	SLD = 174

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
309-0018 /82/M/A2	SCREENING/03JUN2014	NTL:1/LIVE	BOTH HEPATIC LOBE	CT		.	
	SCREENING/03JUN2014	NTL:2/LIVE	PORTAL VEIN	CT		.	
	WEEK12/25AUG2014	TL:1/LIVER	RIGHT LOBE	CT		174	
	WEEK12/25AUG2014	TL:2/LIVER	SEGMENT 6	CT		25	
	WEEK12/25AUG2014	NTL:1/LIVE	BOTH HEPATIC LOBE	CT	UP	.	
	WEEK12/25AUG2014	NTL:2/LIVE	PORTAL VEIN	CT	UP	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
309-0018 /82/M/A2	WEEK12/25AUG2014	NTL:3/LIVE	MULTIPLE TUMOR IN LEFT HEPATIC LOBE	CT	New	.	
	Summary:					.	SLD = 199, %CN = 14.37, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 01SEP2014
309-0021 /54/F/A2	SCREENING/04JUL2014	TL:1/NODES	AORTO-CAVAL	CT		34	
	SCREENING/04JUL2014	TL:2/LUNG	LEFT LUNG	CT		19	
	SCREENING/04JUL2014	TL:3/LUNG	RIGHT LUNG	CT		14	SLD = 67
	SCREENING/04JUL2014	NTL:1/LUNG	BOTH LUNG	CT		.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
309-0021 /54/F/A2	UNSCHEDULED/16SEP2014	TL:1/NODES	AORTO-CAVAL	CT		40	
	UNSCHEDULED/16SEP2014	TL:2/LUNG	LEFT LUNG	CT		44	
	UNSCHEDULED/16SEP2014	TL:3/LUNG	RIGHT LUNG	CT		38	
	UNSCHEDULED/16SEP2014	NTL:1/LUNG	BOTH LUNG	CT	UP	.	
	UNSCHEDULED/16SEP2014	NTL:2/LUNG	MULTIPLE NEW TUMORS IN BOTH LUNGS	CT	New	.	
	Summary:					.	SLD = 122, %CN = 82.09, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 22SEP2014

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
309-0025 /49/M/A2	SCREENING/12AUG2014	TL:1/LIVER	RIGHT LOBE	CT		183	
	SCREENING/12AUG2014	TL:2/LIVER	RIGHT LOBE	CT		64	
	SCREENING/12AUG2014	TL:3/BONE	RIGHT 7TH RIB	CT		41	
	SCREENING/12AUG2014	TL:4/BONE	L-SPINE 5	CT		34	
	SCREENING/12AUG2014	TL:5/LUNG	RIGHT UPPER LUNG	CT		20	SLD = 342
	SCREENING/12AUG2014	NTL:1/LIVE	MULTIPLE NODULES IN LIVER	CT		.	

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[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
309-0025 /49/M/A2	SCREENING/12AUG2014	NTL:2/LUNG	INNUMERABLE NODULES IN BOTH LUNGS	CT		.	
	SCREENING/12AUG2014	NTL:3/BONE	RIGHT ILIUM	CT		.	
309-0026 /41/M/A2	SCREENING/09SEP2014	TL:1/LIVER	SEGMENT 6	CT		134	
	SCREENING/09SEP2014	TL:2/LIVER	SEGMENT 8	CT		102	
	SCREENING/09SEP2014	TL:3/NODES	CELIAC NODE	CT		97	SLD = 333
	SCREENING/09SEP2014	NTL:1/PLEU	RIGHT PLEURA	CT		.	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
309-0026 /41/M/A2	SCREENING/09SEP2014	NTL:2/LIVE	BILATERAL HEPATIC LOBES	CT		.	
	UNSCHEDULED/04NOV2014	TL:1/LIVER	SEGMENT 6	CT		156	
	UNSCHEDULED/04NOV2014	TL:2/LIVER	SEGMENT 8	CT		91	
	UNSCHEDULED/04NOV2014	TL:3/NODES	CELIAC NODE	CT		123	
	UNSCHEDULED/04NOV2014	NTL:1/PLEU	RIGHT PLEURAL	CT	Absent	.	
	UNSCHEDULED/04NOV2014	NTL:2/LIVE	BILATERAL HEPATIC LOBES	CT	Present	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
309-0026 /41/M/A2	Summary:					.	SLD = 774, %CN = 132.43, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK12/01DEC2014	TL:1/LIVER	SEGMENT 6	CT		162	
	WEEK12/01DEC2014	TL:2/LIVER	SEGMENT 8	CT		97	
	WEEK12/01DEC2014	TL:3/NODES	CELIAC NODE	CT		121	
	WEEK12/01DEC2014	NTL:1/PLEU	RIGHT PLEURA	CT	Absent	.	
	WEEK12/01DEC2014	NTL:2/LIVE	BILATERAL HEPATIC LOBES	CT	Present	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
309-0026 /41/M/A2	Summary:					.	SLD = 380, %CN = 14.11, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	UNSCHEDULED/28JAN2015	TL:1/LIVER	SEGMENT 6	CT		173	
	UNSCHEDULED/28JAN2015	TL:2/LIVER	SEGMENT 8	CT		95	
	UNSCHEDULED/28JAN2015	TL:3/NODES	CELIAC NODE	CT		136	
	UNSCHEDULED/28JAN2015	NTL:1/PLEU	RIGHT PLEURAL	CT	Absent	.	
	UNSCHEDULED/28JAN2015	NTL:2/LIVE	BILATERAL HEPATIC LOBES	CT	UP	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
309-0026 /41/M/A2	Summary:					.	SLD = 774, %CN = 132.43, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 29JAN2015
309-0028 /62/M/A2	SCREENING/22OCT2014	TL:1/LIVER	SEGMENT 7	CT		55	
	SCREENING/22OCT2014	TL:2/LIVER	SEGMENT 4	CT		35	SLD = 90
	SCREENING/22OCT2014	NTL:1/LIVE	THROMBI IN HEPATIC VEIN	CT		.	
	SCREENING/22OCT2014	NTL:2/SOFT	THROMBI IN INFERIOR VENA CAVA	CT		.	
	WEEK12/12JAN2015	TL:1/LIVER	SEGMENT 7	CT		72	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
309-0028 /62/M/A2	WEEK12/12JAN2015	TL:2/LIVER	SEGMENT 4	CT		33	
	WEEK12/12JAN2015	NTL:1/LIVE	THROMBI IN HEPATIC VEIN	CT	Present	.	
	WEEK12/12JAN2015	NTL:2/SOFT	THROMBI IN INFERIOR VENA CAVA	CT	Present	.	
	Summary:					.	SLD = 105, %CN = 16.67, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK24/08APR2015	TL:1/LIVER	SEGMENT 7	CT		95	
	WEEK24/08APR2015	TL:2/LIVER	SEGMENT 4	CT		65	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
309-0028 /62/M/A2	WEEK24/08APR2015	NTL:1/LIVE	THROMBI IN HEPATIC VEIN	CT	Present	.	
	WEEK24/08APR2015	NTL:2/SOFT	THROMBI IN INFERIOR VENA CAVA	CT	Present	.	
	Summary:					.	SLD = 160, %CN = 77.78, TL: PD, NTL: IncompleteResponse/SD, OR: PD, PD confirmed: Yes, 13APR2015
309-0030 /33/M/A2	SCREENING/04DEC2014	TL:1/LIVER	RIGHT LOBE	CT		128	
	SCREENING/04DEC2014	TL:2/LIVER	SEGMENT 2	CT		12	SLD = 140
	SCREENING/04DEC2014	NTL:1/LIVE	LIVER OF BOTH LOBES	CT		.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
309-0030 /33/M/A2	SCREENING/04DEC2014	NTL:2/LIVE	PORTAL VEIN	CT		.	
	SCREENING/04DEC2014	NTL:3/SOFT	PERITONEAL SEEDING	CT		.	
	UNSCHEDULED/08FEB2015	NTL:4/NODE	LIVER HILUM	CT	New	.	
	UNSCHEDULED/08FEB2015	NTL:5/GU	RIGHT ADRENAL GLAND	CT	New	.	
	Summary:					.	SLD = ., %CN = ., TL: NotAssessed, NTL: PD, OR: PD, PD confirmed: Yes, 09FEB2015
309-0031 /34/M/A2	SCREENING/18DEC2014	TL:1/LIVER	SEGMENT 5-6	CT		118	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
309-0031 /34/M/A2	SCREENING/18DEC2014	TL:2/LUNG	LEFT LUNG	CT		35	
	SCREENING/18DEC2014	TL:3/NODES	MEDIASTINUM LYMPH NODES	CT		57	
	SCREENING/18DEC2014	TL:4/NODES	MEDIASTINUM LYMPH NODES	CT		41	
	SCREENING/18DEC2014	TL:5/BONE	RIGHT ACETABULUM	CT		58	SLD = 309
	SCREENING/18DEC2014	NTL:1/LIVE	BILATERAL LOBES	CT		.	
	SCREENING/18DEC2014	NTL:2/NODE	BILATERAL PULMONARY HILA	CT		.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
309-0031 /34/M/A2	SCREENING/18DEC2014	NTL:3/BONE	RIGHT PUBIC BONE	CT		.	
	SCREENING/18DEC2014	NTL:4/LUNG	BILATERAL LUNGS	CT		.	
	SCREENING/18DEC2014	NTL:5/SOFT	TUMOR THROMBI	CT		.	
	WEEK12/05MAR2015	TL:1/LIVER	SEGMENT 5-6	CT		168	
	WEEK12/05MAR2015	TL:2/LUNG	LEFT LUNG	CT		58	
	WEEK12/05MAR2015	TL:3/NODES	MEDIASTINUM LYMPH NODES	CT		60	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
309-0031 /34/M/A2	WEEK12/05MAR2015	TL:4/NODES	MEDIASTINUM LYMPH NODES	CT		54	
	WEEK12/05MAR2015	TL:5/BONE	RIGHT ACETABULUM	CT		137	
	WEEK12/05MAR2015	NTL:1/LIVE	BILATERAL LOBES	CT	UP	.	
	WEEK12/05MAR2015	NTL:2/NODE	BILATERAL PULMONARY HILA	CT	UP	.	
	WEEK12/05MAR2015	NTL:3/BONE	RIGHT PUBIC BONE	CT	UP	.	
	WEEK12/05MAR2015	NTL:4/LUNG	BILATERAL LUNGS	CT	UP	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
309-0031 /34/M/A2	WEEK12/05MAR2015	NTL:5/SOFT	TUMOR THROMBI	CT	UP	.	
	WEEK12/05MAR2015	NTL:6/LIVE	BILATERAL LIVER	CT	New	.	
	WEEK12/05MAR2015	NTL:7/LUNG	BILATERAL LUNGS	CT	New	.	
	Summary:					.	SLD = 477, %CN = 54.37, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 09MAR2015
	UNSCHEDULED/12MAR2015	TL:5/BONE	RIGHT ACETABULUM	MRI	UP	.	
	UNSCHEDULED/12MAR2015	NTL:3/BONE	RIGHT PUBIC	MRI	UP	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
309-0031 /34/M/A2	UNSCHEDULED/12MAR2015	NTL:8/BONE	THORACIC-SPINE 3	MRI	New	.	
	Summary:					.	SLD = ., %CN = ., TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 13MAR2015
309-0032 /63/M/A2	SCREENING/26DEC2014	TL:1/LIVER	OVER SEGMENT4-8,INVASION TO SUBPHRENIC REGION, MIDDLE HEPATIC VEIN AND ADJACENT PERITONEAL CAVITY	CT		90	
	SCREENING/26DEC2014	TL:2/LUNG	LEFT LUNG	CT		35	
	SCREENING/26DEC2014	TL:3/LUNG	LEFT LUNG	CT		36	SLD = 161
	SCREENING/26DEC2014	NTL:1/LIVE	SEGMENT 4,SEGMENT 8	CT		.	

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Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
309-0032 /63/M/A2	SCREENING/26DEC2014	NTL:2/LUNG	BOTH LUNGS	CT		.	
	WEEK12/19MAR2015	TL:1/LIVER	OVER SEGMENT4-8,INVASION TO SUBPHRENIC REGION, MIDDLE HEPATIC VEIN AND ADJACENT PERITONEAL CAVITY	CT		98	
	WEEK12/19MAR2015	TL:2/LUNG	LEFT LUNG	CT		22	
	WEEK12/19MAR2015	TL:3/LUNG	LEFT LUNG	CT		11	
	WEEK12/19MAR2015	NTL:1/LIVE	SEGMENT 4,SEGMENT 8	CT	UP	.	
	WEEK12/19MAR2015	NTL:2/LUNG	BOTH LUNGS	CT	UP	.	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
309-0032 /63/M/A2	WEEK12/19MAR2015	NTL:3/LUNG	BOTH LUNGS	CT	New	.	
	WEEK12/19MAR2015	NTL:4/SPLE	LOWER PORTION	CT	New	.	
	Summary:					.	SLD = 131, %CN = -18.63, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 26MAR2015
309-0033 /78/F/A2	SCREENING/16JAN2015	TL:1/LIVER	SEGMENT 6	CT		61	
	SCREENING/16JAN2015	TL:2/LIVER	SEGMENT 6	CT		38	
	SCREENING/16JAN2015	TL:3/SOFTT	PERITONEUM	CT		33	SLD = 132

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
309-0033 /78/F/A2	SCREENING/16JAN2015	NTL:1/LIVE	RIGHT LOBE	CT		.	
	WEEK12/09APR2015	TL:1/LIVER	SEGMENT 6	CT		72	
	WEEK12/09APR2015	TL:2/LIVER	SEGMENT 6	CT		50	
	WEEK12/09APR2015	TL:3/SOFTT	PERITONEUM	CT		29	
	WEEK12/09APR2015	NTL:1/LIVE	RIGHT LOBE	CT	Present	.	
	Summary:					.	SLD = 151, %CN = 14.39, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
309-0033 /78/F/A2	WEEK24/02JUL2015	TL:1/LIVER	SEGMENT 6	CT		76	
	WEEK24/02JUL2015	TL:2/LIVER	SEGMENT 6	CT		51	
	WEEK24/02JUL2015	TL:3/SOFTT	PERITONEUM	CT		16	
	WEEK24/02JUL2015	NTL:1/LIVE	RIGHT LOBE	CT	UP	.	
	Summary:					.	SLD = 143, %CN = 8.33, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 08JUL2015
310-0001 /61/M/A2	SCREENING/12JUN2012	TL:1/LIVER	S5	CT		18	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
310-0001 /61/M/A2	SCREENING/12JUN2012	TL:2/LIVER	S3	CT		16	
	SCREENING/12JUN2012	TL:3/BONE	OSTEOLYTIC LESION OVER LEFT ILIAC BONE	CT		87	
	SCREENING/12JUN2012	TL:4/BONE	T6-7 SPINE AND ADJACENT RIBS	CT		61	SLD = 182
	SCREENING/12JUN2012	NTL:1/LIVE	HEPATIC NODULE AT LIVER DOME	CT		.	
	UNSCHEDULED/21AUG2012	TL:1/LIVER	S5	CT		24	
	UNSCHEDULED/21AUG2012	TL:2/LIVER	S3	CT		15	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
310-0001 /61/M/A2	UNSCHEDULED/21AUG2012	TL:3/BONE	OSTEOLYTIC LESION OVER LEFT ILIAC BONE	CT		90	
	UNSCHEDULED/21AUG2012	TL:4/BONE	T6-7 SPINE AND ADJACENT RIBS	CT		62	
	UNSCHEDULED/21AUG2012	NTL:/LIVER	HEPATIC NODULE AT LIVER DOME	CT	UP	.	
	Summary:					.	SLD = 191, %CN = 4.95, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 22AUG2012
310-0002 /55/M/A2	SCREENING/28JUN2012	TL:1/LIVER	S5	CT		11	
	SCREENING/28JUN2012	TL:2/NODES	SUBCARINAL	CT		15	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
310-0002 /55/M/A2	SCREENING/28JUN2012	TL:3/NODES	LEFT HILUM	CT		34	
	SCREENING/28JUN2012	TL:4/LUNG	RIGHT LOWER LUNG	CT		22	
	SCREENING/28JUN2012	TL:5/LUNG	LEFT LOWER LUNG	CT		19	SLD = 101
	SCREENING/28JUN2012	NTL:1/LIVE	HEPATIC MASS OVER LEFT LUBE AND ONE NODULE AT S6	CT		.	
	SCREENING/28JUN2012	NTL:2/LUNG	BOTH PULMONARY HILUM AND MEDIASTINUM LYMPHADENOPATHY	CT		.	
	SCREENING/28JUN2012	NTL:3/LUNG	BOTH LUNG METASTATIC NODULES	CT		.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
310-0003 /61/M/A2	SCREENING/18JAN2013	TL:1/LIVER	SEGMENT 7	CT		18	
	SCREENING/18JAN2013	TL:2/LUNG	RIGHT MIDDLE LUNG	CT		15	
	SCREENING/18JAN2013	TL:3/LUNG	RIGHT LOW LUNG	CT		19	
	SCREENING/18JAN2013	TL:4/SOFTT	LEFT UPPER GUARDRANT	CT		40	
	SCREENING/18JAN2013	TL:5/SOFTT	RIGHT UPPER GUARDRANT	CT		38	SLD = 130
	SCREENING/18JAN2013	NTL:1/SOFT	PERITONEAL NODULES	CT		.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
310-0003 /61/M/A2	SCREENING/18JAN2013	NTL:2/LUNG	BOTH LUNG NODULES	CT		.	
	WEEK12/24APR2013	TL:1/LIVER	SEGMENT 7	CT		26	
	WEEK12/24APR2013	TL:2/LUNG	RIGHT MIDDLE LUNG	CT		17	
	WEEK12/24APR2013	TL:3/LUNG	RIGHT LOW LUNG	CT		22	
	WEEK12/24APR2013	TL:4/SOFTT	LEFT UPPER GUARDRANT	CT		44	
	WEEK12/24APR2013	TL:5/SOFTT	RIGHT UPPER GUARDRANT	CT		64	

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Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
310-0003 /61/M/A2	WEEK12/24APR2013	NTL:1/SOFT	PERITONEAL NODULES	CT	UP	.	
	WEEK12/24APR2013	NTL:2/LUNG	BOTH LUNG NODULES	CT	UP	.	
	WEEK12/24APR2013	NTL:3/NODE	LEFT SUPRACLAVICULAR LYMPHADENOPATHY	CT	New	.	
	WEEK12/24APR2013	NTL:4/NODE	PARAAORTIC LYMPHADENOPATHY	CT	New	.	
	WEEK12/24APR2013	NTL:5/LIVE	SEGMENT 2 HEPATIC NODULE	CT	New	.	
	Summary:					.	SLD = 173, %CN = 33.08, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 24APR2013

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
310-0008 /49/M/A2	SCREENING/30MAY2013	TL:1/LUNG	LEFT LOW LUNG	CT		20	
	SCREENING/30MAY2013	TL:2/LUNG	RIGHT LOW LUNG	CT		24	
	SCREENING/30MAY2013	TL:3/NODES	AORTOCAVAL	CT		20	SLD = 64
	SCREENING/30MAY2013	NTL:1/LIVE	SEGMENT 7 HYPODENSE LESIONS	CT		.	
	SCREENING/30MAY2013	NTL:2/PLEU	PLEURAL SEEDING	CT		.	
310-0012 /73/M/A2	SCREENING/01NOV2013	TL:1/LIVER	RIGHT SUBPHRENIC	CT		34	

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Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
310-0012 /73/M/A2	SCREENING/01NOV2013	TL:2/SOFTT	RIGHT PELVIS	CT		15	SLD = 49
	SCREENING/01NOV2013	NTL:1/NODE	INCREASED FAT STRANDING AND SMALL NODULARITY OF CENDING MESOCOLON	CT		.	
	SCREENING/01NOV2013	NTL:2/GI	MILD ASCITES	CT		.	
	WEEK12/16JAN2014	TL:1/LIVER	RIGHT SUBPHRENIC	CT		18	
	WEEK12/16JAN2014	TL:2/SOFTT	RIGHT PELVIS	CT		21	
	WEEK12/16JAN2014	NTL:1/NODE	INCREASED FAT STRANDING AND SMALL NODULARITY OF CENDING MESOCOLON	CT	Present	.	

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Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
310-0012 /73/M/A2	WEEK12/16JAN2014	NTL:2/GI	MILD ASCITES	CT	Present	.	
	Summary:					.	SLD = 39, %CN = -20.41, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK24/10APR2014	TL:1/LIVER	RIGHT SUBPHRENIC	CT		17	
	WEEK24/10APR2014	TL:2/SOFTT	RIGHT PELVIS	CT		17	
	WEEK24/10APR2014	NTL:1/NODE	INCREASED FAT STRANDING AND SMALL NODULARITY OF CENDING MESOCOLON	CT	Present	.	
	WEEK24/10APR2014	NTL:2/GI	MILD ASCITES	CT	Present	.	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
310-0012 /73/M/A2	WEEK24/10APR2014	NTL:3/SOFT	LEFT PELVIS	CT	New	.	
	Summary:					.	SLD = 34, %CN = 0, TL: PR, NTL: PD, OR: PD, PD confirmed: Yes, 14APR2014
310-0013 /54/M/A2	SCREENING/14AUG2014	TL:1/LIVER	RIGHT LOBE	CT		162	
	SCREENING/14AUG2014	TL:2/LIVER	SEGMENT 5	CT		25	
	SCREENING/14AUG2014	TL:3/NODES	PARAESOPHAGEAL	CT		22	
	SCREENING/14AUG2014	TL:4/LUNG	LEFT UPPER LOBE	CT		20	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
310-0013 /54/M/A2	SCREENING/14AUG2014	TL:5/LUNG	RIGHT LOWER LOBE	CT		33	SLD = 262
	SCREENING/14AUG2014	NTL:1/LUNG	BOTH LUNG NODULES	CT		.	
	SCREENING/14AUG2014	NTL:2/LIVE	BILATERAL LIVER NODULES	CT		.	
	WEEK12/12NOV2014	TL:1/LIVER	RIGHT LOBE	CT		171	
	WEEK12/12NOV2014	TL:2/LIVER	SEGMENT 5	CT		56	
	WEEK12/12NOV2014	TL:3/NODES	PARAESOPHAGEAL	CT		25	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
310-0013 /54/M/A2	WEEK12/12NOV2014	TL:4/LUNG	LEFT UPPER LOBE	CT		23	
	WEEK12/12NOV2014	TL:5/LUNG	RIGHT LOWER LOBE	CT		50	
	WEEK12/12NOV2014	NTL:1/LUNG	BOTH LUNG NODULES	CT	UP	.	
	WEEK12/12NOV2014	NTL:2/LIVE	BILATERAL LIVER NODULES	CT	UP	.	
	WEEK12/12NOV2014	NTL:3/NODE	PRECARINAL METASTASIS LYMPH NODE	CT	New	.	
	Summary:					.	SLD = 325, %CN = 24.05, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 17NOV2014

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
311-0002 /60/M/A2	SCREENING/08AUG2013	TL:1/LIVER	SEGMENT 2	CT		23	
	SCREENING/08AUG2013	TL:2/LIVER	SEGMENT3	CT		17	
	SCREENING/08AUG2013	TL:3/GU	RIGHT ADRENAL GLAND	CT		33	SLD = 73
	SCREENING/08AUG2013	NTL:1/LIVE	BOTH HEPATIC LOBES	CT		.	
	UNSCHEDULED/10OCT2013	TL:1/LIVER	SEGMENT 2	CT		23	
	UNSCHEDULED/10OCT2013	TL:2/LIVER	SEGMENT 3	CT		32	

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[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
311-0002 /60/M/A2	UNSCHEDULED/10OCT2013	TL:3/GU	RIGHT ADRENAL GLAND	CT		27	
	UNSCHEDULED/10OCT2013	NTL:1/LIVE	BOTH HEPATIC LOBES	CT	UP	.	
	Summary:					.	SLD = 82, %CN = 12.33, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 16OCT2013
311-0007 /55/M/A2	SCREENING/12NOV2013	TL:1/GU	LEFT SUPRARENAL REGIONS	CT		26	
	SCREENING/12NOV2013	TL:2/GU	PERIRENAL REGIONS	CT		20	
	SCREENING/12NOV2013	TL:3/GI	PARAORTIC REGION	CT		23	SLD = 69

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[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
311-0007 /55/M/A2	WEEK12/27JAN2014	TL:1/GU	LEFT SUPRARENAL REGIONS	CT		31	
	WEEK12/27JAN2014	TL:2/GU	PERIRENAL REGIONS	CT		25	
	WEEK12/27JAN2014	TL:3/GI	PARAORTIC REGION	CT		30	
	WEEK12/27JAN2014	NTL:1/LIVE	SEGMENT 7 OF LIVER	CT	New	.	
	Summary:					.	SLD = 86, %CN = 24.64, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 27JAN2013
311-0008 /71/M/A2	SCREENING/08MAY2014	TL:1/LIVER	SEGMENT 8	CT		77	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
311-0008 /71/M/A2	SCREENING/08MAY2014	TL:2/LIVER	SEGMENT 5	CT		65	SLD = 142
	SCREENING/08MAY2014	NTL:1/LUNG	BOTH LUNG ZONE	CT		.	
	SCREENING/08MAY2014	NTL:2/LIVE	SEGMENT 4	CT		.	
	SCREENING/08MAY2014	NTL:3/LIVE	SEGMENT 8	CT		.	
	UNSCHEDULED/09JUL2014	TL:1/LIVER	SEGMENT 8	CT		73	
	UNSCHEDULED/09JUL2014	TL:2/LIVER	SEGMENT 5	CT		74	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
311-0008 /71/M/A2	UNSCHEDULED/09JUL2014	NTL:1/LUNG	BOTH LUNGS	CT	UP	.	
	UNSCHEDULED/09JUL2014	NTL:2/LIVE	SEGMENT 4	CT	Present	.	
	UNSCHEDULED/09JUL2014	NTL:3/LIVE	SEGMENT 8	CT	Present	.	
	Summary:					.	SLD = 147, %CN = 3.52, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 09JUL2014
401-0003 /36/M/A7	SCREENING/17JUN2013	TL:1/NODES	RIGHT HILAR LAP	CT		32	
	SCREENING/17JUN2013	TL:2/SPLEE		CT		78	

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[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
401-0003 /36/M/A7	SCREENING/17JUN2013	TL:3/ADREN	LEFT	CT		43	
	SCREENING/17JUN2013	TL:4/ADREN	RIGHT	CT		25	SLD = 178
	SCREENING/17JUN2013	NTL:2/SOFT	LEFT SOLEUS	MRI		.	
	SCREENING/20JUN2013	NTL:1/BONE	LEFT TIBIA	MRI		.	
	UNSCHEDULED/03SEP2013	TL:1/NODES	RIGHT. HILAR LAP	CT		50	
	UNSCHEDULED/03SEP2013	TL:2/SPLEE		CT		99	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
401-0003 /36/M/A7	UNSCHEDULED/03SEP2013	TL:3/ADREN	LEFT	CT		84	
	UNSCHEDULED/03SEP2013	TL:4/ADREN	RIGHT	CT		27	
	UNSCHEDULED/03SEP2013	NTL:1/BONE	LEFT TIBIA	MRI	Present	.	
	UNSCHEDULED/03SEP2013	NTL:2/SOFT	LEFT SOLEUS	MRI	Present	.	
	Summary:					.	SLD = 260, %CN = 46.07, TL: PD, NTL: IncompleteResponse/SD, OR: PD, PD confirmed: Yes, 03SEP2013
401-0005 /58/M/A7	SCREENING/10OCT2013	TL:1/LUNG	RIGHT LOWER LOBE	CT		35	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
401-0005 /58/M/A7	SCREENING/10OCT2013	TL:2/LUNG	LEFT LOWER LOBE	CT		29	SLD = 64
	SCREENING/10OCT2013	NTL:1/BONE	T11 SPINE	CT		.	
	SCREENING/10OCT2013	NTL:2/BONE	L1 SPINE	CT		.	
	UNSCHEDULED/18DEC2013	TL:1/LUNG	RIGHT LOWER LOBE	CT		46	
	UNSCHEDULED/18DEC2013	TL:2/LUNG	LEFT LOWER LOBE	CT		29	
	UNSCHEDULED/18DEC2013	NTL:1/BONE	T11 SPINE	CT	UP	.	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
401-0005 /58/M/A7	UNSCHEDULED/18DEC2013	NTL:2/BONE	L1 SPINE	CT	UP	.	
	UNSCHEDULED/18DEC2013	NTL:3/NODE	MEDIASTINAL LAP	CT	New	.	
	Summary:					.	SLD = 75, %CN = 17.19, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 18DEC2013
402-0003 /75/M/A7	SCREENING/02APR2013	TL:1/NODES	LEFT SUPRACLAVICULAR	CT		16	
	SCREENING/02APR2013	TL:2/LIVER	S6	CT		26	
	SCREENING/02APR2013	TL:3/LIVER	S7	CT		22	SLD = 64

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
402-0003 /75/M/A7	SCREENING/02APR2013	NTL:1/NODE	INTRAABDOMINAL LYMPH NODES	CT		.	
	SCREENING/02APR2013	NTL:2/NODE	THORACIC LYMPH NODES	CT		.	
	WEEK12/16JUL2013	TL:1/NODES	LEFT SUPRACLAVICULAR	CT		14	
	WEEK12/16JUL2013	TL:2/LIVER	S6	CT		28	
	WEEK12/16JUL2013	TL:3/LIVER	S7	CT		20	
	WEEK12/16JUL2013	NTL:1/NODE	INTRAABDOMINAL LYMPH NODES	CT	Present	.	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
402-0003 /75/M/A7	WEEK12/16JUL2013	NTL:2/NODE	THORACIC LYMPH NODES	CT	Present	.	
	Summary:					.	SLD = 62, %CN = -3.13, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK24/08OCT2013	TL:1/NODES	LEFT SUPRACLAVICULAR	CT		23	
	WEEK24/08OCT2013	TL:2/LIVER	S6	CT		30	
	WEEK24/08OCT2013	TL:3/LIVER	S7	CT		28	
	WEEK24/08OCT2013	NTL:1/NODE	INTRAABDOMINAL LYMPH NODES	CT	UP	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
402-0003 /75/M/A7	WEEK24/08OCT2013	NTL:2/NODE	THORACIC LYMPH NODES	CT	UP	.	
	Summary:					.	SLD = 81, %CN = 30.65, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 08OCT2013
402-0006 /71/M/A7	SCREENING/09APR2013	TL:1/LUNG	LEFT UPPER LOBE	CT		26	
	SCREENING/09APR2013	TL:2/NODES	CARDIOPHRENIC LYMPH NODES	CT		45	SLD = 71
	SCREENING/09APR2013	NTL:1/LUNG	MULTIPLE METASTATIC NODULE	CT		.	
	SCREENING/09APR2013	NTL:2/LIVE	NODULES	CT		.	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
402-0006 /71/M/A7	WEEK12/22JUL2013	TL:1/LUNG	LEFT UPPER LOBE	CT		41	
	WEEK12/22JUL2013	TL:2/NODES	CARDIOPHRENIC LYMPH NODES	CT		41	
	WEEK12/22JUL2013	NTL:1/LUNG	MULTIPLE METASTATIC NODULE	CT	UP	.	
	WEEK12/22JUL2013	NTL:2/LIVE	NODULES	CT	UP	.	
	Summary:					.	SLD = 82, %CN = 15.49, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 30JUL2013
402-0008 /43/M/A7	SCREENING/08MAY2013	TL:1/GI	PERITONEAL WALL	CT		37	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
402-0008 /43/M/A7	SCREENING/08MAY2013	TL:2/GI	PARAAORTIC MASS	CT		62	
	SCREENING/08MAY2013	TL:3/LIVER	S3	CT		30	
	SCREENING/08MAY2013	TL:4/LIVER	S2	CT		18	SLD = 147
	SCREENING/08MAY2013	NTL:1/NODE	PERITONEAL METASTATIC LYMPH NODES	CT		.	
	SCREENING/08MAY2013	NTL:2/LIVE	MULTIPLE HEPATIC METASTASIS	CT		.	
	UNSCHEDULED/04JUN2013	TL:1/GI	PERITONEAL WALL	CT		37	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
402-0008 /43/M/A7	UNSCHEDULED/04JUN2013	TL:2/GI	PARAAORTIC MASS	CT		68	
	UNSCHEDULED/04JUN2013	TL:3/LIVER	S3	CT		32	
	UNSCHEDULED/04JUN2013	TL:4/LIVER	S2	CT		22	
	UNSCHEDULED/04JUN2013	NTL:1/NODE	PERITONEAL METASTATIC LYMPH NODES	CT	Present	.	
	UNSCHEDULED/04JUN2013	NTL:2/LIVE	MULTIPLE HEPATIC METASTASIS	CT	UP	.	
	Summary:					.	SLD = 159, %CN = 8.16, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 14JUN2013

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[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
402-0009 /70/M/A7	SCREENING/09MAY2013	TL:1/LIVER	LEFT LATERAL SEGMENT	CT		23	
	SCREENING/09MAY2013	TL:2/LIVER	S3	CT		20	SLD = 43
	SCREENING/09MAY2013	NTL:1/LIVE	HYPOVASCULAR INDETERMINATE LESIONS	CT		.	
	UNSCHEDULED/04JUL2013	TL:1/LUNG		CT		96	
	UNSCHEDULED/04JUL2013	TL:2/LIVER		CT		40	
	UNSCHEDULED/04JUL2013	NTL:1/LUNG		CT	UP	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
402-0009 /70/M/A7	Summary:					.	SLD = 136, %CN = 216.28, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 11JUL2013
402-0011 /64/M/A7	Summary:					.	SLD = 165, %CN = .,
	WEEK12/.	TL:3/		CT		.	
	SCREENING/14MAY2013	TL:1/LIVER	S7	CT		42	
	SCREENING/14MAY2013	TL:2/LIVER	S6	CT		11	
	SCREENING/14MAY2013	TL:3/LUNG	LEFT UPPER LOBE	CT		42	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
402-0011 /64/M/A7	SCREENING/14MAY2013	TL:4/LUNG	RIGHT LOWER LOBE	CT		38	SLD = 133
	UNSCHEDULED/04JUL2013	TL:1/LIVER		CT		37	
	UNSCHEDULED/04JUL2013	TL:2/LIVER		CT		12	
	UNSCHEDULED/04JUL2013	TL:3/LUNG		CT		62	
	UNSCHEDULED/04JUL2013	TL:4/LUNG		CT		54	
	Summary:					.	SLD = ., %CN = ., TL: PD, NTL: NotAssessed, OR: PD, PD confirmed: Yes, 11JUL2013

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
402-0017 /50/M/A7	SCREENING/27MAY2013	TL:1/LUNG	LEFT LOWER LOBE NODULE	CT		21	
	SCREENING/27MAY2013	TL:2/LIVER	S4	CT		58	SLD = 79
	SCREENING/27MAY2013	NTL:1/LUNG	MULTIPLE LUNG METASTASIS	CT		.	
402-0018 /48/M/A7	SCREENING/27MAY2013	TL:1/SPLEE	SPLEEN	CT		52	
	SCREENING/27MAY2013	TL:2/BONE	LEFT THIGH	CT		56	SLD = 108
	SCREENING/27MAY2013	NTL:1/LUNG	METASTATIC LUNG NODULE	CT		.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
402-0018 /48/M/A7	WEEK12/09SEP2013	TL:1/SPLEE	SPLEEN	CT		65	
	WEEK12/09SEP2013	TL:2/BONE	LEFT THIGH	CT		65	
	WEEK12/09SEP2013	NTL:1/LUNG	METASTATIC LUNG NODULE	CT	UP	.	
	Summary:					.	SLD = 130, %CN = 20.37, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 16SEP2013
402-0019 /54/M/A7	SCREENING/10JUN2013	TL:1/LIVER	S8	CT		40	
	SCREENING/10JUN2013	TL:2/LIVER	S7	CT		24	SLD = 64

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
402-0019 /54/M/A7	SCREENING/10JUN2013	NTL:1/LUNG	TINY LUNG NODULE	CT		.	
	WEEK12/16SEP2013	TL:1/LIVER	S8	CT		44	
	WEEK12/16SEP2013	TL:2/LIVER	S7	CT		40	
	WEEK12/16SEP2013	NTL:1/LUNG	TINY LUNG NODULE	CT	Present	.	
	Summary:					.	SLD = 84, %CN = 31.25, TL: PD, NTL: IncompleteResponse/SD, OR: PD, PD confirmed: Yes, 16SEP2013
402-0021 /64/M/A7	SCREENING/25JUL2013	TL:1/LIVER	S4 MASS	CT		29	SLD = 29

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
402-0021 /64/M/A7	SCREENING/25JUL2013	NTL:1/LUNG	METASTATIC LUNG NODULES	CT		.	
	WEEK12/29OCT2013	TL:1/LIVER	S4 MASS	CT		32	
	WEEK12/29OCT2013	NTL:1/LUNG	METASTATIC LUNG NODULES	CT	Present	.	
	Summary:					.	SLD = 32, %CN = 10.34, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK24/21JAN2014	TL:1/LIVER	S4 MASS	CT		29	
	WEEK24/21JAN2014	NTL:1/LUNG	METASTATIC LUNG NODULES	CT	Present	.	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
402-0021 /64/M/A7	Summary:					.	SLD = 29, %CN = 3.57, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK36/09APR2014	TL:1/LIVER	S4 MASS	CT		30	
	WEEK36/09APR2014	NTL:1/LUNG	METASTATIC LUNG NODULES	CT	Present	.	
	Summary:					.	SLD = 30, %CN = 7.14, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK48/08JUL2014	TL:1/LIVER	S4 MASS	CT		28	
	WEEK48/08JUL2014	NTL:1/LUNG	METASTATIC LUNG NODULES	CT	Present	.	

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[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
402-0021 /64/M/A7	Summary:					.	SLD = 28, %CN = 0, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK60/29SEP2014	TL:1/LIVER	S4 MASS	CT		41	
	WEEK60/29SEP2014	NTL:1/LUNG	METASTATIC LUNG NODULES	CT	Present	.	
	Summary:					.	SLD = 41, %CN = 46.43, TL: PD, NTL: IncompleteResponse/SD, OR: PD, PD confirmed: Yes, 07OCT2014
402-0024 /57/M/A7	SCREENING/06AUG2013	TL:1/PERIC	RETROCAVAL MASS	CT		40	SLD = 40
	SCREENING/06AUG2013	NTL:1/LUNG	SUBPLEURAL NODULES	CT		.	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
402-0024 /57/M/A7	SCREENING/06AUG2013	NTL:2/NODE		CT		.	
	UNSCHEDULED/05NOV2013	TL:1/PERIC	RETROCAVAL MASS	CT		70	
	UNSCHEDULED/05NOV2013	NTL:1/LUNG	SUBPLEURAL NODULES	CT	Present	.	
	UNSCHEDULED/05NOV2013	NTL:2/NODE		CT	Present	.	
	UNSCHEDULED/05NOV2013	NTL:3/PLEU		CT	New	.	
	Summary:					.	SLD = 70, %CN = 75, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 05NOV2013

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
402-0025 /58/M/A7	SCREENING/16SEP2013	TL:1/LUNG	RIGHT LOWER LOBE	CT		60	
	SCREENING/16SEP2013	TL:2/LUNG	LIGHT LOWER LOBE	CT		31	SLD = 91
	SCREENING/16SEP2013	NTL:1/LIVE	VIABLE TUMOR	CT		.	
	SCREENING/16SEP2013	NTL:2/LUNG	MULTIPLE METASTASIS	CT		.	
	WEEK12/12DEC2013	TL:1/LUNG	RIGHT LOWER LOBE	CT		72	
	WEEK12/12DEC2013	TL:2/LUNG	LIGHT LOWER LOBE	CT		43	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
402-0025 /58/M/A7	WEEK12/12DEC2013	NTL:1/LIVE	VIABLE TUMOR	CT	Present	.	
	WEEK12/12DEC2013	NTL:2/LUNG	MULTIPLE METASTASIS	CT	UP	.	
	Summary:					.	SLD = 115, %CN = 26.37, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 19DEC2013
402-0027 /52/M/A7	SCREENING/25SEP2013	TL:1/LIVER		CT		22	
	SCREENING/25SEP2013	TL:2/LUNG		CT		43	
	SCREENING/25SEP2013	TL:3/NODES		CT		19	SLD = 84

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
402-0027 /52/M/A7	SCREENING/25SEP2013	NTL:1/NODE		CT		.	
	UNSCHEDULED/21NOV2013	TL:1/LIVER		CT		32	
	UNSCHEDULED/21NOV2013	TL:2/LUNG		CT		76	
	UNSCHEDULED/21NOV2013	TL:3/NODES		CT		31	
	UNSCHEDULED/21NOV2013	NTL:1/NODE		CT	UP	.	
	Summary:					.	SLD = 139, %CN = 65.48, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 21NOV2013

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
402-0028 /60/M/A7	SCREENING/26SEP2013	TL:1/LUNG	LEFT LOWER LOBE NODULE	CT		13	SLD = 13
	SCREENING/26SEP2013	NTL:1/LUNG	MULTIPLE LUNG METASTASIS	CT		.	
402-0031 /65/M/A7	SCREENING/05NOV2013	TL:1/NODES	PARATRACHEAL LYMPHNODES	CT		40	
	SCREENING/05NOV2013	TL:2/LUNG	LEFT LOWER LOBE NODULE	CT		11	SLD = 51
	SCREENING/05NOV2013	NTL:1/LUNG	MULTIPLE LUNG METASTASIS	CT		.	
	WEEK12/29JAN2014	TL:1/NODES	PARATRACHEAL LYMPHNODES	CT		53	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
402-0031 /65/M/A7	WEEK12/29JAN2014	TL:2/LUNG	LEFT LOWER LOBE NODULE	CT		11	
	WEEK12/29JAN2014	NTL:1/LUNG	MULTIPLE LUNG METASTASIS	CT	Present	.	
	Summary:					.	SLD = 64, %CN = 25.49, TL: PD, NTL: IncompleteResponse/SD, OR: PD, PD confirmed: Yes, 29JAN2014
402-0033 /63/F/A7	SCREENING/29NOV2013	TL:1/LIVER	S4 MASS	CT		11	
	SCREENING/29NOV2013	TL:2/LIVER	S3,4,5	CT		60	SLD = 71
	SCREENING/29NOV2013	NTL:1/NODE	MULTIPLE ABDOMINAL LYMPH NODES	CT		.	

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[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
402-0033 /63/F/A7	UNSCHEDULED/27JAN2014	TL:1/LIVER	S4 MASS	CT		30	
	UNSCHEDULED/27JAN2014	TL:2/LIVER	S3, 4, 5	CT		60	
	UNSCHEDULED/27JAN2014	NTL:1/NODE	MULTIPLE ABDOMINAL LYMPH NODES	CT	Present	.	
	UNSCHEDULED/27JAN2014	NTL:2/LIVE	MULTIPLE NEW METASTASIS	CT	New	.	
	Summary:					.	SLD = 90, %CN = 26.76, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 07FEB2014
402-0035 /44/M/A7	SCREENING/18DEC2013	TL:1/LIVER	S7/8	CT		109	

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[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
402-0035 /44/M/A7	SCREENING/18DEC2013	TL:2/LUNG	RIGHT LUNG	CT		56	SLD = 165
	SCREENING/18DEC2013	NTL:1/LUNG	MULTIPLE LUNG METASTASIS	CT		.	
403-0001 /55/M/A7	SCREENING/22MAY2013	TL:1/LUNG	RUL METASTASIS	CT		50	
	SCREENING/22MAY2013	TL:2/LUNG	RLL METASTASIS	CT		63	
	SCREENING/22MAY2013	TL:3/NODES	RT. INFRAHILAR LN	CT		29	
	SCREENING/22MAY2013	TL:4/NODES	LT.INFRAHILAR LN	CT		25	SLD = 167

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
403-0001 /55/M/A7	SCREENING/22MAY2013	NTL:1/LUNG	OTHER MULTIPLE METASTASIS ON THE BOTH LUNG	CT		.	
	SCREENING/22MAY2013	NTL:2/NODE	MULTIPLE LNS ON THE MEDIATINUM AND HILUM	CT		.	
	UNSCHEDULED/01JUL2013	TL:1/LUNG	RUL METASTASIS	CT		63	
	UNSCHEDULED/01JUL2013	TL:2/LUNG	RLL METASTASIS	CT		72	
	UNSCHEDULED/01JUL2013	TL:3/NODES	RT INFRAHILAR LN METASTASIS	CT		38	
	UNSCHEDULED/01JUL2013	TL:4/NODES	LT INFRAHILAR LN METASTASIS	CT		32	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
403-0001 /55/M/A7	UNSCHEDULED/01JUL2013	NTL:1/LUNG	OTHER MULTIPLE METASTASIS ON THE BOTH LUNGS	CT	UP	.	
	UNSCHEDULED/01JUL2013	NTL:2/NODE	MULTIPLE METASTATIC LNS ON THE MEDIASTINUM AND HILUM	CT	UP	.	
	UNSCHEDULED/01JUL2013	NTL:3/PLEU	RT SIDE PLEURAL EFFUSION	CT	New	.	
	UNSCHEDULED/01JUL2013	NTL:3/LIVE	RT HEPATIC METASTASIS	CT	New	.	
	Summary:					.	SLD = 205, %CN = 22.75, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 03JUL2013
403-0002 /52/M/A7	SCREENING/23MAY2013	TL:1/LUNG	LLL METASTASIS	CT		17	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
403-0002 /52/M/A7	SCREENING/23MAY2013	TL:2/LIVER	S5 METASTASIS	CT		20	SLD = 37
	SCREENING/23MAY2013	NTL:1/LIVE	MULTIPLE HCC WITH RT PORTAL VEIN BRANCH OBLITERATION	CT		.	
	UNSCHEDULED/21AUG2013	TL:1/LUNG	LLL METASTASIS	CT		23	
	UNSCHEDULED/21AUG2013	TL:2/LIVER	S5 METASTASIS	CT		30	
	UNSCHEDULED/21AUG2013	NTL:1/LIVE	MULTIPLE HCC WITH RT PORTAL VEIN BRANCH OBLITERATION	CT	UP	.	
	UNSCHEDULED/21AUG2013	NTL:2/LUNG	MULTIPLE LUNG METASTASIS ON THE BOTH LUNGS	CT	New	.	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
403-0002 /52/M/A7	Summary:					.	SLD = 53, %CN = 43.24, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 22AUG2013
403-0005 /50/F/A7	SCREENING/15JUL2013	TL:1/LUNG	LUNG METASTASIS IN LLL	CT		50	
	SCREENING/15JUL2013	TL:2/LUNG	LUNG METASTASIS IN RML	CT		29	
	SCREENING/15JUL2013	TL:3/NODES	LN METASTASIS IN AP WINDOW	CT		30	
	SCREENING/15JUL2013	TL:4/NODES	LN METASTASIS IN RT HILUM	CT		19	SLD = 128
	SCREENING/15JUL2013	NTL:1/NODE	LT GASTRIC LNS METASTASIS	CT		.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

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403-0005 /50/F/A7	SCREENING/15JUL2013	NTL:2/NODE	OTHER MULTIPLE MEDIASTINAL LNS METASTASIS	CT		.	
	SCREENING/15JUL2013	NTL:3/LUNG	MULTIPLE LUNG METASTASIS IN BOTH LUNGS	CT		.	
	UNSCHEDULED/01AUG2013	NTL:4/BRAI	BRAIN METASTASIS	MRI	New	.	
	Summary:					.	SLD = ., %CN = ., TL: NotAssessed, NTL: PD, OR: PD, PD confirmed: Yes, 02AUG2013
403-0006 /66/M/A7	SCREENING/08JUL2013	TL:1/LUNG	RLL METASTASIS	CT		12	SLD = 12
	SCREENING/08JUL2013	NTL:1/LUNG	MULTIPLE LUNG METASTASIS IN BOTH LUNG	CT		.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
403-0006 /66/M/A7	WEEK12/17OCT2013	TL:1/LUNG	RLL METASTASIS	CT		20	
	WEEK12/17OCT2013	NTL:1/LUNG	MULTIPLE LUNG METASTASIS IN BOTH LUNG	CT	UP	.	
	Summary:					.	SLD = 20, %CN = 66.67, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 23OCT2013
403-0007 /64/M/MI X	SCREENING/16AUG2013	TL:1/LUNG	LUL MASS	CT		73	
	SCREENING/16AUG2013	TL:2/LUNG	LLL METASTASIS	CT		25	SLD = 98
	SCREENING/16AUG2013	NTL:1/LUNG	MULTIPLE LUNG METASTASIS IN BOTH LUNGS	CT		.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
403-0007 /64/M/MI X	SCREENING/16AUG2013	NTL:2/NODE	BILATERAL HILAR LNS METASTASIS	CT		.	
	SCREENING/16AUG2013	NTL:3/BRAI	MULTIPLE BRAIN METASTASIS	MRI		.	
	UNSCHEDULED/01OCT2013	TL:1/LUNG	LUL MASS	CT		86	
	UNSCHEDULED/01OCT2013	TL:2/LUNG	LLL METASTASIS	CT		26	
	UNSCHEDULED/01OCT2013	NTL:1/LUNG	MULTIPLE LUNG METASTASIS IN BOTH LUNGS.	CT	Present	.	
	UNSCHEDULED/01OCT2013	NTL:2/NODE	BILATERAL HILAR LNS METASTASIS	CT	Present	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
403-0007 /64/M/MIX	Summary:					.	SLD = 112, %CN = 14.29, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK12/07NOV2013	TL:1/LUNG	LUL MASS	CT		84	
	WEEK12/07NOV2013	TL:2/LUNG	LLL METASTASIS	CT		26	
	WEEK12/07NOV2013	NTL:1/LUNG	MULTIPLE LUNG METASTASIS IN BOTH LUNGS	CT	Present	.	
	WEEK12/07NOV2013	NTL:2/NODE	BILATERAL HILAR LNS METASTASIS	CT	Present	.	
	WEEK12/07NOV2013	NTL:3/BRAI	MULTIPLE BRAIN METASTASIS	MRI	UP	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
403-0007 /64/M/MIX	WEEK12/07NOV2013	NTL:4/LUNG	NEWLY DEVELOPED CONSOLIDATION IN LUL, R/O METASTASIS OR PNEUMONIA	CT	New	.	
	Summary:					.	SLD = 110, %CN = 12.24, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 14NOV2013
404-0001 /71/M/A7	SCREENING/08JUL2013	TL:1/NODES	LYMPH NODES(LEFT SUPRACLAVICULAR)	CT		28	SLD = 28
	SCREENING/08JUL2013	NTL:1/NODE	LYMPH NODES(PERICARDIAC)	CT		.	
	SCREENING/08JUL2013	NTL:2/NODE	LYMPH NODES(PERIHEPATIC)	CT		.	
	UNSCHEDULED/12AUG2013	TL:1/NODES	LYMPH NODES(LEFT SUPRACLAVICULAR)	CT		35	

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Tumor Assessment Summary Listing
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Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
404-0001 /71/M/A7	UNSCHEDULED/12AUG2013	NTL:1/NODE	LYMPH NODES(PERICARDIAC)	CT	Present	.	
	UNSCHEDULED/12AUG2013	NTL:2/NODE	LYMPH NODES(PERIHEPATIC)	CT	Present	.	
	Summary:					.	SLD = 35, %CN = 25, TL: PD, NTL: IncompleteResponse/SD, OR: PD, PD confirmed: Yes, 12AUG2013
404-0002 /56/F/A7	SCREENING/12AUG2013	TL:1/LUNG	RIGHT MEDIAL LOBE	CT		12	
	SCREENING/12AUG2013	TL:2/LUNG	LLL	CT		12	
	SCREENING/12AUG2013	TL:3/GU	RIGHT ADRENAL GLAND	CT		74	SLD = 98

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Tumor Assessment Summary Listing
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Treatment Group: ADI-PEG 20

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404-0002 /56/F/A7	SCREENING/12AUG2013	NTL:1/LUNG	MULTIPLE	CT		.	
	UNSCHEDULED/12SEP2013	TL:1/LUNG	RIGHT MEDIAL LOBE	CT		14	
	UNSCHEDULED/12SEP2013	TL:2/LUNG	LEFT MEDIAL LOBE	CT		15	
	UNSCHEDULED/12SEP2013	TL:3/GU	RIGHT ADRENAL GLAND	CT		74	
	UNSCHEDULED/12SEP2013	NTL:1/LUNG	MULTIPLE	CT	UP	.	
	Summary:					.	SLD = 103, %CN = 5.1, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 12SEP2013

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Tumor Assessment Summary Listing
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Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
405-0002 /46/M/A7	SCREENING/03APR2013	TL:1/LIVER	SEGMENT 4 (SE71 IM19)	CT		40	SLD = 40
405-0004 /38/M/A7	SCREENING/23APR2013	TL:1/LIVER	SEGMENTATION 6	CT		23	
	SCREENING/23APR2013	TL:2/LIVER	SEGMENT 8	CT		23	
	SCREENING/23APR2013	TL:3/LUNG	LEFT LOWER LOBE	CT		27	
	SCREENING/23APR2013	TL:4/LUNG	LEFT UPPER LOBE	CT		20	SLD = 93
	SCREENING/23APR2013	NTL:1/LIVE	MULTIPLE	CT		.	

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Tumor Assessment Summary Listing
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Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
405-0004 /38/M/A7	SCREENING/23APR2013	NTL:2/LUNG	MULTIPLE	CT		.	
	WEEK12/10JUL2013	TL:1/LIVER	SEGMENTATION 6	CT		31	
	WEEK12/10JUL2013	TL:2/LIVER	SEGMENT 8	CT		26	
	WEEK12/10JUL2013	TL:3/LUNG	LEFT LOWER LOBE	CT		33	
	WEEK12/10JUL2013	TL:4/LUNG	LEFT UPPER LOBE	CT		29	
	WEEK12/10JUL2013	NTL:1/LIVE	MULTIPLE	CT	Present	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
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Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
405-0004 /38/M/A7	WEEK12/10JUL2013	NTL:2/LUNG	MULTIPLE	CT	UP	.	
	Summary:					.	SLD = 119, %CN = 27.96, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 10JUL2013
405-0006 /62/M/A7	SCREENING/23APR2013	TL:1/LUNG	LEFT LOWER LOBE	CT		44	
	SCREENING/23APR2013	TL:2/LUNG	RIGHT LOWER LOBE	CT		69	SLD = 113
	SCREENING/23APR2013	NTL:1/LIVE	MULTIPLE	CT		.	
	SCREENING/23APR2013	NTL:2/LUNG	MULTIPLE	CT		.	

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Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
405-0007 /53/M/A7	SCREENING/06MAY2013	TL:1/LUNG	RIGHT, SE4 IM 54	CT		14	
	SCREENING/06MAY2013	TL:2/LUNG	LEFT, SE4 IM41	CT		14	SLD = 28
	SCREENING/06MAY2013	NTL:1/LUNG	MULTIPLE	CT		.	
	UNSCHEDULED/25JUN2013	TL:1/LUNG	RIGHT(SE4, IM54)	CT		12	
	UNSCHEDULED/25JUN2013	TL:2/LUNG	LEFT(SE4, IM41)	CT		16	
	UNSCHEDULED/25JUN2013	NTL:1/LUNG	MULTIPLE	CT	Present	.	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
405-0007 /53/M/A7	Summary:					.	SLD = 63, %CN = 125, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK12/23JUL2013	TL:1/LUNG	RIGHT, SE4 IM 54	CT		14	
	WEEK12/23JUL2013	TL:2/LUNG	LEFT, SE4 IM41	CT		16	
	WEEK12/23JUL2013	NTL:1/LUNG	MULTIPLE	CT	Present	.	
	Summary:					.	SLD = 30, %CN = 7.14, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	UNSCHEDULED/26SEP2013	NTL:2/LIVE	MULTIPLE	CT	New	.	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
405-0007 /53/M/A7	UNSCHEDULED/03OCT2013	TL:1/LUNG	RIGHT SEGMENT8	CT		16	
	UNSCHEDULED/03OCT2013	TL:2/LUNG	LEFT SEGMENT4	CT		19	
	UNSCHEDULED/03OCT2013	NTL:1/LUNG	MULTIPLE	CT	Present	.	
405-0009 /50/M/A7	SCREENING/29APR2013	TL:1/LIVER	SEG5	CT		29	
	SCREENING/29APR2013	TL:2/LIVER	SEG3	CT		77	
	SCREENING/29APR2013	TL:3/NODES	LT.PARATRACHEAL	CT		17	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
405-0009 /50/M/A7	SCREENING/29APR2013	TL:4/SOFTT	ANT.MEDIASTINUM	CT		20	SLD = 143
	SCREENING/29APR2013	NTL:1/LIVE	SEG2	CT		.	
	SCREENING/29APR2013	NTL:2/LUNG	MULTIPLE	CT		.	
	SCREENING/29APR2013	NTL:3/NODE	MEDIASTINUM	CT		.	
	UNSCHEDULED/10JUN2013	TL:1/LIVER	SEGMENT 5	CT		31	
	UNSCHEDULED/10JUN2013	TL:2/LIVER	SEGMENT 3	CT		90	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
405-0009 /50/M/A7	UNSCHEDULED/10JUN2013	TL:3/NODES	LEFT PARATRACHEAL	CT		21	
	UNSCHEDULED/10JUN2013	TL:4/SOFTT	ANTERIAL MEDIASTINUM	CT		28	
	UNSCHEDULED/10JUN2013	NTL:1/LIVE	SEGMENT2	CT	Present	.	
	UNSCHEDULED/10JUN2013	NTL:2/LUNG	MULTIPLE	CT	Present	.	
	UNSCHEDULED/10JUN2013	NTL:3/NODE	MEDIASTINUM, MULTIPLE	CT	Present	.	
	Summary:					.	SLD = 170, %CN = 18.88, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
405-0010 /39/M/A7	SCREENING/19MAY2013	TL:1/SOFTT	PERITONEUM,ANTERIOR	CT		35	
	SCREENING/19MAY2013	TL:2/SOFTT	PERITONEUM,LEFT	CT		40	SLD = 75
	SCREENING/19MAY2013	NTL:1/LIVE	MULTIPLE	CT		.	
	SCREENING/19MAY2013	NTL:2/LUNG	MULTIPLE	CT		.	
	SCREENING/19MAY2013	NTL:3/SOFT	PERITONEUM,MULTIPLE	CT		.	
	WEEK12/06AUG2013	TL:1/SOFTT	PERITONEUM,ANTERIOR	CT		50	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
405-0010 /39/M/A7	WEEK12/06AUG2013	TL:2/SOFTT	PERITONEUM,LEFT	CT		71	
	WEEK12/06AUG2013	NTL:1/LIVE	MULTIPLE	CT	Present	.	
	WEEK12/06AUG2013	NTL:2/LUNG	MULTIPLE	CT	UP	.	
	WEEK12/06AUG2013	NTL:3/SOFT	PERITONEUM,MULTIPLE	CT	UP	.	
	WEEK12/06AUG2013	NTL:4/SOFT	PERITONEUM, MULTIPLE	CT	New	.	
	Summary:					.	SLD = 121, %CN = 61.33, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 07AUG2013

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
405-0011 /63/M/A7	SCREENING/09MAY2013	TL:1/LUNG	LEFT UPPER LOBE	CT		16	
	SCREENING/09MAY2013	TL:2/LUNG	RIGHT LOWER LOBE	CT		13	SLD = 29
	SCREENING/09MAY2013	NTL:1/LUNG	MULTIPLE	CT		.	
	UNSCHEDULED/01JUL2013	TL:1/LUNG	LEFT UPPER LOBE	CT		15	
	UNSCHEDULED/01JUL2013	TL:2/LUNG	RIGHT LOWER LOBE	CT		12	
	UNSCHEDULED/01JUL2013	NTL:1/LUNG	MULTIPLE	CT	Present	.	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
405-0011 /63/M/A7	UNSCHEDULED/01JUL2013	NTL:1/LUNG	MULTIPLE	CT	Present	.	
	Summary:					.	SLD = 27, %CN = 22.73, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK12/29JUL2013	TL:1/LUNG	LEFT UPPER LOBE	CT		12	
	WEEK12/29JUL2013	TL:2/LUNG	RIGHT LOWER LOBE	CT		10	
	WEEK12/29JUL2013	NTL:1/LUNG	MULTIPLE	CT	Present	.	
	Summary:					.	SLD = 22, %CN = -24.14, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
405-0011 /63/M/A7	WEEK24/21OCT2013	TL:1/LUNG	LEFT UPPER LOBE	CT		12	
	WEEK24/21OCT2013	TL:2/LUNG	RIGHT LOWER LOBE	CT		13	
	WEEK24/21OCT2013	NTL:1/LUNG	MULTIPLE	CT	UP	.	
	Summary:					.	SLD = 25, %CN = 13.64, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 21OCT2013
405-0013 /45/M/A7	SCREENING/19MAY2013	TL:1/GI	PERITONEUM/LEFT SUBPHRENIC SPACE	CT		120	
	SCREENING/19MAY2013	TL:2/GI	PERITONEUM/RIGHT PELVIS	CT		48	SLD = 168

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
405-0013 /45/M/A7	SCREENING/19MAY2013	NTL:1/LIVE	LEFT LOBE	CT		.	
	SCREENING/19MAY2013	NTL:2/GI	PERITONEUM/MULTIPLE	CT		.	
	UNSCHEDULED/08JUL2013	TL:1/GI	PERITONEUM(LEFT SUBPHRENIC SPACE)	CT		125	
	UNSCHEDULED/08JUL2013	TL:2/GI	PERITONEUM(RIGHT PELVIS)	CT		44	
	UNSCHEDULED/08JUL2013	NTL:1/LIVE	LEFT LOBE	CT	Present	.	
	UNSCHEDULED/08JUL2013	NTL:2/GI	PERITONEUM(MULTIPLE)	CT	Present	.	

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[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
405-0013 /45/M/A7	Summary:					.	SLD = 169, %CN = 0.6, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK12/05AUG2013	TL:1/GI	PERITONEUM/LEFT SUBPHRENIC SPACE	CT		133	
	WEEK12/05AUG2013	TL:2/GI	PERITONEUM/RIGHT PELVIS	CT		40	
	WEEK12/05AUG2013	NTL:1/LIVE	LEFT LOBE	CT	Present	.	
	WEEK12/05AUG2013	NTL:2/GI	PERITONEUM/MULTIPLE	CT	Present	.	
	Summary:					.	SLD = 173, %CN = 2.98, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
405-0014 /35/M/A7	SCREENING/23MAY2013	TL:1/LUNG	RIGHT MEDIAL LOBE	CT		17	
	SCREENING/23MAY2013	TL:2/LUNG	LEFT LOWER LOBE	CT		15	SLD = 32
	SCREENING/23MAY2013	NTL:1/LIVE	MULTIPLE	CT		.	
	SCREENING/23MAY2013	NTL:2/LUNG	MULTIPLE	CT		.	
	SCREENING/23MAY2013	NTL:3/BONE	L2	CT		.	
	UNSCHEDULED/30JUN2013	TL:1/LUNG	RIGHT MEDIAL LOBE	CT		53	

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[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
405-0014 /35/M/A7	UNSCHEDULED/30JUN2013	TL:2/LUNG	LEFT LOWER LOBE	CT		21	
	UNSCHEDULED/30JUN2013	NTL:1/LIVE	MULTIPLE	CT	UP	.	
	UNSCHEDULED/30JUN2013	NTL:2/LUNG	MULTIPLE	CT	UP	.	
	UNSCHEDULED/30JUN2013	NTL:3/BONE	L2	CT	Present	.	
	Summary:					.	SLD = 74, %CN = 131.25, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 03JUL2013
405-0016 /41/M/A7	SCREENING/20MAY2013	TL:1/GI	PERITONEUM/ANT. PANCREAS	CT		38	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
405-0016 /41/M/A7	SCREENING/20MAY2013	TL:2/SOFTT	PERITONEUM/PELVIS	CT		37	
	SCREENING/20MAY2013	TL:3/LUNG	RIGHT MEDIAL LOBE	CT		21	
	SCREENING/20MAY2013	TL:4/NODES	PARAESOPHAGEAL LYMPH NODE	CT		23	SLD = 119
	SCREENING/20MAY2013	NTL:1/LIVE	MULTIPLE	CT		.	
	SCREENING/20MAY2013	NTL:2/SOFT	PERITONEUM/MULTIPLE	CT		.	
	SCREENING/20MAY2013	NTL:3/LUNG	MULTIPLE	CT		.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
405-0016 /41/M/A7	SCREENING/20MAY2013	NTL:4/NODE	LT.INTERLOBAR LYMPH NODE	CT		.	
	UNSCHEDULED/24JUN2013	TL:1/GI	PERITONEUM, ANTERIOR PANCREAS	CT		67	
	UNSCHEDULED/24JUN2013	TL:2/SOFTT	PERITONEAUM, PELVIS	CT		70	
	UNSCHEDULED/24JUN2013	TL:3/LUNG	RIGHT MEDIAL LOBE	CT		23	
	UNSCHEDULED/24JUN2013	TL:4/NODES	PARA ESOPHAGEAL LYMPHNODE	CT		26	
	UNSCHEDULED/24JUN2013	NTL:1/LIVE	MULTIPLE	CT	UP	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
405-0016 /41/M/A7	UNSCHEDULED/24JUN2013	NTL:2/SOFT	PERITONEUM, MULTIPLE	CT	UP	.	
	UNSCHEDULED/24JUN2013	NTL:3/LUNG	MULTIPLE	CT	UP	.	
	UNSCHEDULED/24JUN2013	NTL:4/NODE	LEFT INTERLOBAR	CT	NE	.	
	Summary:					.	SLD = 186, %CN = 56.3, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 25JUN2013
405-0018 /70/F/A7	SCREENING/31MAY2013	TL:1/LIVER	RT.LOBE	CT		124	
	SCREENING/31MAY2013	TL:2/SOFTT	PERITONEUM, RT.PERIHEPATIC SPACE	CT		24	

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[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
405-0018 /70/F/A7	SCREENING/31MAY2013	TL:3/LUNG	RIGHT UPPER LOBE	CT		26	
	SCREENING/31MAY2013	TL:4/LUNG	LEFT LOWER LOBE	CT		18	SLD = 192
	SCREENING/31MAY2013	NTL:1/NODE	AORTOCAVAL	CT		.	
	SCREENING/31MAY2013	NTL:2/LIVE	MULTIPLE	CT		.	
	SCREENING/31MAY2013	NTL:3/SOFT	PERITONEUM/PELVIS	CT		.	
	SCREENING/31MAY2013	NTL:4/LUNG	MULTIPLE	CT		.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
405-0018 /70/F/A7	UNSCHEDULED/02JUL2013	TL:1/LIVER	RIGHT LOBE	CT		146	
	UNSCHEDULED/02JUL2013	TL:2/SOFTT	PERITONEUM, RIGHT PERIHEPATIC SPACE	CT		16	
	UNSCHEDULED/02JUL2013	TL:3/LUNG	RIGHT UPPER LOBE	CT		33	
	UNSCHEDULED/02JUL2013	TL:4/LUNG	LEFT LOWER LOBE	CT		22	
	UNSCHEDULED/02JUL2013	NTL:1/NODE	AORTOCAVAL	CT	Present	.	
	UNSCHEDULED/02JUL2013	NTL:2/LIVE	MULTIPLE	CT	UP	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
405-0018 /70/F/A7	UNSCHEDULED/02JUL2013	NTL:3/SOFT	PERITONEUM, PELVIS	CT	Present	.	
	UNSCHEDULED/02JUL2013	NTL:4/LUNG	MULTIPLE	CT	UP	.	
	Summary:					.	SLD = 217, %CN = 13.02, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 03JUL2013
405-0020 /69/M/A7	WEEK48/14MAY2013	NTL:2/PERI	HEART/RIGHT VENTRICLE	CT	Present	.	
	SCREENING/12JUN2013	TL:1/LUNG	RIGHT LOWER LOBE	CT		18	
	SCREENING/12JUN2013	TL:2/LUNG	LEFT LOWER LOBE	CT		15	SLD = 33

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
405-0020 /69/M/A7	SCREENING/12JUN2013	NTL:1/LUNG	MULTIPLE	CT		.	
	SCREENING/12JUN2013	NTL:2/PERI	HEART/RIGHT VENTRICLE	CT		.	
	SCREENING/12JUN2013	NTL:3/PERI	HEART/INTERVENT RICULAR SEPTUM	CT		.	
	WEEK12/04SEP2013	TL:1/LUNG	RIGHT LOWER LOBE	CT		18	
	WEEK12/04SEP2013	TL:2/LUNG	LEFT LOWER LOBE	CT		14	
	WEEK12/04SEP2013	NTL:1/LUNG	MULTIPLE	CT	Present	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
405-0020 /69/M/A7	WEEK12/04SEP2013	NTL:2/PERI	HEART/RIGHT VENTRICLE	CT	Present	.	
	WEEK12/04SEP2013	NTL:3/PERI	HEART/INTERVENT RICULAR SEPTUM	CT	Present	.	
	Summary:					.	SLD = 32, %CN = -3.03, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK24/27NOV2013	TL:1/LUNG	RIGHT LOWER LOBE	CT		20	
	WEEK24/27NOV2013	TL:2/LUNG	LEFT LOWER LOBE	CT		16	
	WEEK24/27NOV2013	NTL:1/LUNG	MULTIPLE	CT	Present	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
405-0020 /69/M/A7	WEEK24/27NOV2013	NTL:2/PERI	HEART/RIGHT VENTRICLE	CT	Present	.	
	WEEK24/27NOV2013	NTL:3/PERI	HEART/INTERVENT RICULAR SEPTUM	CT	Present	.	
	Summary:					.	SLD = 36, %CN = 12.5, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK36/19FEB2014	TL:1/LUNG	RIGHT LEFT LOBE	CT		20	
	WEEK36/19FEB2014	TL:2/LUNG	LEFT LOWER LOBE	CT		17	
	WEEK36/19FEB2014	NTL:1/LUNG	MULTIPLE	CT	Present	.	

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Tumor Assessment Summary Listing
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Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
405-0020 /69/M/A7	WEEK36/19FEB2014	NTL:2/PERI	HEART/RIGHT VENTRICLE	CT	Present	.	
	WEEK36/19FEB2014	NTL:3/PERI	HEART/INTERVENTRICULAR SEPTUM	CT	Present	.	
	Summary:					.	SLD = 37, %CN = 15.63, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK48/14MAY2014	TL:1/LUNG	RIGHT LEFT LOBE	CT		25	
	WEEK48/14MAY2014	TL:2/LUNG	LEFT LOWER LOBE	CT		20	
	WEEK48/14MAY2014	NTL:1/LUNG	MULTIPLE	CT	UP	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
405-0020 /69/M/A7	WEEK48/14MAY2014	NTL:3/PERI	HEART/INTERVENTRICULAR SEPTUM	CT	Present	.	
	Summary:					.	SLD = 45, %CN = 40.63, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 14MAY2014
405-0021 /47/M/A7	SCREENING/17JUN2013	TL:1/SOFTT	RIGHT PERITONEUM	CT		80	
	SCREENING/17JUN2013	TL:2/SOFTT	LEFT PERITONEUM	CT		74	
	SCREENING/17JUN2013	TL:3/LUNG	RIGHT MEDIAL LOBE	CT		41	
	SCREENING/17JUN2013	TL:4/LUNG	LEFT LOWER LOBE	CT		40	SLD = 235

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
405-0021 /47/M/A7	SCREENING/17JUN2013	NTL:1/LIVE	LIPIODOLIZED	CT		.	
	SCREENING/17JUN2013	NTL:2/SOFT	PERITONEUM/MULTIPLE	CT		.	
	SCREENING/17JUN2013	NTL:3/LUNG	MULTIPLE	CT		.	
	WEEK12/04SEP2013	TL:1/SOFTT	RIGHT PERITONEUM	CT		87	
	WEEK12/04SEP2013	TL:2/SOFTT	LEFT PERITONEUM	CT		76	
	WEEK12/04SEP2013	TL:3/LUNG	RIGHT MEDIAL LOBE	CT		41	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
405-0021 /47/M/A7	WEEK12/04SEP2013	TL:4/LUNG	LEFT LOWER LOBE	CT		41	
	WEEK12/04SEP2013	NTL:1/LIVE	LIPIODOLIZED	CT	Present	.	
	WEEK12/04SEP2013	NTL:2/SOFT	PERITONEUM/MULTIPLE	CT	Present	.	
	WEEK12/04SEP2013	NTL:3/LUNG	MULTIPLE	CT	Present	.	
	Summary:					.	SLD = 245, %CN = 4.26, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	UNSCHEDULED/11OCT2013	TL:1/SOFTT	RIGHT PERITONEUM	CT		93	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
405-0021 /47/M/A7	UNSCHEDULED/11OCT2013	TL:2/SOFTT	LEFT PERITONEUM	CT		74	
	UNSCHEDULED/11OCT2013	TL:3/LUNG	RIGHT MEDIAL LOBE	CT		39	
	UNSCHEDULED/11OCT2013	TL:4/LUNG	LEFT LOWER LOBE	CT		40	
	UNSCHEDULED/11OCT2013	NTL:1/LIVE	LIPIODOLIZED	CT	Present	.	
	UNSCHEDULED/11OCT2013	NTL:2/SOFT	PERITONEUM, MULTIPLE	CT	Present	.	
	UNSCHEDULED/11OCT2013	NTL:3/LUNG	MULTIPLE	CT	Present	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
405-0021 /47/M/A7	Summary:					.	SLD = 802, %CN = 241.28, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK24/27NOV2013	TL:1/SOFTT	RIGHT PERITONEUM	CT		92	
	WEEK24/27NOV2013	TL:2/SOFTT	LEFT PERITONEUM	CT		76	
	WEEK24/27NOV2013	TL:3/LUNG	RIGHT MEDIAL LOBE	CT		40	
	WEEK24/27NOV2013	TL:4/LUNG	LEFT LOWER LOBE	CT		42	
	WEEK24/27NOV2013	NTL:1/LIVE	LIPIODOLIZED	CT	Present	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
405-0021 /47/M/A7	WEEK24/27NOV2013	NTL:2/SOFT	PERITONEUM/MULTIPLE	CT	Present	.	
	WEEK24/27NOV2013	NTL:3/LUNG	MULTIPLE	CT	Present	.	
	Summary:					.	SLD = 250, %CN = 6.38, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK36/17FEB2014	TL:1/SOFTT	RIGHT PERITONEUM	CT		98	
	WEEK36/17FEB2014	TL:2/SOFTT	LEFT PERITONEUM	CT		76	
	WEEK36/17FEB2014	TL:3/LUNG	RIGHT MEDIAL LOBE	CT		34	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
405-0021 /47/M/A7	WEEK36/17FEB2014	TL:4/LUNG	LEFT LOWER LOBE	CT		45	
	WEEK36/17FEB2014	NTL:1/LIVE	LIPIODOLIZED	CT	Present	.	
	WEEK36/17FEB2014	NTL:2/SOFT	PERITONEUM/MULTIPLE	CT	Present	.	
	WEEK36/17FEB2014	NTL:3/LUNG	MULTIPLE	CT	Present	.	
	Summary:					.	SLD = 253, %CN = 7.66, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK48/14MAY2014	TL:1/SOFTT	RIGHT PERITONEUM	CT		111	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
405-0021 /47/M/A7	WEEK48/14MAY2014	TL:2/SOFTT	LEFT PERITONEUM	CT		76	
	WEEK48/14MAY2014	TL:3/LUNG	RIGHT MEDIAL LOBE	CT		35	
	WEEK48/14MAY2014	TL:4/LUNG	LEFT LOWER LOBE	CT		46	
	WEEK48/14MAY2014	NTL:1/LIVE	LIPIODOLIZED	CT	Present	.	
	WEEK48/14MAY2014	NTL:2/SOFT	PERITONEUM/MULTIPLE	CT	Present	.	
	WEEK48/14MAY2014	NTL:3/LUNG	MULTIPLE	CT	Present	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
405-0021 /47/M/A7	Summary:					.	SLD = 268, %CN = 14.04, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	UNSCHEDULED/04JUL2014	TL:1/SOFTT	RIGHT PERITONEUM	CT		115	
	UNSCHEDULED/04JUL2014	TL:2/SOFTT	LEFT PERITONEUM	CT		74	
	UNSCHEDULED/04JUL2014	TL:3/LUNG	RIGHT MEDIAL LOBE	CT		32	
	UNSCHEDULED/04JUL2014	TL:4/LUNG	LEFT LOWER LOBE	CT		48	
	UNSCHEDULED/04JUL2014	NTL:1/LIVE	LIPIODOLIZED	CT	Present	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
405-0021 /47/M/A7	UNSCHEDULED/04JUL2014	NTL:2/SOFT	PERITONEUM, MULTIPLE	CT	Present	.	
	UNSCHEDULED/04JUL2014	NTL:3/LUNG	MULTIPLE	CT	Present	.	
	Summary:					.	SLD = 802, %CN = 241.28, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	UNSCHEDULED/06AUG2014	TL:1/SOFTT	PERITONEUM, RIGHT	CT		131	
	UNSCHEDULED/06AUG2014	TL:2/SOFTT	PERITONEUM,LEFT	CT		75	
	UNSCHEDULED/06AUG2014	TL:3/LUNG	RIGHT MIDDLE LOBE	CT		33	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
405-0021 /47/M/A7	UNSCHEDULED/06AUG2014	TL:4/LUNG	LEFT LOWER LOBE	CT		48	
	UNSCHEDULED/06AUG2014	NTL:1/LIVE	LIPIODOLIZED	CT	UP	.	
	UNSCHEDULED/06AUG2014	NTL:2/SOFT	PERITONEUM, MULTIPLE	CT	UP	.	
	UNSCHEDULED/06AUG2014	NTL:3/LUNG	MULTIPLE	CT	Present	.	
	Summary:					.	SLD = 802, %CN = 241.28, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 07AUG2014
405-0022 /65/M/A7	SCREENING/18JUN2013	TL:1/LIVER	SEGMENT2	CT		30	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
405-0022 /65/M/A7	SCREENING/18JUN2013	TL:2/SOFTT	PERITONEUM/LEFT ANTERIAL ABDOMEN	CT		107	
	SCREENING/18JUN2013	TL:3/SOFTT	PERITONEUM/LEFT LOWER QUADRANT	CT		117	
	SCREENING/18JUN2013	TL:4/LUNG	RIGHT MERIAL LOBE	CT		17	SLD = 271
	SCREENING/18JUN2013	NTL:1/LIVE	MULTIPLE	CT		.	
	SCREENING/18JUN2013	NTL:2/LUNG	MULTIPLE	CT		.	
	UNSCHEDULED/26AUG2013	TL:1/LIVER	SEGMENT 2	CT		37	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
405-0022 /65/M/A7	UNSCHEDULED/26AUG2013	TL:2/SOFTT	PERITONEUM, LEFT ANTERIAL ABDOMEN	CT		106	
	UNSCHEDULED/26AUG2013	TL:3/SOFTT	LEFT LOWER QUADRANT	CT		119	
	UNSCHEDULED/26AUG2013	TL:4/LUNG	RIGHT MEDIAL LOBE	CT		16	
	UNSCHEDULED/26AUG2013	NTL:1/LIVE	MULTIPLE	CT	Present	.	
	UNSCHEDULED/26AUG2013	NTL:2/LUNG	MULTIPLE	CT	Present	.	
	Summary:					.	SLD = 278, %CN = 2.58, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
405-0022 /65/M/A7	WEEK12/16SEP2013	TL:1/LIVER	SEGMENT2	CT		44	
	WEEK12/16SEP2013	TL:2/SOFTT	PERITONEUM/LEFT ANTERIAL ABDOMEN	CT		104	
	WEEK12/16SEP2013	TL:3/SOFTT	PERITONEUM/LEFT LOWER QUADRANT	CT		114	
	WEEK12/16SEP2013	TL:4/LUNG	RIGHT MERIAL LOBE	CT		16	
	WEEK12/16SEP2013	NTL:1/LIVE	MULTIPLE	CT	Present	.	
	WEEK12/16SEP2013	NTL:2/LUNG	MULTIPLE	CT	Present	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
405-0022 /65/M/A7	Summary:					.	SLD = 278, %CN = 2.58, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK24/11DEC2013	TL:1/LIVER	SEGMENT2	CT		62	
	WEEK24/11DEC2013	TL:2/SOFTT	PERITONEUM/LEFT ANTERIAL ABDOMEN	CT		105	
	WEEK24/11DEC2013	TL:3/SOFTT	PERITONEUM/LEFT LOWER QUADRANT	CT		121	
	WEEK24/11DEC2013	TL:4/LUNG	RIGHT MERIAL LOBE	CT		16	
	WEEK24/11DEC2013	NTL:1/LIVE	MULTIPLE	CT	UP	.	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
405-0022 /65/M/A7	WEEK24/11DEC2013	NTL:2/LUNG	MULTIPLE	CT	UP	.	
	Summary:					.	SLD = 304, %CN = 12.18, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 18DEC2013
405-0023 /46/M/A7	SCREENING/17JUN2013	TL:1/LUNG	LEFT LOWER LOBE	CT		41	
	SCREENING/17JUN2013	TL:2/LUNG	RIGHT UPPER LOBE	CT		14	SLD = 55
	SCREENING/17JUN2013	NTL:1/LUNG	MULTIPLE	CT		.	
	SCREENING/17JUN2013	NTL:2/LIVE	LIPIODOLIZED	CT		.	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
405-0023 /46/M/A7	WEEK12/02SEP2013	TL:1/LUNG	LEFT LOWER LOBE	CT		58	
	WEEK12/02SEP2013	TL:2/LUNG	RIGHT UPPER LOBE	CT		23	
	WEEK12/02SEP2013	NTL:1/LUNG	MULTIPLE	CT	UP	.	
	WEEK12/02SEP2013	NTL:2/LIVE	LIPIODOLIZED	CT	Present	.	
	Summary:					.	SLD = 81, %CN = 47.27, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 09SEP2013
405-0025 /47/M/A7	SCREENING/16JUN2013	TL:1/LIVER	SEGMENT8	CT		96	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
405-0025 /47/M/A7	SCREENING/16JUN2013	TL:2/LIVER	SEGMENT8	CT		41	
	SCREENING/16JUN2013	TL:3/NODES	LT.GASTRIC LYMPH NODE	CT		33	
	SCREENING/16JUN2013	TL:4/NODES	PARA SPLENIC LYMPH NODE	CT		43	
	SCREENING/16JUN2013	TL:5/LUNG	LEFT LOWER LOBE	CT		21	SLD = 234
	SCREENING/16JUN2013	NTL:1/LIVE	MULTIPLE	CT		.	
	SCREENING/16JUN2013	NTL:2/NODE	MEDIASTINAL	CT		.	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
405-0025 /47/M/A7	SCREENING/16JUN2013	NTL:3/LUNG	MULTIPLE	CT		.	
	UNSCHEDULED/17JUL2013	TL:1/LIVER	SEGMENT8	CT		94	
	UNSCHEDULED/17JUL2013	TL:2/LIVER	SEGMENT8	CT		43	
	UNSCHEDULED/17JUL2013	TL:3/NODES	LEFT GASTRIC LYMPH NODE	CT		36	
	UNSCHEDULED/17JUL2013	TL:4/NODES	PARA-SPLENIC LYMPH NODE	CT		44	
	UNSCHEDULED/17JUL2013	NTL:1/LIVE	MULTIPLE	CT	Present	.	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
405-0025 /47/M/A7	Summary:					.	SLD = 238, %CN = 1.71, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 24JUL2013
	UNSCHEDULED/24JUL2013	TL:5/LUNG	LEFT LOWER LOBE	CT		21	
	UNSCHEDULED/24JUL2013	NTL:2/NODE	MEDIASTINAL	CT	UP	.	
	UNSCHEDULED/24JUL2013	NTL:3/LUNG	MULTIPLE	CT	UP	.	
405-0028 /67/M/A7	SCREENING/24JUL2013	TL:1/NODES	LEFT PAR-AAORTIC	CT		28	
	SCREENING/24JUL2013	TL:2/LUNG	RIGHT MIDDLE LOBE	CT		11	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
405-0028 /67/M/A7	SCREENING/24JUL2013	TL:3/LUNG	RIGHT LOWER LOBE	CT		16	SLD = 55
	SCREENING/24JUL2013	NTL:1/NODE	LEFT NECK	CT		.	
	SCREENING/24JUL2013	NTL:2/LUNG	MUTIPLE	CT		.	
	SCREENING/24JUL2013	NTL:3/GI	PERITONEUM	CT		.	
	WEEK12/07OCT2013	TL:1/NODES	LEFT PAR-AAORTIC	CT		32	
	WEEK12/07OCT2013	TL:2/LUNG	RIGHT MIDDLE LOBE	CT		17	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
405-0028 /67/M/A7	WEEK12/07OCT2013	TL:3/LUNG	RIGHT LOWER LOBE	CT		22	
	WEEK12/07OCT2013	NTL:1/NODE	LEFT NECK	CT	Present	.	
	WEEK12/07OCT2013	NTL:2/LUNG	MUTIPLE	CT	UP	.	
	WEEK12/07OCT2013	NTL:3/GI	PERITONEUM	CT	Present	.	
	Summary:					.	SLD = 71, %CN = 29.09, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 07OCT2013
405-0030 /35/M/A7	SCREENING/31JUL2013	TL:1/LIVER	SEGMENT 6	CT		21	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
405-0030 /35/M/A7	SCREENING/31JUL2013	TL:2/LIVER	SEGMENT 6	CT		15	
	SCREENING/31JUL2013	TL:3/LUNG	RIGHT MIDDLE LOBE	CT		17	
	SCREENING/31JUL2013	TL:4/LUNG	LEFT LOWER LOBE	CT		18	SLD = 71
	SCREENING/31JUL2013	NTL:1/LIVE	MULTIPLE	CT		.	
	SCREENING/31JUL2013	NTL:2/LUNG	MULTIPLE	CT		.	
	SCREENING/31JUL2013	NTL:3/NODE	INTRA-ABDOMINAL	CT		.	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
405-0030 /35/M/A7	UNSCHEDULED/25SEP2013	TL:1/LIVER	SEGMENT 6	CT		55	
	UNSCHEDULED/25SEP2013	TL:2/LIVER	SEGMENT 6	CT		55	
	UNSCHEDULED/25SEP2013	TL:3/LUNG	RIGHT MIDDLE LOBE	CT		19	
	UNSCHEDULED/25SEP2013	TL:4/LUNG	LEFT LOWER LOBE	CT		25	
	UNSCHEDULED/25SEP2013	NTL:1/LUNG	MULTIPLE	CT	UP	.	
	UNSCHEDULED/25SEP2013	NTL:2/LUNG	MULTIPLE	CT	UP	.	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
405-0030 /35/M/A7	UNSCHEDULED/25SEP2013	NTL:3/NODE	INTRA-ABDOMINAL	CT	Present	.	
	Summary:					.	SLD = 154, %CN = 116.9, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 25SEP2013
405-0032 /69/M/A7	SCREENING/15JUL2013	TL:1/NODES	LEFT HILAR SE8, IM24	CT		16	SLD = 16
	SCREENING/15JUL2013	NTL:1/LUNG	MULTIPLE	CT		.	
	SCREENING/15JUL2013	NTL:2/NODE	MEDIASTINAL MULTIPLE	CT		.	
	WEEK12/08OCT2013	TL:1/NODES	LEFT HILAR SE8, IM24	CT		13	

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[3] UP=Unequivocally Progressed
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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
405-0032 /69/M/A7	WEEK12/08OCT2013	NTL:1/LUNG	MULTIPLE	CT	Present	.	
	WEEK12/08OCT2013	NTL:2/NODE	MEDIASTINAL MULTIPLE	CT	Present	.	
	Summary:					.	SLD = 13, %CN = -18.75, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK24/30DEC2013	TL:1/NODES	LEFT HILAR SE8, IM24	CT		13	
	WEEK24/30DEC2013	NTL:1/LUNG	MULTIPLE	CT	Present	.	
	WEEK24/30DEC2013	NTL:2/NODE	MEDIASTINAL MULTIPLE	CT	Present	.	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
405-0032 /69/M/A7	Summary:					.	SLD = 13, %CN = 0, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK36/24MAR2014	TL:1/NODES	LEFT HILAR SE8, IM24	CT		13	
	WEEK36/24MAR2014	NTL:1/LUNG	MULTIPLE	CT	Present	.	
	WEEK36/24MAR2014	NTL:2/NODE	MEDIASTINAL MULTIPLE	CT	Present	.	
	Summary:					.	SLD = 13, %CN = 0, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK48/16JUN2014	TL:1/NODES	LEFT HILAR SE8, IM24	CT		16	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
405-0032 /69/M/A7	WEEK48/16JUN2014	NTL:1/LUNG	MULTIPLE	CT	Present	.	
	WEEK48/16JUN2014	NTL:2/NODE	MEDIASTINAL MULTIPLE	CT	Present	.	
	Summary:					.	SLD = 16, %CN = 23.08, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK60/05SEP2014	TL:1/NODES	LEFT HILAR SE8, IM24	CT		29	
	WEEK60/05SEP2014	NTL:1/LUNG	MULTIPLE	CT	UP	.	
	WEEK60/05SEP2014	NTL:2/NODE	MEDIASTINAL MULTIPLE	CT	UP	.	

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[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
405-0032 /69/M/A7	WEEK60/05SEP2014	NTL:3/LIVE	MULTIPLE	CT	New	.	
	Summary:					.	SLD = 29, %CN = 123.08, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 15SEP2014
405-0033 /43/M/A7	SCREENING/08AUG2013	TL:1/LUNG	LUL NODULE	CT		10	
	SCREENING/08AUG2013	TL:2/NODES	PORTA CAVAL LYMPH NODE	CT		27	
	SCREENING/08AUG2013	TL:3/GI	PERITONEAL SEEDING	CT		20	SLD = 57
	SCREENING/08AUG2013	NTL:1/LUNG	LUL	CT		.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
405-0033 /43/M/A7	SCREENING/08AUG2013	NTL:2/GI	PERITONEAL SEEDING	CT		.	
	WEEK12/23OCT2013	TL:1/LUNG	LUL NODULE	CT		17	
	WEEK12/23OCT2013	TL:2/NODES	PORTA CAVAL LYMPH NODE	CT		34	
	WEEK12/23OCT2013	TL:3/GI	PERITONEAL SEEDING	CT		41	
	WEEK12/23OCT2013	NTL:1/LUNG	LUL	CT	UP	.	
	WEEK12/23OCT2013	NTL:2/GI	PERITONEAL SEEDING	CT	UP	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
405-0033 /43/M/A7	Summary:					.	SLD = 92, %CN = 61.4, TL: PD, NTL: IncompleteResponse/SD, OR: PD, PD confirmed: Yes, 23OCT2013
405-0034 /61/M/A7	SCREENING/08AUG2013	TL:1/LIVER	LEFT LOBE	CT		15	
	SCREENING/08AUG2013	TL:2/LIVER	LEFT LOBE NODULE	CT		14	
	SCREENING/08AUG2013	TL:3/NODES	RIGHT ADRENAL GLAND	CT		63	SLD = 92
	SCREENING/08AUG2013	NTL:1/LUNG	MULTIPLE	CT		.	
	SCREENING/08AUG2013	NTL:2/LIVE	MULTIPLE	CT		.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
405-0034 /61/M/A7	WEEK12/23OCT2013	TL:1/LIVER	LEFT LOBE	CT		22	
	WEEK12/23OCT2013	TL:2/LIVER	LEFT LOBE NODULE	CT		21	
	WEEK12/23OCT2013	TL:3/NODES	RIGHT ADRENAL GLAND	CT		101	
	WEEK12/23OCT2013	NTL:1/LUNG	MULTIPLE	CT	UP	.	
	WEEK12/23OCT2013	NTL:2/LIVE	MULTIPLE	CT	UP	.	
	Summary:					.	SLD = 144, %CN = 56.52, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 23OCT2013

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
405-0035 /66/M/A7	SCREENING/02AUG2013	TL:1/LIVER	SEGMENT 8	CT		16	
	SCREENING/02AUG2013	TL:2/LIVER	SEGMENT 5	CT		23	
	SCREENING/02AUG2013	TL:3/SOFTT	MEDIASTINUM, ADJACENT TO DIAPHRAGM	CT		36	
	SCREENING/02AUG2013	TL:4/SOFTT	PERITONEUM/RECT OVESICAL POUCH	CT		44	SLD = 119
	UNSCHEDULED/11OCT2013	TL:1/LIVER	SEGMENT 8	CT		20	
	UNSCHEDULED/11OCT2013	TL:2/LIVER	SEGMENT5	CT		21	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
405-0035 /66/M/A7	UNSCHEDULED/11OCT2013	TL:3/SOFTT	MEDIASTINUM, ADJACENT TO DIAPHRAGM	CT		37	
	UNSCHEDULED/11OCT2013	TL:4/SOFTT	PERITONEAUM/RECTOVESICAL POUCH	CT		82	
	Summary:					.	SLD = 160, %CN = 34.45, TL: PD, NTL: NotAssessed, OR: PD, PD confirmed: Yes, 16OCT2013
405-0039 /73/M/A7	SCREENING/09SEP2013	TL:1/LIVER	SEGMENT 5	CT		23	
	SCREENING/09SEP2013	TL:2/LIVER	SEGMENT 6	CT		65	SLD = 88
	SCREENING/09SEP2013	NTL:1/LIVE	MULTIPLE	CT		.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
405-0039 /73/M/A7	UNSCHEDULED/05NOV2013	TL:1/LIVER	SEGMENT 5	CT		31	
	UNSCHEDULED/05NOV2013	TL:2/LIVER	SEGMENT 6	CT		73	
	UNSCHEDULED/05NOV2013	NTL:1/LIVE	MULTIPLE	CT	Present	.	
	Summary:					.	SLD = 104, %CN = 18.18, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK12/03DEC2013	TL:1/LIVER	SEGMENT 5	CT		31	
	WEEK12/03DEC2013	TL:2/LIVER	SEGMENT 6	CT		77	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
405-0039 /73/M/A7	WEEK12/03DEC2013	NTL:1/LIVE	MULTIPLE	CT	UP	.	
	Summary:					.	SLD = 108, %CN = 22.73, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 03DEC2013
405-0040 /65/M/A7	SCREENING/23SEP2013	TL:1/LUNG	LUNG NODULE	CT		59	SLD = 59
	SCREENING/23SEP2013	NTL:1/LUNG	MULTIPLE	CT		.	
	SCREENING/23SEP2013	NTL:2/LIVE	MULTIPLE	CT		.	
	WEEK12/09DEC2013	TL:1/LUNG	LUNG NODULE	CT		71	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
405-0040 /65/M/A7	WEEK12/09DEC2013	NTL:1/LUNG	MULTIPLE	CT	UP	.	
	WEEK12/09DEC2013	NTL:2/LIVE	MULTIPLE	CT	UP	.	
	Summary:					.	SLD = 71, %CN = 20.34, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 09DEC2013
405-0042 /53/M/A7	SCREENING/04OCT2013	TL:1/LUNG	LEFT UPPER LOBE	CT		21	
	SCREENING/04OCT2013	TL:2/LUNG	LEFT LOWER LOBE	CT		22	SLD = 43
	SCREENING/04OCT2013	NTL:1/LIVE	MULTIPLE	CT		.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
405-0042 /53/M/A7	SCREENING/04OCT2013	NTL:2/LUNG	MULTIPLE	CT		.	
	UNSCHEDULED/27NOV2013	TL:1/LUNG	LEFT UPPER LOBE	CT		28	
	UNSCHEDULED/27NOV2013	TL:2/LUNG	LEFT LOWER LOBE	CT		30	
	UNSCHEDULED/27NOV2013	NTL:1/LIVE	MULTIPLE	CT	UP	.	
	UNSCHEDULED/27NOV2013	NTL:2/LUNG	MULTIPLE	CT	UP	.	
	Summary:					.	SLD = 58, %CN = 34.88, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 06DEC2013

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
405-0043 /49/M/A7	SCREENING/25SEP2013	TL:1/LIVER	SEGMENT 4	CT		28	
	SCREENING/25SEP2013	TL:2/LIVER	SEGMENT 4	CT		12	
	SCREENING/25SEP2013	TL:3/LUNG	LEFT LOW LOBE	CT		17	
	SCREENING/25SEP2013	TL:4/LUNG	RIGHT UPPER LOBE	CT		12	SLD = 69
	SCREENING/25SEP2013	NTL:1/LIVE	MULTIPLE	CT		.	
	SCREENING/25SEP2013	NTL:2/LUNG	MULTIPLE	CT		.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
405-0043 /49/M/A7	UNSCHEDULED/05DEC2013	TL:1/LIVER	SEGMENT 4	CT		68	
	UNSCHEDULED/05DEC2013	TL:2/LIVER	SEGMENT 4	CT		38	
	UNSCHEDULED/05DEC2013	TL:3/LUNG	LEFT LOW LOBE	CT		41	
	UNSCHEDULED/05DEC2013	TL:4/LUNG	RIGHT UPPER LOBE	CT		34	
	UNSCHEDULED/05DEC2013	NTL:1/LIVE	MULTIPLE	CT	UP	.	
	UNSCHEDULED/05DEC2013	NTL:2/LUNG	MULTIPLE	CT	UP	.	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
405-0043 /49/M/A7	UNSCHEDULED/05DEC2013	NTL:3/BRAI	MULTIPLE	CT	New	.	
	Summary:					.	SLD = 181, %CN = 162.32, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 05DEC2013
405-0044 /56/M/A7	SCREENING/11SEP2013	TL:1/LUNG	LEFT LOW LOBE	CT		13	
	SCREENING/11SEP2013	TL:2/LUNG	LEFT UPPER LOBE	CT		10	SLD = 23
	SCREENING/11SEP2013	NTL:1/LIVE	MULTIPLE	CT		.	
	SCREENING/11SEP2013	NTL:2/LUNG	MULTIPLE	CT		.	

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[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
405-0044 /56/M/A7	UNSCHEDULED/13NOV2013	TL:1/LUNG	LEFT LOW LOBE	CT		17	
	UNSCHEDULED/13NOV2013	TL:2/LUNG	LEFT UPPER LOBE	CT		13	
	UNSCHEDULED/13NOV2013	NTL:1/LIVE	MULTIPLE	CT	UP	.	
	UNSCHEDULED/13NOV2013	NTL:2/LUNG	MULTIPLE	CT	Present	.	
	Summary:					.	SLD = 30, %CN = 30.43, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 13NOV2013
501-0001 /59/M/A1	SCREENING/05NOV2013	TL:1/LUNG	RIGHT LUNG	CT		40	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
501-0001 /59/M/A1	SCREENING/05NOV2013	TL:2/LUNG	LEFT LUNG	CT		37	
	SCREENING/05NOV2013	TL:3/LIVER	RIGHT LIVER	CT		15	SLD = 92
	SCREENING/05NOV2013	NTL:1/LUNG	BILATERAL PULMONARY	CT		.	
	SCREENING/05NOV2013	NTL:2/LIVE	LIVER	CT		.	
	SCREENING/05NOV2013	NTL:3/	RIGHT SUPRARENAL	CT		.	
	WEEK12/23JAN2014	TL:1/LUNG	RIGHT LUNG	CT		75	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
501-0001 /59/M/A1	WEEK12/23JAN2014	TL:2/LUNG	LEFT LUNG	CT		50	
	WEEK12/23JAN2014	TL:3/LIVER	RIGHT LIVER	CT		30	
	WEEK12/23JAN2014	NTL:1/LUNG	BILATERAL PULMONARY	CT	UP	.	
	WEEK12/23JAN2014	NTL:2/LIVE	LIVER	CT	Present	.	
	WEEK12/23JAN2014	NTL:3/	RIGHT SUPRARENAL	CT	UP	.	
	WEEK12/23JAN2014	NTL:4/LUNG	BILATERAL PULMONARY	CT	New	.	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
501-0001 /59/M/A1	Summary:					.	SLD = 155, %CN = 68.48, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 23JAN2014
501-0002 /36/F/A1	SCREENING/27NOV2013	TL:1/LUNG	LEFT SUPERIOR LUNG	CT		20	
	SCREENING/27NOV2013	TL:2/LUNG	RIGHT LOWER LUNG	CT		17	SLD = 37
	SCREENING/27NOV2013	NTL:1/LUNG	TWO LUNGS	CT		.	
	WEEK12/17FEB2014	TL:1/LUNG	LEFT SUPERIOR LUNG	CT		20	
	WEEK12/17FEB2014	TL:2/LUNG	RIGHT LOWER LUNG	CT		20	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
501-0002 /36/F/A1	WEEK12/17FEB2014	NTL:1/LUNG	TWO LUNGS	CT	Present	.	
	WEEK12/17FEB2014	NTL:2/GI	LEFT ADRENAL	CT	New	.	
	Summary:					.	SLD = 40, %CN = 8.11, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 19FEB2014
501-0005 /80/M/A1	SCREENING/14JAN2014	TL:1/LIVER	LEFT LIVER	CT		110	
	SCREENING/14JAN2014	TL:2/SOFTT	THE LEFT SIDE OF THE CHEST WALL	CT		20	SLD = 130
	SCREENING/14JAN2014	NTL:1/LIVE	INTRAHEPATIC MULTIPLE METASTASES.	CT		.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
501-0005 /80/M/A1	SCREENING/14JAN2014	NTL:2/PLEU	MULTIPLE METASTASES OF THE LEFT PLEURAL.	CT		.	
	SCREENING/14JAN2014	NTL:3/BONE	THE BONE MULTIPLE METASTATIC	CT		.	
	WEEK12/10APR2014	TL:1/LIVER	LEFT LIVER	CT		110	
	WEEK12/10APR2014	TL:2/SOFTT	THE LEFT SIDE OF THE CHEST WALL	CT	Resolved	.	
	WEEK12/10APR2014	NTL:1/LIVE	INTRAHEPATIC MULTIPLE METASTASES.	CT	Present	.	
	WEEK12/10APR2014	NTL:2/PLEU	MULTIPLE METASTASES OF THE LEFT PLEURAL.	CT	Present	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
501-0005 /80/M/A1	WEEK12/10APR2014	NTL:3/BONE	THE BONE MULTIPLE METASTATIC	CT	Present	.	
	Summary:					.	SLD = ., %CN = ., TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK24/03JUL2014	TL:1/LIVER	LEFT LIVER	CT		124	
	WEEK24/03JUL2014	TL:2/SOFTT	THE LEFT SIDE OF THE CHEST WALL	CT	Resolved	.	
	WEEK24/03JUL2014	NTL:1/LIVE	INTRAHEPATIC MULTIPLE METASTASES.	CT	Present	.	
	WEEK24/03JUL2014	NTL:2/PLEU	MULTIPLE METASTASES OF THE LEFT PLEURAL.	CT	Present	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
501-0005 /80/M/A1	WEEK24/03JUL2014	NTL:3/BONE	THE BONE MULTIPLE METASTATIC	CT	Present	.	
	Summary:					.	SLD = ., %CN = ., TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK36/24SEP2014	TL:1/LIVER	LEFT LIVER	CT		125	
	WEEK36/24SEP2014	TL:2/SOFTT	THE LEFT SIDE OF THE CHEST WALL	CT	Resolved	.	
	WEEK36/24SEP2014	NTL:1/LIVE	INTRAHEPATIC MULTIPLE METASTASES.	CT	Present	.	
	WEEK36/24SEP2014	NTL:2/PLEU	MULTIPLE METASTASES OF THE LEFT PLEURAL.	CT	Present	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
501-0005 /80/M/A1	WEEK36/24SEP2014	NTL:3/BONE	THE BONE MULTIPLE METASTATIC	CT	Present	.	
	Summary:					.	SLD = ., %CN = ., TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK48/20DEC2014	TL:1/LIVER	LEFT LIVER	CT		125	
	WEEK48/20DEC2014	TL:2/SOFTT	THE LEFT SIDE OF THE CHEST WALL	CT	Resolved	.	
	WEEK48/20DEC2014	NTL:1/LIVE	INTRAHEPATIC MULTIPLE METASTASES.	CT	Present	.	
	WEEK48/20DEC2014	NTL:2/PLEU	MULTIPLE METASTASES OF THE LEFT PLEURAL.	CT	Present	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
501-0005 /80/M/A1	WEEK48/20DEC2014	NTL:3/BONE	THE BONE MULTIPLE METASTATIC	CT	Present	.	
	Summary:					.	SLD = ., %CN = ., TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK60/12MAR2015	TL:1/LIVER	LEFT LIVER	CT		126	
	WEEK60/12MAR2015	TL:2/SOFTT	THE LEFT SIDE OF THE CHEST WALL	CT	Resolved	.	
	WEEK60/12MAR2015	NTL:1/LIVE	INTRAHEPATIC MULTIPLE METASTASES.	CT	Present	.	
	WEEK60/12MAR2015	NTL:2/PLEU	MULTIPLE METASTASES OF THE LEFT PLEURAL.	CT	Present	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
501-0005 /80/M/A1	WEEK60/12MAR2015	NTL:3/BONE	THE BONE MULTIPLE METASTATIC	CT	Present	.	
	Summary:					.	SLD = ., %CN = ., TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK72/03JUN2015	TL:1/LIVER	LEFT LIVER	CT		125	
	WEEK72/03JUN2015	TL:2/SOFTT	THE LEFT SIDE OF THE CHEST WALL	CT	Resolved	.	
	WEEK72/03JUN2015	NTL:1/LIVE	INTRAHEPATIC MULTIPLE METASTASES.	CT	Present	.	
	WEEK72/03JUN2015	NTL:2/PLEU	MULTIPLE METASTASES OF THE LEFT PLEURAL.	CT	Present	.	

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[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
501-0005 /80/M/A1	WEEK72/03JUN2015	NTL:3/BONE	THE BONE MULTIPLE METASTATIC	CT	Present	.	
	WEEK72/03JUN2015	NTL:4/SOFT	CHEST WALL	CT	New	.	
	WEEK72/03JUN2015	NTL:5/LIVE		CT	New	.	
	Summary:					.	SLD = ., %CN = ., TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 03JUN2015
501-0006 /60/M/A1	SCREENING/07FEB2014	TL:1/LUNG	MIDDLE LOBE OF RIGHT LUNG	CT		15	
	SCREENING/07FEB2014	TL:2/LUNG	INFERIOR LOBE OF RIGHT LUNG	CT		17	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
501-0006 /60/M/A1	SCREENING/07FEB2014	TL:3/NODES	BY THE ABDOMINAL AORTA	CT		35	SLD = 67
	SCREENING/07FEB2014	NTL:1/LUNG	DOUBLE LUNG	CT		.	
	SCREENING/07FEB2014	NTL:2/NODE	MULTIPLE LYMPH NODES	CT		.	
	SCREENING/07FEB2014	NTL:3/LIVE	THE RIGHT LIVER	CT		.	
	SCREENING/07FEB2014	NTL:4/ASCI		CT		.	
	WEEK12/28APR2014	TL:1/LUNG	MIDDLE LOBE OF RIGHT LUNG	CT		18	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
501-0006 /60/M/A1	WEEK12/28APR2014	TL:2/LUNG	INFERIOR LOBE OF RIGHT LUNG	CT		25	
	WEEK12/28APR2014	TL:3/NODES	BY THE ABDOMINAL AORTA	CT		40	
	WEEK12/28APR2014	NTL:1/LUNG	DOUBLE LUNG	CT	UP	.	
	WEEK12/28APR2014	NTL:2/NODE	MULTIPLE LYMPH NODES	CT	Absent	.	
	WEEK12/28APR2014	NTL:3/LIVE	THE RIGHT LIVER	CT	Absent	.	
	WEEK12/28APR2014	NTL:4/ASCI		CT	Present	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
501-0006 /60/M/A1	WEEK12/28APR2014	NTL:5/LUNG	BILATERAL PULMONARY	CT	New	.	
	Summary:					.	SLD = 83, %CN = 23.88, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 28APR2014
501-0007 /43/M/A1	SCREENING/26FEB2014	TL:1/LUNG	RIGHT LUNG	CT		15	
	SCREENING/26FEB2014	TL:2/LUNG	RIGHT LUNG	CT		18	
	SCREENING/26FEB2014	TL:3/NODES	LEFT LUNG HILUM LYMPH NODE	CT		22	SLD = 55
	SCREENING/26FEB2014	NTL:1/LUNG	BILATERAL PULMONARY	CT		.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
501-0007 /43/M/A1	SCREENING/26FEB2014	NTL:2/LIVE	LIVER	CT		.	
	SCREENING/26FEB2014	NTL:3/LIVE	PORTAL VEIN TUMOR THROMBUS	CT		.	
	WEEK12/19MAY2014	TL:1/LUNG	RIGHT LUNG	CT		20	
	WEEK12/19MAY2014	TL:2/LUNG	RIGHT LUNG	CT		43	
	WEEK12/19MAY2014	TL:3/NODES	LEFT LUNG HILUM LYMPH NODE	CT		33	
	WEEK12/19MAY2014	NTL:1/LUNG	BILATERAL PULMONARY	CT	UP	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
501-0007 /43/M/A1	WEEK12/19MAY2014	NTL:2/LIVE	LIVER	CT	Present	.	
	WEEK12/19MAY2014	NTL:3/LIVE	PORTAL VEIN TUMOR THROMBUS	CT	Present	.	
	WEEK12/19MAY2014	NTL:4/LUNG	BILATERAL PULMONARY	CT	New	.	
	WEEK12/19MAY2014	NTL:5/LIVE	LIVER	CT	New	.	
	WEEK12/19MAY2014	NTL:6/NODE	HILUM OF LEFT LUNG LYMPH NODES	CT	New	.	
	Summary:					.	SLD = 96, %CN = 74.55, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 19MAY2014

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
501-0008 /76/F/A1	SCREENING/11APR2014	TL:1/LUNG	RIGHT LUNG	CT		24	
	SCREENING/11APR2014	TL:2/LUNG	LEFT LUNG	CT		54	SLD = 78
	WEEK12/01JUL2014	TL:1/LUNG	RIGHT LUNG	CT		44	
	WEEK12/01JUL2014	TL:2/LUNG	LEFT LUNG	CT		70	
	Summary:					.	SLD = 114, %CN = 46.15, TL: PD, NTL: NotAssessed, OR: PD, PD confirmed: Yes, 02JUL2014
501-0009 /62/M/A1	SCREENING/12JUL2014	TL:1/LIVER	LEFT LIVER	CT		38	SLD = 38

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
501-0009 /62/M/A1	SCREENING/12JUL2014	NTL:1/LIVE	RIGHT LIVER	CT		.	
	SCREENING/12JUL2014	NTL:2/SPLE	SPLEEN	CT		.	
	WEEK12/29SEP2014	TL:1/LIVER	LEFT LIVER	CT		47	
	WEEK12/29SEP2014	NTL:1/LIVE	RIGHT LIVER	CT	Present	.	
	WEEK12/29SEP2014	NTL:2/SPLE	SPLEEN	CT	Present	.	
	Summary:					.	SLD = 47, %CN = 23.68, TL: PD, NTL: IncompleteResponse/SD, OR: PD, PD confirmed: Yes, 29SEP2014

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Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
501-0010 /65/M/A1	SCREENING/02SEP2014	TL:1/LIVER	LEFT LIVER	CT		17	SLD = 17
	SCREENING/02SEP2014	NTL:1/LUNG	RIGHT LUNG	CT		.	
	SCREENING/02SEP2014	NTL:2/LIVE	LIVER	CT		.	
	WEEK12/26NOV2014	TL:1/LIVER	LEFT LIVER	CT		32	
	WEEK12/26NOV2014	NTL:1/LUNG	RIGHT LUNG	CT	Present	.	
	WEEK12/26NOV2014	NTL:2/LIVE	LIVER	CT	UP	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
501-0010 /65/M/A1	WEEK12/26NOV2014	NTL:3/LUNG	RIGHT LUNG	CT	New	.	
	WEEK12/26NOV2014	NTL:4/LIVE	LIVER	CT	New	.	
	WEEK12/26NOV2014	NTL:5/SOFT	SUBCUTANEOUS NODULE IN RIGHT RIB AREA	CT	New	.	
	Summary:					.	SLD = 32, %CN = 88.24, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 26NOV2014
502-0002 /65/M/A1	SCREENING/08JAN2014	TL:1/LUNG	METASTATIC NODULES IN LEFT LUNG	CT		30	
	SCREENING/08JAN2014	TL:2/LUNG	METASTATIC NODULES IN RIGHT LUNG	CT		35	SLD = 65

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Listing 16.2.6.2
Tumor Assessment Summary Listing
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Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
502-0002 /65/M/A1	SCREENING/08JAN2014	NTL:1/NODE	MEDIASTINAL LYMPH NODE METASTASIS	CT		.	
	SCREENING/08JAN2014	NTL:2/NODE	HILAR LYMPH NODE METASTASIS	CT		.	
503-0001 /32/M/A1	SCREENING/06DEC2013	TL:1/LUNG	RIGHT LOWER LOBE UNDER THE TRACHEAL BIFURCATION	CT		20	
	SCREENING/06DEC2013	TL:2/LUNG	RIGHT LOWER LOBE UNDER THE TRACHEAL BIFURCATION 4.5CM	CT		23	SLD = 43
	SCREENING/06DEC2013	NTL:1/LUNG	BILATERAL PULMONARY	CT		.	
	SCREENING/06DEC2013	NTL:2/LIVE	LIVER	CT		.	

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Tumor Assessment Summary Listing
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Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
503-0001 /32/M/A1	SCREENING/06DEC2013	NTL:3/	ABDOMINOPELVIC RIGHT SIDE OF THE MIDDLE	CT		.	
	SCREENING/06DEC2013	NTL:4/	ABDOMINOPELVIC RIGHT	CT		.	
	UNSCHEDULED/06JAN2014	TL:1/LUNG	RIGHT LOWER LOBE UNDER THE TRACHEAL BIFURCATION	CT		27	
	UNSCHEDULED/06JAN2014	TL:2/LUNG	RIGHT LOWER LUNG UNDER THE TRACHEAL BIFURCATION 4.5CM	CT		24	
	UNSCHEDULED/06JAN2014	NTL:1/LUNG	BILATERAL PULMONARY	CT	Present	.	
	UNSCHEDULED/06JAN2014	NTL:2/LIVE	LIVER	CT	Present	.	

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Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
503-0001 /32/M/A1	UNSCHEDULED/06JAN2014	NTL:3/	ABDOMINOPELVIC RIGHT SIDE OF THE MIDDLE	CT	Present	.	
	UNSCHEDULED/06JAN2014	NTL:4/	ABDOMINOPELVIC RIGHT	CT	Present	.	
	Summary:					.	SLD = 51, %CN = 18.6, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 03JAN2014
503-0004 /49/M/A1	SCREENING/11MAR2014	TL:1/LIVER	RIGHT-LOBE LIVER	CT		279	
	SCREENING/11MAR2014	TL:2/LIVER	RIGHT-LOBE LIVER	CT		320	
	SCREENING/11MAR2014	TL:3/LIVER	RIGHT-LOBE LIVER	CT		528	SLD = 1127

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

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503-0004 /49/M/A1	SCREENING/11MAR2014	NTL:1/LIVE	MULTIPLE	CT		.	
	SCREENING/11MAR2014	NTL:2/BONE	THE LEFT ILIUM	CT		.	
503-0006 /54/M/A1	SCREENING/04AUG2014	TL:1/LIVER	RIGHT LOBE OF LIVER	CT		13	
	SCREENING/04AUG2014	TL:2/LIVER	RIGHT LOBE OF LIVER	CT		40	SLD = 53
	WEEK12/23OCT2014	TL:1/LIVER	RIGHT LOBE OF LIVER	CT		15	
	WEEK12/23OCT2014	TL:2/LIVER	RIGHT LOBE OF LIVER	CT		40	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

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503-0006 /54/M/A1	Summary:					.	SLD = 55, %CN = 3.77, TL: SD, NTL: NotAssessed, OR: SD, PD confirmed: No
	WEEK24/14JAN2015	TL:1/LIVER	RIGHT LOBE OF LIVER	CT		15	
	WEEK24/14JAN2015	TL:2/LIVER	RIGHT LOBE OF LIVER	CT		40	
	Summary:					.	SLD = 55, %CN = 3.77, TL: SD, NTL: NotAssessed, OR: SD, PD confirmed: No
503-0007 /57/M/A1	SCREENING/23OCT2014	TL:1/LIVER	RIGHT LOBE OF LIVER, NEAR THE TOP OF MEDIASTINUM	CT		30	
	SCREENING/23OCT2014	TL:2/LIVER	RIGHT LOBE OF LIVER	CT		20	SLD = 50

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Tumor Assessment Summary Listing
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Treatment Group: ADI-PEG 20

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503-0007 /57/M/A1	SCREENING/23OCT2014	NTL:1/LIVE	INTRAHEPATIC SPREAD IN LOW DENSITY SHADOW	CT		.	
	WEEK12/14JAN2015	TL:1/LIVER	RIGHT LOBE OF LIVER, NEAR THE TOP OF MEDIASTINUM	CT		20	
	WEEK12/14JAN2015	TL:2/LIVER	RIGHT LOBE OF LIVER	CT		25	
	WEEK12/14JAN2015	NTL:1/LIVE	INTRAHEPATIC SPREAD IN LOW DENSITY SHADOW	CT	UP	.	
	Summary:					.	SLD = 45, %CN = -10, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 12JAN2015
503-0008 /50/M/A1	Summary:					.	SLD = 144, %CN = 51.58,

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Tumor Assessment Summary Listing
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Treatment Group: ADI-PEG 20

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503-0008 /50/M/A1	SCREENING/29OCT2014	TL:1/LIVER	RIGHT LOBE OF LIVER	CT		95	SLD = 95
	UNSCHEDULED/11DEC2014	TL:1/LIVER	RIGHT LOBE OF LIVER	CT		144	
503-0009 /57/M/A1	SCREENING/18NOV2014	TL:1/LIVER	SOLID LESION ON THE MIDDLE OF LIVER	CT		44	SLD = 44
	SCREENING/18NOV2014	NTL:1/BREA	EFFUSION ON THE RIGHT SIDE PLEURAL	CT		.	
504-0001 /47/M/A1	SCREENING/13FEB2014	TL:1/LIVER	LEFT LOBE OF LIVER	CT		50	
	SCREENING/13FEB2014	TL:2/LIVER	RIGHT LOBE OF LIVER	CT		50	SLD = 100

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Tumor Assessment Summary Listing
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Treatment Group: ADI-PEG 20

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504-0001 /47/M/A1	SCREENING/13FEB2014	NTL:1/LIVE	INTRAHEPATIC MULTIPLE LESIONS	CT		.	
	WEEK12/06MAY2014	TL:1/LIVER	LEFT LOBE OF LIVER	CT		62	
	WEEK12/06MAY2014	TL:2/LIVER	RIGHT LOBE OF LIVER	CT		53	
	WEEK12/06MAY2014	NTL:1/LIVE	INTRAHEPATIC MULTIPLE LESIONS	CT	Present	.	
	Summary:					.	SLD = 115, %CN = 15, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
504-0007 /32/M/A1	SCREENING/26SEP2014	TL:1/LIVER		CT		30	

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504-0007 /32/M/A1	SCREENING/26SEP2014	TL:2/BREAS	MEDIASTINAL LYMPH NODE	CT		18	
	SCREENING/26SEP2014	TL:3/LYMPH	ABDOMINAL LYMPH NODES	CT		25	SLD = 73
	SCREENING/26SEP2014	NTL:1/LIVE	2.EXIST	CT		.	
	SCREENING/26SEP2014	NTL:2/BONE	2.EXIST	CT		.	
	SCREENING/26SEP2014	NTL:3/BLOO	HEPATIC PORTAL VEIN THROMBOSIS 2.EXIST	CT		.	
	SCREENING/26SEP2014	NTL:4/LYMP	MEDIASTINAL LYMPH NODE METASTASIS 2.EXIST	CT		.	

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504-0007 /32/M/A1	SCREENING/26SEP2014	NTL:5/LYMP	1.METMEDIASTINAL LYMPH NODE METASTASIS 2. EXIST	CT		.	
505-0001 /70/M/A1	SCREENING/14AUG2014	TL:1/LUNG	LEFT	CT		120	
	SCREENING/14AUG2014	TL:2/LUNG	LEFT	CT		100	SLD = 220
	SCREENING/14AUG2014	NTL:1/BONE	LEFT SCAPULA	CT		.	
	UNSCHEDULED/28SEP2014	TL:1/LUNG	LEFT	CT		160	
	UNSCHEDULED/28SEP2014	TL:2/LUNG	LEFT	CT		140	

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505-0001 /70/M/A1	UNSCHEDULED/28SEP2014	NTL:1/BONE	LEFT SCAPULA	CT	Present	.	
	UNSCHEDULED/28SEP2014	NTL:2/PLEU	PLEURAL EFFUSSION	CT	New	.	
	UNSCHEDULED/28SEP2014	NTL:3/ASCI		CT	New	.	
	Summary:					.	SLD = 300, %CN = 36.36, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 28SEP2014
506-0002 /54/M/A1	SCREENING/05MAY2014	TL:1/LIVER	LIVER	MRI		176	
	SCREENING/05MAY2014	TL:2/BREAS	INTERCOSTAL	MRI		73	

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506-0002 /54/M/A1	SCREENING/05MAY2014	TL:3/GI	ENTEROCOELIA	MRI		106	SLD = 355
	SCREENING/05MAY2014	NTL:1/NODE	MULTIPLE LYMPH NODES	MRI		.	
	SCREENING/05MAY2014	NTL:2/ASCI	ABDOMINAL CAVITY EFFUSION	MRI		.	
	SCREENING/05MAY2014	NTL:3/LIVE	PORTAL VEIN CANCER EMBOLUS	MRI		.	
	SCREENING/05MAY2014	NTL:4/BREA	RIGHT ATRIAL CANCER EMBOLUS	MRI		.	
	SCREENING/05MAY2014	NTL:5/BREA	DOUBLE SIDE PLEURAL EFFUSION	CT		.	

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506-0002 /54/M/A1	UNSCHEDULED/11JUN2014	NTL:/BREAS	DOUBLE SIDE PLEURAL EFFUSION	CT	Present	.	
	UNSCHEDULED/12JUN2014	TL:1/LIVER	LIVER	MRI		173	
	UNSCHEDULED/12JUN2014	TL:2/BREAS	INTERCOSTAL	MRI		77	
	UNSCHEDULED/12JUN2014	TL:3/GI	ENTEROCOELIA	MRI		112	
	UNSCHEDULED/12JUN2014	NTL:/NODES	MULTIPLE LYMPH NODES	MRI	Present	.	
	UNSCHEDULED/12JUN2014	NTL:/LIVER	PORTAL VEIN CANCER EMBOLUS	MRI	Present	.	

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506-0002 /54/M/A1	UNSCHEDULED/12JUN2014	NTL:/BREAS	RIGHT ATRIAL CANCER EMBOLUS	MRI	Present	.	
	UNSCHEDULED/12JUN2014	NTL:2/ASCI	ABDOMINAL CAVITY EFFUSION	MRI	Present	.	
	Summary:					.	SLD = 362, %CN = 1.97, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK12/30JUL2014	NTL:5/BREA	DOUBLE SIDE PLEURAL EFFUSION	CT	Present	.	
	WEEK12/31JUL2014	TL:1/LIVER	LIVER	MRI		179	
	WEEK12/31JUL2014	TL:2/BREAS	INTERCOSTAL	MRI		75	

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506-0002 /54/M/A1	WEEK12/31JUL2014	TL:3/GI	ENTEROCOELIA	MRI		122	
	WEEK12/31JUL2014	NTL:1/NODE	MULTIPLE LYMPH NODES	MRI	Present	.	
	WEEK12/31JUL2014	NTL:2/ASCI	ABDOMINAL CAVITY EFFUSION	MRI	Present	.	
	WEEK12/31JUL2014	NTL:3/LIVE	PORTAL VEIN CANCER EMBOLUS	MRI	Present	.	
	WEEK12/31JUL2014	NTL:4/BREA	RIGHT ATRIAL CANCER EMBOLUS	MRI	Present	.	
	Summary:					.	SLD = 376, %CN = 5.92, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
506-0002 /54/M/A1	WEEK24/22OCT2014	TL:1/LIVER	LIVER	MRI		180	
	WEEK24/22OCT2014	TL:2/BREAS	INTERCOSTAL	MRI		86	
	WEEK24/22OCT2014	TL:3/GI	ENTEROCOELIA	MRI		127	
	WEEK24/22OCT2014	NTL:1/NODE	MULTIPLE LYMPH NODES	MRI	Present	.	
	WEEK24/22OCT2014	NTL:2/ASCI	ABDOMINAL CAVITY EFFUSION	MRI	Present	.	
	WEEK24/22OCT2014	NTL:3/LIVE	PORTAL VEIN CANCER EMBOLUS	MRI	Present	.	

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[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
506-0002 /54/M/A1	WEEK24/22OCT2014	NTL:4/BREA	RIGHT ATRIAL CANCER EMBOLUS	MRI	Present	.	
	WEEK24/22OCT2014	NTL:5/BREA	DOUBLE SIDE PLEURAL EFFUSION	CT	Present	.	
	Summary:					.	SLD = 393, %CN = 10.7, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK36/14JAN2015	TL:1/LIVER	LIVER	MRI		182	
	WEEK36/14JAN2015	TL:2/BREAS	INTERCOSTAL	MRI		97	
	WEEK36/14JAN2015	TL:3/GI	ENTEROCOELIA	MRI		137	

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[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
506-0002 /54/M/A1	WEEK36/14JAN2015	NTL:1/NODE	MULTIPLE LYMPH NODES	MRI	Present	.	
	WEEK36/14JAN2015	NTL:2/ASCI	ABDOMINAL CAVITY EFFUSION	MRI	Present	.	
	WEEK36/14JAN2015	NTL:3/LIVE	PORTAL VEIN CANCER EMBOLUS	MRI	Present	.	
	WEEK36/14JAN2015	NTL:4/BREA	RIGHT ATRIAL CANCER EMBOLUS	MRI	Present	.	
	WEEK36/14JAN2015	NTL:5/BREA	DOUBLE SIDE PLEURAL EFFUSION	CT	Present	.	
	Summary:					.	SLD = 416, %CN = 17.18, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
506-0002 /54/M/A1	WEEK48/07APR2015	NTL:5/BREA	DOUBLE SIDE PLEURAL EFFUSION	CT	Present	.	
	WEEK48/07APR2015	NTL:6/BREA	LUNG	CT	New	.	
	WEEK48/09APR2015	TL:1/LIVER	LIVER	MRI		183	
	WEEK48/09APR2015	TL:2/BREAS	INTERCOSTAL	MRI		106	
	WEEK48/09APR2015	TL:3/GI	ENTEROCOELIA	MRI		140	
	WEEK48/09APR2015	NTL:1/NODE	MULTIPLE LYMPH NODES	MRI	Present	.	

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[3] UP=Unequivocally Progressed
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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
506-0002 /54/M/A1	WEEK48/09APR2015	NTL:2/ASCI	ABDOMINAL CAVITY EFFUSION	MRI	Present	.	
	WEEK48/09APR2015	NTL:3/LIVE	PORTAL VEIN CANCER EMBOLUS	MRI	Present	.	
	WEEK48/09APR2015	NTL:4/BREA	RIGHT ATRIAL CANCER EMBOLUS	MRI	Present	.	
	Summary:					.	SLD = 429, %CN = 20.85, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 10APR2015
506-0003 /66/M/A1	SCREENING/18AUG2014	TL:1/LUNG	RIGHT UPPER LUNG	CT		32	SLD = 32
	UNSCHEDULED/27OCT2014	TL:1/LUNG	RIGHT UPPER LUNG	CT		46	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
506-0003 /66/M/A1	UNSCHEDULED/27OCT2014	NTL:2/LUNG	LUNG	CT	New	.	
	Summary:					.	SLD = 46, %CN = 43.75, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 29OCT2014
	UNSCHEDULED/28OCT2014	NTL:1/LIVE	LIVER	CT	New	.	
	UNSCHEDULED/28OCT2014	NTL:3/NODE	PELVIC LYMPH NODE	CT	New	.	
506-0004 /49/M/A1	SCREENING/20OCT2014	TL:1/LUNG	MIDDLE LOBE OF RIGHT LUNG	CT		21	
	SCREENING/20OCT2014	TL:2/LUNG	INFERIOR LOBE OF RIGHT LUNG	CT		27	SLD = 48

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
506-0004 /49/M/A1	SCREENING/20OCT2014	NTL:1/NODE	MEDIASTINAL LYMPH NODE	CT		.	
	SCREENING/20OCT2014	NTL:5/LUNG	MULTIPLE METASTASIS	CT		.	
	SCREENING/21OCT2014	NTL:2/ASCI	ASCITES	MRI		.	
	SCREENING/21OCT2014	NTL:3/BONE	LEFT ILIUM AND ACETABULAR BONE	CT		.	
	SCREENING/21OCT2014	NTL:4/LIVE	MULTIPLE METASTASIS	MRI		.	
	UNSCHEDULED/23DEC2014	NTL:2/ASCI	ASCITES	MRI	Present	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
506-0004 /49/M/A1	UNSCHEDULED/23DEC2014	NTL:4/LIVE	MULTIPLE METASTASES	MRI	Present	.	
	UNSCHEDULED/24DEC2014	TL:1/LUNG	MIDDLE LOBE OF RIGHT LUNG	CT		27	
	UNSCHEDULED/24DEC2014	TL:2/LUNG	INFERIOR LOBE OF RIGHT LUNG	CT		39	
	UNSCHEDULED/24DEC2014	NTL:1/NODE	MEDIASTINAL LYMPH NODES	CT	Present	.	
	UNSCHEDULED/24DEC2014	NTL:5/LUNG	MULTIPLE METASTASES	CT	Present	.	
	Summary:					.	SLD = 66, %CN = 37.5, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 25DEC2014

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
506-0004 /49/M/A1	UNSCHEDULED/25DEC2014	NTL:3/BONE	LEFT IEFT AND ACETABULAR BONE	CT	Present	.	
508-0001 /36/M/A1	SCREENING/31DEC2013	TL:1/NODES	MEDIASTINAL LYMPH NODES	CT		38	
	SCREENING/31DEC2013	TL:2/NODES	MEDIASTINAL LYMPH NODES	CT		31	
	SCREENING/31DEC2013	TL:3/LUNG	LEFT LOWER LUNG	CT		15	SLD = 84
	SCREENING/31DEC2013	NTL:1/LUNG	RIGHT UPPER LUNG	CT		.	
	SCREENING/31DEC2013	NTL:2/LUNG	LEFT LOWER LUNG	CT		.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
508-0001 /36/M/A1	SCREENING/31DEC2013	NTL:3/NODE	MEDIASTINAL LYMPH NODES	CT		.	
	SCREENING/31DEC2013	NTL:4/LUNG	RIGHT LOWER LUNG	CT		.	
	UNSCHEDULED/08FEB2014	TL:1/NODES	MEDIASTINAL LYMPH NODES	CT		36	
	UNSCHEDULED/08FEB2014	TL:2/NODES	MEDIASTINAL LYMPH NODES	CT		29	
	UNSCHEDULED/08FEB2014	TL:3/LUNG	LEFT LOWER LUNG	CT		31	
	UNSCHEDULED/08FEB2014	NTL:1/LUNG	RIGHT UPPER LUNG	CT	UP	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
508-0001 /36/M/A1	UNSCHEDULED/08FEB2014	NTL:2/LUNG	LEFT LOWER LUNG	CT	UP	.	
	UNSCHEDULED/08FEB2014	NTL:3/NODE	MEDIASTINAL LYMPH NODES	CT	Present	.	
	UNSCHEDULED/08FEB2014	NTL:4/LUNG	RIGHT LOWER LUNG	CT	Present	.	
	UNSCHEDULED/08FEB2014	NTL:5/NODE	MEDIASTINAL LYMPH NODES	CT	New	.	
	Summary:					.	SLD = 96, %CN = 14.29, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 11FEB2014
508-0003 /49/F/A1	SCREENING/24FEB2014	TL:1/LUNG	RIGHE UPPER LUNG	CT		20	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
508-0003 /49/F/A1	SCREENING/24FEB2014	TL:2/LUNG	LEFT UPPER LUNG(NEAR THE CHEAST WALL)	CT		16	
	SCREENING/24FEB2014	TL:3/LUNG	LEFT UPPER LUNG	CT		16	
	SCREENING/24FEB2014	NTL:1/LIVE	MULTI-FOCAL	CT		.	
	SCREENING/13MAR2014	TL:4/LIVER	LEFT LOBE OF LIVER	CT		25	
	SCREENING/13MAR2014	TL:5/NODES	NEAR THE AORTAVENTRALIS	CT		21	SLD = 98
	SCREENING/13MAR2014	NTL:2/LIVE	RIGHT POSTERIOR PORTAL VEIN	CT		.	

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[3] UP=Unequivocally Progressed
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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
508-0003 /49/F/A1	SCREENING/13MAR2014	NTL:3/LUNG	MULTI-FOCAL	CT		.	
	SCREENING/13MAR2014	NTL:4/NODE	RETROPERITONEAL ,MULTI-FOCAL	CT		.	
509-0001 /45/M/A1	SCREENING/28APR2014	TL:1/LIVER	THE RIGHT HEPATIC LOBE LESIONG:78MM,ME TASTATIC. THE LEFT EXTERNAL HEPATIC LOBE LESION:48MM,MET ASTATI	CT		176	
	SCREENING/28APR2014	TL:2/SPLEE	SPLEEN NODE,METASTATIC .	CT		25	
	SCREENING/28APR2014	TL:3/LUNG	DOUBLE LUNG NODULES,METASTA TIC.	CT		18	SLD = 219
	SCREENING/28APR2014	NTL:1/SOFT	NODULE ON THE RIGHT SIDE OF THE ABDOMINAL WALL	CT		.	

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Tumor Assessment Summary Listing
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509-0001 /45/M/A1	SCREENING/28APR2014	NTL:2/BONE	THE LEFT RIB METASTASES	CT		.	
	SCREENING/28APR2014	NTL:3/LIVE	THE LEFT EXTERNAL HEPATIC LOBE METASTATIC LESION	CT		.	
	SCREENING/28APR2014	NTL:4/LUNG	BILATERAL PULMONARY NODULES	CT		.	
	SCREENING/28APR2014	NTL:5/PLEU	RIGHT PLEURAL EFFUSION	CT		.	
	WEEK12/18JUL2014	TL:1/LIVER	THE ABOVE THREE LESIONS IN SCREENING MERGED INTO ONE LESION.	CT		130	
	WEEK12/18JUL2014	TL:2/SPLEE	SPLEEN NODE,METASTATIC .	CT		24	

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509-0001 /45/M/A1	WEEK12/18JUL2014	TL:3/LUNG	DOUBLE LUNG NODULES,METASTATIC.	CT		30	
	WEEK12/18JUL2014	NTL:1/SOFT	NODULE ON THE RIGHT SIDE OF THE ABDOMINAL WALL	CT	UP	.	
	WEEK12/18JUL2014	NTL:2/BONE	THE LEFT RIB METASTASES	CT	Present	.	
	WEEK12/18JUL2014	NTL:3/LIVE	THE LEFT EXTERNAL HEPATIC LOBE NEW METASTATIC LESION	CT	UP	.	
	WEEK12/18JUL2014	NTL:4/LUNG	THE INCREASE OF BILATERAL PULMONARY NODULES	CT	UP	.	
	WEEK12/18JUL2014	NTL:5/PLEU	RIGHT PLEURAL EFFUSION	CT	Present	.	

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509-0001 /45/M/A1	Summary:					.	SLD = 184, %CN = -15.98, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 18JUL2014
509-0002 /51/M/A1	SCREENING/26MAY2014	TL:1/HEAD&	THE LEFT OF NECK SWELLING LYMPH NODE METASTASIS	CT		38	
	SCREENING/26MAY2014	TL:2/LIVER	THE RIGHT POSTERIOR LIVER NEOPLASM	CT		73	
	SCREENING/26MAY2014	TL:3/SOFTT	SWOLLEN LYMPH NODE METASTASIS BY ABDOMINAL AORTA	CT		35	SLD = 146
	SCREENING/26MAY2014	NTL:1/SOFT	SWOLLEN LYMPH NODE METASTASIS BY ABDOMINAL AORTA,IN HEPATIC PORTAL ANG PANCREATIC HEAD REGION	CT		.	
510-0002 /50/M/A1	SCREENING/21MAY2014	TL:1/LIVER	RIGHT LOBE OF LIVER	CT		135	

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Tumor Assessment Summary Listing
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Treatment Group: ADI-PEG 20

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510-0002 /50/M/A1	SCREENING/21MAY2014	TL:2/LIVER	RIGHT LOBE OF LIVER, TRANSFER	CT		30	SLD = 165
	SCREENING/21MAY2014	NTL:1/LIVE	TRANSFER OF PORTAL VEIN TUMOR THROMBUS	CT		.	
510-0004 /72/M/A1	SCREENING/31JUL2014	TL:1/NODES	CELIAC LYMPH NODES TRANSFER	CT		23	SLD = 23
	SCREENING/31JUL2014	NTL:1/NODE	CELIAC LYMPH NODES;TRANSFER	CT		.	
	WEEK12/15OCT2014	TL:1/NODES	CELIAC LYMPH NODES TRANSFER	CT		29	
	WEEK12/15OCT2014	NTL:1/NODE	CELIAC LYMPH NODES;TRANSFER	CT	UP	.	

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510-0004 /72/M/A1	Summary:					.	SLD = 29, %CN = 26.09, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 15OCT2014
511-0001 /35/M/A1	SCREENING/17JAN2014	TL:1/LIVER	RECURRENCE OF LIVER ENHANCED CT	CT		18	SLD = 18
	SCREENING/17JAN2014	NTL:1/LIVE	OTHER LESIONS IN THE LIVER ENHANCE CT	CT		.	
	SCREENING/17JAN2014	NTL:2/LUNG	DOUBLE LUNG MULTIPLE METASTATIC LESIONS ENHANCE CT	CT		.	
	UNSCHEDULED/25FEB2014	TL:1/LIVER	INTRAHEPATIC RECURRENT LESIONS	CT		80	
	UNSCHEDULED/25FEB2014	NTL:1/LIVE	OTHER LESIONS IN THE LIVER	CT	Present	.	

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511-0001 /35/M/A1	UNSCHEDULED/25FEB2014	NTL:2/LUNG	DOUBLE LUNG METASTATIC LESIONS	CT	UP	.	
	Summary:					.	SLD = 80, %CN = 344.44, TL: PD, NTL: NotAssessed, OR: PD, PD confirmed: Yes, 26FEB2014
511-0002 /49/M/A1	SCREENING/07MAR2014	TL:1/LIVER	LESIONS IN THE LIVER	CT		92	SLD = 92
	WEEK12/27MAY2014	TL:1/LIVER	LESIONS IN THE LIVER	CT		100	
	Summary:					.	SLD = 100, %CN = 8.7, TL: SD, NTL: NotAssessed, OR: SD, PD confirmed: No
	WEEK24/20AUG2014	TL:1/LIVER	LESIONS IN THE LIVER	CT		119	

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511-0002 /49/M/A1	Summary:					.	SLD = 119, %CN = 29.35, TL: PD, NTL: NotAssessed, OR: PD, PD confirmed: Yes, 20AUG2014
512-0001 /59/M/A1	SCREENING/03MAR2014	TL:1/LUNG	LEFT LOWER LOBE	CT		33	
	SCREENING/03MAR2014	TL:2/LUNG	INFERIOR LOBE OF RIGHT LUNG	CT		31	SLD = 64
	SCREENING/03MAR2014	NTL:1/LUNG	SUPERIOR LOBE OF LEFT LUNG	CT		.	
	SCREENING/03MAR2014	NTL:2/LUNG	SUPERIOR LOBE OF LEFT LUNG	CT		.	
	SCREENING/03MAR2014	NTL:3/LUNG	SUPERIOR LOBE OF LEFT LUNG	CT		.	

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512-0001 /59/M/A1	WEEK12/24MAY2014	TL:1/LUNG	LEFT LOWER LOBE	CT		35	
	WEEK12/24MAY2014	TL:2/LUNG	INFERIOR LOBE OF RIGHT LUNG	CT		39	
	WEEK12/24MAY2014	NTL:1/LUNG	SUPERIOR LOBE OF LEFT LUNG	CT	Present	.	
	WEEK12/24MAY2014	NTL:2/LUNG	SUPERIOR LOBE OF LEFT LUNG	CT	Present	.	
	WEEK12/24MAY2014	NTL:3/LUNG	SUPERIOR LOBE OF LEFT LUNG	CT	Present	.	
	Summary:					.	SLD = 74, %CN = 15.63, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No

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513-0001 /28/M/A1	SCREENING/04APR2014	TL:1/LIVER	RIGHT LOBE OF LIVER SEGMENT,ANTERIOR	CT		40	
	SCREENING/04APR2014	TL:2/LUNG	POSTERIOR SEGMENT OF RIGHT UPPER LOBE OF LUNG;METASTASIS	CT		17	SLD = 57
	SCREENING/04APR2014	NTL:1/LUNG	DOUBLE LUNG	CT		.	
	SCREENING/04APR2014	NTL:2/BONE	THE LEFT SACRUM;METASTASIS	CT		.	
	UNSCHEDULED/26MAY2014	TL:1/LIVER	RIGHT LOBE OF LIVER SEGMENT,ANTERIOR	CT		46	
	UNSCHEDULED/26MAY2014	TL:2/LUNG	POSTERIOR SEGMENT OF RIGHT UPPER LOBE OF LUNG;METASTASIS	CT		25	

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513-0001 /28/M/A1	UNSCHEDULED/26MAY2014	NTL:1/LUNG	DOUBLE LUNG	CT	UP	.	
	Summary:					.	SLD = 71, %CN = 24.56, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 22MAY2014
513-0004 /46/M/A1	SCREENING/17JUN2014	TL:1/LIVER	THE LEFT LOBE LIVER,METASTASIS.	CT		43	
	SCREENING/17JUN2014	TL:2/	THE LEFT LOWER ABDOMEN,METASTASIS.	CT		48	SLD = 91
	SCREENING/17JUN2014	NTL:1/LUNG	DOUBLE LUNG,METASTASIS.	CT		.	
	SCREENING/17JUN2014	NTL:2/GI	ANTERIOR RECTUM, MATASTASIS	CT		.	

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513-0004 /46/M/A1	UNSCHEDULED/16JUL2014	NTL:3/ASCI	ASCITES	Oth	New	.	
	Summary:					.	SLD = ., %CN = ., TL: NotAssessed, NTL: PD, OR: PD, PD confirmed: Yes, 16JUL2014
513-0005 /61/M/A1	SCREENING/31OCT2014	TL:1/LUNG	THE UPPER OF THE RIGHT LUNG	CT		10	
	SCREENING/31OCT2014	TL:2/LIVER	THE RIGHT HEPATIC LOBE,METASTASIS .	CT		45	SLD = 55
	SCREENING/31OCT2014	NTL:1/LIVE	THE PORTAL VEIN;METASTASIS . LEFT LUNG.	CT		.	
	SCREENING/31OCT2014	NTL:2/LUNG	THE RIGHT LUNG	CT		.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
513-0005 /61/M/A1	WEEK12/14JAN2015	TL:1/LUNG	THE UPPER OF THE RIGHT LUNG	CT		18	
	WEEK12/14JAN2015	TL:2/LIVER	THE RIGHT HEPATIC LOBE,METASTASIS .	CT		48	
	WEEK12/14JAN2015	NTL:1/LIVE	THE PORTAL VEIN;METASTASIS . LEFT LUNG.	CT	UP	.	
	WEEK12/14JAN2015	NTL:2/LUNG	THE RIGHT LUNG	CT	UP	.	
	Summary:					.	SLD = 66, %CN = 20, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 20JAN2015
515-0001 /64/M/A1	SCREENING/17FEB2014	TL:1/LUNG	SUPERIOR LOBE OF LEFT LUNG	CT		30	

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[3] UP=Unequivocally Progressed
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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
515-0001 /64/M/A1	SCREENING/17FEB2014	TL:2/LUNG	LINGUAL SEGMENT OF UPPER LOBE OF LEFT LUNG	CT		11	
	SCREENING/17FEB2014	TL:3/SOFTT	THE RIGHT ADRENAL GLAND	CT		19	
	SCREENING/17FEB2014	TL:4/NODES	RETROPERITONEAL LYMPH NODE	CT		72	SLD = 132
	SCREENING/17FEB2014	NTL:1/LUNG	DOUBLE LUNG DIFFUSE SPORADIC SMALL NODULES	CT		.	
	SCREENING/17FEB2014	NTL:2/PLEU	RIGHT PLEURAL EFFUSION (LITTLE)	CT		.	
	WEEK12/06MAY2014	NTL:3/BRAI	LEFT OCCIPITAL LOBE OF BRAIN METASTASES	CT	New	.	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
515-0001 /64/M/A1	WEEK12/07MAY2014	TL:4/NODES	RETROPERITONEAL LYMPH NODE	CT		72	
	WEEK12/07MAY2014	NTL:1/LUNG	DOUBLE LUNG DIFFUSE SPORADIC SMALL NODULES	CT	Present	.	
	WEEK12/07MAY2014	NTL:2/PLEU	RIGHT PLEURAL EFFUSION (LITTLE)	CT	Present	.	
	Summary:					.	SLD = 140, %CN = 6.06, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 07MAY2014
	WEEK12/08MAY2014	TL:1/LUNG	SUPERIOR LOBE OF LEFT LUNG	CT		35	
	WEEK12/08MAY2014	TL:2/LUNG	LINGUAL SEGMENT OF UPPER LOBE OF LEFT LUNG	CT		17	

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[3] UP=Unequivocally Progressed
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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
515-0001 /64/M/A1	WEEK12/08MAY2014	TL:3/SOFTT	THE RIGHT ADRENAL GLAND	CT		16	
515-0003 /69/M/A1	SCREENING/09MAY2014	TL:1/LIVER	THE RIGHT LOBE OF THE LIVER SEGMENT VIII	CT		29	
	SCREENING/09MAY2014	TL:2/LUNG	RIGHT LOWER LOBE	CT		12	SLD = 41
	SCREENING/09MAY2014	NTL:1/LUNG	MULTIPLE PULMONARY METASTASES	CT		.	
	WEEK12/29JUL2014	TL:1/LIVER	THE RIGHT LOBE OF THE LIVER SEGMENT VIII	CT		40	
	WEEK12/29JUL2014	TL:2/LUNG	RIGHT LOWER LOBE	CT		18	

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[3] UP=Unequivocally Progressed
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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
515-0003 /69/M/A1	WEEK12/29JUL2014	NTL:1/LUNG	MULTIPLE PULMONARY METASTASES	CT	UP	.	
	WEEK12/29JUL2014	NTL:2/LIVE	SUPERIOR VENA CAVA TUMOR THROMBUS	CT	New	.	
	WEEK12/29JUL2014	NTL:3/PLEU	A SMALL AMOUNT THE RIGHT SIDE OF PLEURAL EFFUSION	CT	New	.	
	Summary:					.	SLD = 58, %CN = 41.46, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 29JUL2014
515-0004 /52/M/A1	SCREENING/22MAY2014	TL:1/LUNG	HILUM OF LEFT LUNG METASTASES	CT		31	
	SCREENING/22MAY2014	TL:2/LIVER	SECTION VII OF LIVER	CT		33	SLD = 64

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
515-0004 /52/M/A1	SCREENING/22MAY2014	NTL:1/LUNG	MULTIPLE PULMONARY METASTASIS	CT		.	
	WEEK12/11AUG2014	TL:1/LUNG	HILUM OF LEFT LUNG METASTASES	CT		32	
	WEEK12/11AUG2014	TL:2/LIVER	SECTION VII OF LIVER	CT		33	
	WEEK12/11AUG2014	NTL:1/LUNG	MULTIPLE PULMONARY METASTASIS	CT	Present	.	
	Summary:					.	SLD = 65, %CN = 1.56, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
515-0006 /47/M/A1	SCREENING/23JUL2014	TL:1/LUNG	THE LEFT LUNG TONGUE SEGMENT METASTASIS	CT		15	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
515-0006 /47/M/A1	SCREENING/23JUL2014	TL:2/SOFTT	THE LEFT RETROPERITONEAL COLON	CT		22	SLD = 37
	SCREENING/23JUL2014	NTL:1/LIVE	MULTIPLE LIVER METASTASES	CT		.	
	SCREENING/23JUL2014	NTL:2/PLEU	PERITONEAL MULTIPLE METASTATIC LESIONS	CT		.	
	SCREENING/23JUL2014	NTL:3/ASCI	MILD ASCITES	CT		.	
	WEEK12/20OCT2014	TL:1/LUNG	THE LEFT LUNG TONGUE SEGMENT METASTASIS	CT		27	
	WEEK12/20OCT2014	TL:2/SOFTT	THE LEFT RETROPERITONEAL COLON	CT		17	

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[3] UP=Unequivocally Progressed
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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
515-0006 /47/M/A1	WEEK12/20OCT2014	NTL:1/LIVE	MULTIPLE LIVER METASTASES	CT	Present	.	
	WEEK12/20OCT2014	NTL:2/PLEU	PERITONEAL MULTIPLE METASTATIC LESIONS	CT	Present	.	
	WEEK12/20OCT2014	NTL:3/ASCI	MILD ASCITES	CT	Present	.	
	WEEK12/20OCT2014	NTL:4/LUNG	MULTIPLE METASTATIC LESIONS OF THE LUNG	CT	New	.	
	Summary:					.	SLD = 44, %CN = 18.92, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 20OCT2014
515-0007 /39/M/A1	SCREENING/12SEP2014	TL:1/LUNG	THE OUTER SIDE OF THE MIDDLE LOBE OF THE RIGHT LUNG METASTATIC LESIONS	CT		16	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
515-0007 /39/M/A1	SCREENING/12SEP2014	TL:2/LUNG	THE LEFT HILAR LYMPH NODE METASTASIS	CT		31	
	SCREENING/12SEP2014	TL:3/NODES	THE LEFT ADRENAL METASTASIS	CT		76	SLD = 123
	SCREENING/12SEP2014	NTL:1/LUNG	MULTIPLE LUNG METASTASES	CT		.	
	SCREENING/12SEP2014	NTL:2/NODE	MEDIASTINAL MULTIPLE LYMPH NODE METASTASIS	CT		.	
515-0008 /60/M/A1	SCREENING/21NOV2014	TL:1/LUNG	THE BACK SECTION OF LOWER LOBE OF RIGHT LUNG METASTASES	CT		33	SLD = 33
	SCREENING/21NOV2014	NTL:1/LUNG	THE RIGHT LUNG MULTIPLE METASTASES	CT		.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
515-0008 /60/M/A1	WEEK12/09FEB2015	TL:1/LUNG	THE BACK SECTION OF LOWER LOBE OF RIGHT LUNG METASTASES	CT		64	
	WEEK12/09FEB2015	NTL:1/LUNG	THE RIGHT LUNG MULTIPLE METASTASES	CT	UP	.	
	WEEK12/09FEB2015	NTL:2/NODE	RIGHT ADRENAL METASTASES	CT	New	.	
	WEEK12/09FEB2015	NTL:3/LUNG	RIGHT PULMONARY VEIN TUMOR THROMBUS	CT	New	.	
	WEEK12/09FEB2015	NTL:4/LUNG	BILATERAL PULMONARY MULTIPLE METASTATIC	CT	New	.	
	Summary:					.	SLD = 64, %CN = 93.94, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 11FEB2015

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Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
516-0001 /45/M/A1	SCREENING/05AUG2014	TL:1/LUNG	RIGHT LUNG TRANSFER	CT		27	SLD = 27
	SCREENING/05AUG2014	NTL:1/LUNG	MULTIPLE NODULES ON RUGHT LUNG	CT		.	
	SCREENING/05AUG2014	NTL:2/PLEU	MULTIPLE NODULES ON PLEURA	CT		.	
	WEEK12/25OCT2014	TL:1/LUNG	RIGHT LUNG TRANSFER	CT		27	
	WEEK12/25OCT2014	NTL:1/LUNG	MULTIPLE NODULES ON RUGHT LUNG	CT	Present	.	
	WEEK12/25OCT2014	NTL:2/PLEU	MULTIPLE NODULES ON PLEURA	CT	Present	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
516-0001 /45/M/A1	Summary:					.	SLD = 27, %CN = 0, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK24/16JAN2015	TL:1/LUNG	RIGHT LUNG TRANSFER	CT		35	
	WEEK24/16JAN2015	NTL:1/LUNG	MULTIPLE NODULES ON RUGHT LUNG	CT	Present	.	
	WEEK24/16JAN2015	NTL:2/PLEU	MULTIPLE NODULES ON PLEURA	CT	Present	.	
	Summary:					.	SLD = 35, %CN = 29.63, TL: PD, NTL: IncompleteResponse/SD, OR: PD, PD confirmed: Yes, 16JAN2015
517-0001 /42/M/A1	SCREENING/18DEC2013	TL:1/LIVER	THE LOWER RIGHT LOBE OF LIVER	CT		48	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
517-0001 /42/M/A1	SCREENING/18DEC2013	TL:2/LIVER	THE UPSIDE RIGHT LOBE OF THE LIVER	CT		55	
	SCREENING/18DEC2013	TL:3/LUNG	RIGHT LOWER LOBE OF LUNG			68	
	SCREENING/18DEC2013	TL:4/LUNG	RIGHT UPPER LOBE OF LUNG PAPILLARY PLANE	CT		47	SLD = 218
	SCREENING/18DEC2013	NTL:1/BONE	THE FOURTH LUMBAR VERTEBRA AND ITS RIGHT SIDE	CT		.	
	SCREENING/18DEC2013	NTL:2/LUNG	MULTIPLE LUNG METASTASES	CT		.	
	SCREENING/18DEC2013	NTL:3/LIVE	MULTIPLE LIVER METASTASIS	CT		.	

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[3] UP=Unequivocally Progressed
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517-0001 /42/M/A1	UNSCHEDULED/27JAN2014	TL:1/LIVER	THE LOWER RIGHT LOBE OF LIVER	CT		60	
	UNSCHEDULED/27JAN2014	TL:2/LIVER	THE UPSIDE RIGHT LOBE OF THE LIVER	CT		69	
	UNSCHEDULED/27JAN2014	TL:3/LUNG	RIGHT LOWER LOBE OF LUNG	CT		71	
	UNSCHEDULED/27JAN2014	TL:4/LUNG	RIGHT UPPER LOBE OF LUNG PAPILLARY PLANE	CT		58	
	UNSCHEDULED/27JAN2014	NTL:1/LIVE	MULTIPLE LIVER METASTASIS	CT	Present	.	
	UNSCHEDULED/27JAN2014	NTL:2/LUNG	MULTIPLE LUNG METASTASES	CT	UP	.	

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517-0001 /42/M/A1	UNSCHEDULED/27JAN2014	NTL:3/BONE	THE FOURTH LUMBAR VERTEBRA AND ITS RIGHT SIDE	CT	Present	.	
	Summary:					.	SLD = 258, %CN = 18.35, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 20JAN2014
517-0002 /43/M/A1	SCREENING/21MAR2014	TL:1/LIVER	LOBE OF THE RIGHT LIVER/METASTASIS	CT		16	
	SCREENING/21MAR2014	TL:2/LIVER	THE GAP BETWEEN LIVER AND KIDNEY	CT		17	
	SCREENING/21MAR2014	TL:3/GU	THE GAP BETWEEN LIVER AND KIDNEY	CT		17	
	SCREENING/21MAR2014	TL:4/GI	THE RIGHT SIDE OF RECTUM	CT		37	

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Tumor Assessment Summary Listing
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517-0002 /43/M/A1	SCREENING/21MAR2014	TL:5/GU	THE BLADDER BACK SIDE	CT		40	SLD = 127
	SCREENING/21MAR2014	NTL:1/GI	ASCENDING COLON SOFT MEMBRANE BAG PIECE	CT		.	
	SCREENING/21MAR2014	NTL:2/GI	THE RECTUM BEFORE BAG PIECE	CT		.	
	SCREENING/21MAR2014	NTL:3/GI	OTHER ABDOMINAL MASS	CT		.	
	WEEK12/12JUN2014	TL:1/LIVER	LOBE OF THE RIGHT LIVER/METASTASIS	CT		17	
	WEEK12/12JUN2014	TL:2/LIVER	THE GAP BETWEEN LIVER AND KIDNEY	CT		22	

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Tumor Assessment Summary Listing
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Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
517-0002 /43/M/A1	WEEK12/12JUN2014	TL:3/GU	THE GAP BETWEEN LIVER AND KIDNEY	CT		16	
	WEEK12/12JUN2014	TL:4/GI	THE RIGHT SIDE OF RECTUM	CT		38	
	WEEK12/12JUN2014	TL:5/GU	THE BLADDER BACK SIDE	CT		42	
	WEEK12/12JUN2014	NTL:1/GI	ASCENDING COLON SOFT MEMBRANE BAG PIECE	CT	Present	.	
	WEEK12/12JUN2014	NTL:2/GI	THE RECTUM BEFORE BAG PIECE	CT	Present	.	
	WEEK12/12JUN2014	NTL:3/GI	OTHER ABDOMINAL MASS	CT	Present	.	

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517-0002 /43/M/A1	Summary:					.	SLD = 135, %CN = 6.3, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK24/04SEP2014	TL:1/LIVER	LOBE OF THE RIGHT LIVER/METASTASIS	CT		18	
	WEEK24/04SEP2014	TL:2/LIVER	THE GAP BETWEEN LIVER AND KIDNEY	CT		25	
	WEEK24/04SEP2014	TL:3/GU	THE GAP BETWEEN LIVER AND KIDNEY	CT		23	
	WEEK24/04SEP2014	TL:4/GI	THE RIGHT SIDE OF RECTUM	CT		48	
	WEEK24/04SEP2014	TL:5/GU	THE BLADDER BACK SIDE	CT		56	

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517-0002 /43/M/A1	WEEK24/04SEP2014	NTL:1/GI	ASCENDING COLON SOFT MEMBRANE BAG PIECE	CT	Present	.	
	WEEK24/04SEP2014	NTL:2/GI	THE RECTUM BEFORE BAG PIECE	CT	UP	.	
	WEEK24/04SEP2014	NTL:3/GI	OTHER ABDOMINAL MASS	CT	New	.	
	Summary:					.	SLD = 170, %CN = 33.86, TL: PD, NTL: IncompleteResponse/SD, OR: PD, PD confirmed: Yes, 04SEP2014
517-0005 /46/M/MI X	SCREENING/23MAY2014	TL:1/LIVER	THE SIXTH LOBE OF LIVER	CT		78	
	SCREENING/23MAY2014	TL:2/LIVER	THE SEVENTH LOBE OF LIVER	CT		60	SLD = 138

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517-0006 /67/F/A1	SCREENING/11AUG2014	TL:1/LIVER	LIVER FLAT HEART PLANE(TRANSFER)	CT		17	
	SCREENING/11AUG2014	TL:2/LIVER	LIVER FLAT STOMACH PLANE(TRANSFER)	CT		14	SLD = 31
	SCREENING/11AUG2014	NTL:1/LIVE	THE TOP 8 HEPATIC LOBE	CT		.	
	WEEK12/12NOV2014	TL:1/LIVER	LIVER FLAT HEART PLANE(TRANSFER)	CT		17	
	WEEK12/12NOV2014	TL:2/LIVER	LIVER FLAT STOMACH PLANE(TRANSFER)	CT		18	
	WEEK12/12NOV2014	NTL:1/LIVE	THE TOP 8 HEPATIC LOBE	CT	Present	.	

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517-0006 /67/F/A1	Summary:					.	SLD = 35, %CN = 12.9, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK24/02FEB2015	TL:1/LIVER	LIVER FLAT HEART PLANE(TRANSFER)	CT		17	
	WEEK24/02FEB2015	TL:2/LIVER	LIVER FLAT STOMACH PLANE(TRANSFER)	CT		19	
	WEEK24/02FEB2015	NTL:1/LIVE	THE TOP 8 HEPATIC LOBE	CT	Present	.	
	Summary:					.	SLD = 36, %CN = 16.13, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK36/23APR2015	TL:1/LIVER	LIVER FLAT HEART PLANE(TRANSFER)	CT		21	

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517-0006 /67/F/A1	WEEK36/23APR2015	TL:2/LIVER	LIVER FLAT STOMACH PLANE(TRANSFER)	CT		28	
	WEEK36/23APR2015	NTL:1/LIVE	THE TOP 8 HEPATIC LOBE	CT	Present	.	
	Summary:					.	SLD = 49, %CN = 58.06, TL: PD, NTL: IncompleteResponse/SD, OR: PD, PD confirmed: Yes, 23APR2015
517-0007 /66/M/A1	SCREENING/07AUG2014	TL:1/LIVER	LIVER TOP 8 PAGES	CT		21	
	SCREENING/07AUG2014	TL:2/LIVER	LIVER ON PAGE 6	CT		27	
	SCREENING/07AUG2014	TL:3/LIVER	CARDIOPHRENIC ANGLE	CT		11	

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517-0007 /66/M/A1	SCREENING/07AUG2014	TL:4/LIVER	THE LEFT LUNG HEART FLAT LARGE BLOOD VESSELS	CT		10	
	SCREENING/07AUG2014	TL:5/LIVER	MEDIASTINAL LYMPH NODES ON THE PROMONTORY	CT		21	SLD = 90
	SCREENING/07AUG2014	NTL:1/LIVE	WIDESPREAD METASTASIS	CT		.	
	SCREENING/07AUG2014	NTL:2/LUNG	WIDESPREAD METASTASIS	CT		.	
	SCREENING/07AUG2014	NTL:3/NODE	POSTERIOR MEDIASTINAL LYMPH NODESMULTIPLE METASTATIC	CT		.	
517-0008 /59/M/A1	SCREENING/18AUG2014	TL:1/LUNG	THE LEFT LUNG RETROSTERNAL	CT		57	

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517-0008 /59/M/A1	SCREENING/18AUG2014	TL:2/LUNG	ON THE BACK RIBS IN FRONT OF THE RIGHT LUNG	CT		25	SLD = 82
	SCREENING/18AUG2014	NTL:1/LUNG	MULTIPLE METASTASES	CT		.	
517-0009 /23/M/A1	SCREENING/26AUG2014	NTL:1/LUNG	MULTIPLE LUNG LESIONS	CT		.	
	SCREENING/12SEP2014	TL:1/LIVER	RIGHT LOBE OF LIVER	CT		13	
	SCREENING/12SEP2014	TL:2/LUNG	THE MIDDLE OF THE RIGHT LUNG	CT		34	
	SCREENING/12SEP2014	TL:3/LUNG	SUPERIOR LOBE OF LEFT LUNG	CT		19	SLD = 66

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517-0009 /23/M/A1	WEEK12/04DEC2014	NTL:1/LUNG	MULTIPLE LUNG LESIONS	CT	UP	.	
	WEEK12/10DEC2014	TL:1/LIVER	RIGHT LOBE OF LIVER	CT		34	
	WEEK12/10DEC2014	TL:2/LUNG	THE MIDDLE OF THE RIGHT LUNG	CT		45	
	WEEK12/10DEC2014	TL:3/LUNG	SUPERIOR LOBE OF LEFT LUNG	CT		27	
	Summary:					.	SLD = 106, %CN = 60.61, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 10DEC2014

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
101-0002 /70/M/OT H	SCREENING/13JUL2011	TL:1/LIVER		CT		200	SLD = 200

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
101-0002 /70/M/OTH	WEEK12/14OCT2011	TL:1/LIVER		CT		204	
	WEEK12/14OCT2011	NTL:1/LIVE		CT	New	.	
	WEEK12/14OCT2011	NTL:2/LIVE		CT	New	.	
	Summary:					.	SLD = 204, %CN = 2, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 18OCT2011
101-0004 /78/F/A2	SCREENING/22JUL2011	TL:1/LIVER	S100 I29	CT		19	SLD = 19
	WEEK12/21OCT2011	TL:1/LIVER	S100 I29	CT		13	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
101-0004 /78/F/A2	Summary:					.	SLD = 13, %CN = -31.58, TL: SD, NTL: NotAssessed, OR: SD, PD confirmed: No
	WEEK24/13JAN2012	TL:1/LIVER	S100 I29	CT		18	
	Summary:					.	SLD = 18, %CN = 38.46, TL: PD, NTL: NotAssessed, OR: PD, PD confirmed: Yes, 13JAN2012
	WEEK36/10APR2012	TL:1/LIVER	S100 I29	CT		21	
	Summary:					.	SLD = 21, %CN = 61.54, TL: PD, NTL: NotAssessed, OR: PD, PD confirmed: Yes, 13JAN2012
	WEEK48/29JUN2012	TL:1/LIVER	S100 I29	CT		22	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
101-0004 /78/F/A2	Summary:					.	SLD = 22, %CN = 69.23, TL: PD, NTL: NotAssessed, OR: PD, PD confirmed: Yes, 13JAN2012
	WEEK60/21SEP2012	TL:1/LIVER	S100 I29	CT		26	
	Summary:					.	SLD = 26, %CN = 100, TL: PD, NTL: NotAssessed, OR: PD, PD confirmed: Yes, 13JAN2012
101-0010 /43/M/BL	SCREENING/26AUG2011	TL:1/LIVER		CT		32	
	SCREENING/26AUG2011	TL:2/LIVER		CT		81	
	SCREENING/26AUG2011	TL:3/BONE		CT		116	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
101-0010 /43/M/BL	SCREENING/26AUG2011	TL:4/LUNG		CT		17	SLD = 246
101-0014 /61/M/W2	SCREENING/03JAN2012	TL:1/LIVER	SERIES 100 IMAGE 24	CT		23	
	SCREENING/03JAN2012	TL:2/LIVER	SERIES 100 IMAGE 35	CT		17	
	SCREENING/03JAN2012	TL:3/BONE	SERIES 101 IMAGE 23	CT		118	
	SCREENING/03JAN2012	TL:4/BONE	SERIES 101 IMAGE 91	CT		31	SLD = 189
	WEEK12/16MAR2012	TL:1/LIVER	SERIES 100 IMAGE 24	CT		29	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
101-0014 /61/M/W2	WEEK12/16MAR2012	TL:2/LIVER	SERIES 100 IMAGE 35	CT		25	
	WEEK12/16MAR2012	TL:3/BONE	SERIES 101 IMAGE 23	CT		124	
	WEEK12/16MAR2012	TL:4/BONE	SERIES 101 IMAGE 91	CT		37	
	Summary:					.	SLD = 215, %CN = 13.76, TL: SD, NTL: NotAssessed, OR: SD, PD confirmed: No
101-0015 /65/M/A4	SCREENING/28DEC2011	TL:1/LUNG	SERIES 4, IMAGE 31	CT		12	
	SCREENING/28DEC2011	TL:2/LUNG	SERIES 4, IMAGE 37	CT		12	SLD = 24

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
101-0015 /65/M/A4	SCREENING/28DEC2011	NTL:1/		CT		.	
	WEEK12/22MAR2012	TL:1/LUNG	SERIES 4, IMAGE 31	CT		12	
	WEEK12/22MAR2012	TL:2/LUNG	SERIES 4, IMAGE 37	CT		15	
	WEEK12/22MAR2012	NTL:1/LIVE		CT	New	.	
	Summary:					.	SLD = 27, %CN = 12.5, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 22MAR2012
101-0017 /60/M/W2	SCREENING/31JAN2012	TL:1/NODES	PARAAORTIC NODE. SERIES 101, IMAGE 77.	CT		17	SLD = 17

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
101-0017 /60/M/W2	SCREENING/31JAN2012	NTL:1/LIVE		CT		.	
	SCREENING/31JAN2012	NTL:2/NODE	MEDIASTINAL NODE	CT		.	
	WEEK12/01MAY2012	TL:1/NODES	PARAAORTIC NODE. SERIES 101, IMAGE 77.	CT		10	
	WEEK12/01MAY2012	NTL:1/LIVE		CT	Present	.	
	WEEK12/01MAY2012	NTL:2/NODE	MEDIASTINAL NODE	CT	UP	.	
	Summary:					.	SLD = 10, %CN = -41.18, TL: PR, NTL: PD, OR: PD, PD confirmed: Yes, 01MAY2012

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
101-0020 /86/M/W2	SCREENING/05MAR2012	TL:1/LIVER	S106 I69	CT		28	
	SCREENING/05MAR2012	TL:2/LIVER	S106 I63	CT		27	
	SCREENING/05MAR2012	TL:3/NODES	MEDIASTINAL LYMPH NODE. S106 I42	CT		21	SLD = 76
	WEEK12/05JUN2012	TL:1/LIVER	S106 I69	CT		35	
	WEEK12/05JUN2012	TL:2/LIVER	S106 I63	CT		31	
	WEEK12/05JUN2012	TL:3/NODES	MEDIASTINAL LYMPH NODE. S106 I42	CT		22	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
101-0020 /86/M/W2	Summary:					.	SLD = 88, %CN = 15.79, TL: SD, NTL: NotAssessed, OR: SD, PD confirmed: No
	WEEK24/21AUG2012	TL:1/LIVER	S106 I69	CT		68	
	WEEK24/21AUG2012	TL:2/LIVER	S106 I63	CT		39	
	WEEK24/21AUG2012	TL:3/NODES	MEDIASTINAL LYMPH NODE. S106 I42	CT		18	
	WEEK24/21AUG2012	NTL:1/LIVE	PORTAL VEIN	CT	New	.	
	WEEK24/21AUG2012	NTL:2/GI	PERITONEAL		New	.	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
101-0020 /86/M/W2	Summary:					.	SLD = 125, %CN = 64.47, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 21AUG2012
101-0027 /72/M/W2	SCREENING/30APR2012	TL:1/LIVER	S101 I53	CT		29	
	SCREENING/30APR2012	TL:2/LIVER	S101 I55	CT		15	
	SCREENING/30APR2012	TL:3/BONE	RIGHT PARASPINAL. S101 I23	CT		23	SLD = 67
	SCREENING/30APR2012	NTL:1/BONE	S101 I94	CT		.	
101-0031 /69/F/W2	SCREENING/03JUL2012	TL:1/LUNG	S6I17	CT		18	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
101-0031 /69/F/W2	SCREENING/03JUL2012	TL:2/LUNG	S6I26	CT		16	SLD = 34
	SCREENING/03JUL2012	NTL:1/LUNG	NOT SPECIFIED	CT		.	
	SCREENING/03JUL2012	NTL:2/LIVE	SERIES 4, IMAGE 13			.	
	WEEK12/29SEP2012	TL:1/LUNG	S6I17	CT		31	
	WEEK12/29SEP2012	TL:2/LUNG	S6I12	CT		23	
	WEEK12/29SEP2012	NTL:1/LUNG	NOT SPECIFIED	CT	UP	.	

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[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
101-0031 /69/F/W2	WEEK12/29SEP2012	NTL:2/LIVE	SERIES 4, IMAGE 13	CT	UP	.	
	Summary:					.	SLD = 54, %CN = 58.82, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 29SEP2012
101-0034 /44/M/OT H	SCREENING/07SEP2012	TL:1/LIVER	LIVER LESION	CT		67	
	SCREENING/07SEP2012	TL:2/LIVER	LIVER LESION	CT		25	
	SCREENING/07SEP2012	TL:3/LUNG	LUNG LESION	CT		10	SLD = 102
	SCREENING/07SEP2012	NTL:1/LIVE	PORTAL VEIN	CT		.	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
101-0034 /44/M/OTH	SCREENING/07SEP2012	NTL:2/LUNG	SERIES 6, IMAGE 39	CT		.	
	UNSCHEDULED/02NOV2012	TL:1/LIVER	SERIES 5, IMAGE 64	CT		67	
	UNSCHEDULED/02NOV2012	TL:2/LIVER	SERIES 5, IMAGE 56	CT		30	
	UNSCHEDULED/02NOV2012	TL:3/LUNG	SERIES 6, IMAGE 37	CT		13	
	UNSCHEDULED/02NOV2012	NTL:1/LIVE	PORTAL VEIN. SERIES 5, IMAGE 55	CT	Present	.	
	UNSCHEDULED/02NOV2012	NTL:2/LUNG	SERIES 6, IMAGE 39	CT	Present	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
101-0034 /44/M/OTH	Summary:					.	SLD = 110, %CN = 7.84, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
101-0035 /37/M/A6	SCREENING/20AUG2012	TL:1/PLEUR	SERIES 100 IMAGE 39	CT		34	
	SCREENING/20AUG2012	TL:2/PLEUR	SERIES 100 IMAGE 15	CT		47	
	SCREENING/20AUG2012	TL:3/BONE	SERIES 5 IMAGE 14	CT		59	SLD = 140
	SCREENING/20AUG2012	NTL:1/LUNG	SERIES 5 IMAGE 19	CT		.	
	SCREENING/20AUG2012	NTL:2/LUNG	SERIES 100 IMAGE 40	CT		.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
101-0043 /69/M/W1	SCREENING/03OCT2013	TL:1/LIVER	SERIES 5 IMAGE 64	CT		26	SLD = 26
	SCREENING/03OCT2013	NTL:1/LIVE	SEGMENT 4A. SERIES 5 IMAGE 48	CT		.	
	WEEK12/02JAN2014	TL:1/LIVER	SERIES 5 IMAGE 64	CT		28	
	WEEK12/02JAN2014	NTL:1/LIVE	SEGMENT 4A. SERIES 5 IMAGE 48	CT	Present	.	
	Summary:					.	SLD = 28, %CN = 7.69, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
101-0051 /70/F/W2	SCREENING/13JAN2014	TL:1/LIVER		CT		58	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
101-0051 /70/F/W2	SCREENING/13JAN2014	TL:2/LIVER		CT		28	SLD = 86
102-0006 /66/M/BL	SCREENING/05DEC2013	TL:1/SOFTT	LEFT STERNAL MANUBRIUM	CT		46	
	SCREENING/05DEC2013	TL:2/SOFTT	MEDIAL RIGHT RECTUS MUSCLE	CT		30	
	SCREENING/05DEC2013	TL:3/SOFTT	RIGHT ADRENAL MASS	CT		14	SLD = 90
	WEEK12/23FEB2014	TL:1/SOFTT	LEFT STERNAL MANUBRIUM	CT		69	
	WEEK12/23FEB2014	TL:2/SOFTT	MEDIAL RIGHT RECTUS MUSCLE	CT		36	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
102-0006 /66/M/BL	WEEK12/23FEB2014	TL:3/SOFTT	RIGHT ADRENAL MASS	CT		25	
	Summary:					.	SLD = 130, %CN = 44.44, TL: PD, NTL: NotAssessed, OR: PD, PD confirmed: Yes, 23FEB2014
102-0007 /61/M/W2	SCREENING/23DEC2013	TL:1/LIVER	SEGMENT 4	CT		27	SLD = 27
	WEEK12/19MAR2014	TL:1/LIVER	SEGMENT 4	CT		27	
	Summary:					.	SLD = 27, %CN = 0, TL: SD, NTL: NotAssessed, OR: SD, PD confirmed: No
103-0002 /74/M/W2	SCREENING/07DEC2012	TL:1/LUNG	SUPERIOR SEGMENT RIGHT LOWER LOBE	CT		27	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
103-0002 /74/M/W2	SCREENING/07DEC2012	TL:2/LUNG	LEFT LOWER LOBE POSTERIORLY AND INFERIORLY	CT		10	SLD = 37
	SCREENING/07DEC2012	NTL:1/LUNG	ANTERIOR LATERAL RIGHT LOWER LOBE	CT		.	
	SCREENING/07DEC2012	NTL:2/LUNG	RIGHT LOWER LOBE INFERIOR AND LATERAL	CT		.	
	WEEK12/25FEB2013	TL:1/LUNG	SUPERIOR SEGMENT RIGHT LOWER LOBE	CT		30	
	WEEK12/25FEB2013	TL:2/LUNG	LEFT LOWER LOBE POSTERIORLY AND INFERIORLY	CT		11	
	WEEK12/25FEB2013	NTL:1/LUNG	ANTERIOR LATERAL RIGHT LOWER LOBE	CT	NE	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
103-0002 /74/M/W2	WEEK12/25FEB2013	NTL:2/LUNG	RIGHT LOWER LOBE INFERIOR AND LATERAL	CT	NE	.	
	Summary:					.	SLD = 41, %CN = 10.81, TL: SD, NTL: NotEvaluable, OR: SD, PD confirmed: No
	WEEK24/20MAY2013	TL:1/LUNG	SUPERIOR SEGMENT RIGHT LOWER LOBE	CT		33	
	WEEK24/20MAY2013	TL:2/LUNG	LEFT LOWER LOBE POSTERIORLY AND INFERIORLY	CT		14	
	WEEK24/20MAY2013	NTL:1/LUNG	ANTERIOR LATERAL RIGHT LOWER LOBE	CT	NE	.	
	WEEK24/20MAY2013	NTL:2/LUNG	RIGHT LOWER LOBE INFERIOR AND LATERAL	CT	NE	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
103-0002 /74/M/W2	Summary:					.	SLD = 47, %CN = 27.03, TL: PD, NTL: NotEvaluable, OR: PD, PD confirmed: Yes, 20MAY2013
103-0006 /57/M/W2	SCREENING/29OCT2014	TL:1/SOFTT	RIGHT MID. ABDOMINAL LESION INFERIOR TO THE LIVER	MRI		49	
	SCREENING/29OCT2014	TL:2/SOFTT	LEVEL OF THE UMBILICUS	MRI		31	SLD = 80
	SCREENING/29OCT2014	NTL:1/LIVE	LIVER NODULES	MRI		.	
	SCREENING/29OCT2014	NTL:2/SOFT	ABDOMINAL NODULES	MRI		.	
	WEEK12/04FEB2015	TL:1/SOFTT	RIGHT MID. ABDOMINAL LESION INFERIOR TO THE LIVER	CT	NE	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
103-0006 /57/M/W2	WEEK12/04FEB2015	TL:2/SOFTT	LEVEL OF THE UMBILICUS	CT		55	
	WEEK12/04FEB2015	NTL:1/LIVE	LIVER NODULES	CT	Present	.	
	WEEK12/04FEB2015	NTL:2/SOFT	ABDOMINAL NODULES	CT	Present	.	
	Summary:					.	SLD = ., %CN = ., TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 04FEB2015
104-0002 /80/M/W2	SCREENING/27APR2012	TL:1/LIVER	MEDIAL RIGHT HEPATIC MASS IMG 85	CT		70	SLD = 70
	WEEK12/26JUL2012	TL:1/LIVER	MEDIAL RIGHT HEPATIC MASS IMG 85	CT		70	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
104-0002 /80/M/W2	Summary:					.	SLD = 70, %CN = 0, TL: SD, NTL: NotAssessed, OR: SD, PD confirmed: No
	WEEK24/20OCT2012	TL:1/LIVER	MEDIAL RIGHT HEPATIC MASS IMG 85	CT		74	
	Summary:					.	SLD = 74, %CN = 5.71, TL: SD, NTL: NotAssessed, OR: SD, PD confirmed: No
	WEEK36/12JAN2013	TL:1/LIVER	MEDIAL RIGHT HEPATIC MASS IMG 85	CT		81	
	Summary:					.	SLD = 81, %CN = 15.71, TL: SD, NTL: NotAssessed, OR: SD, PD confirmed: No
104-0007 /89/M/A1	SCREENING/11JUL2013	TL:1/LIVER	LOBULATED MID RIGHT HEPATIC LESION	CT		34	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
104-0007 /89/M/A1	SCREENING/11JUL2013	TL:2/LIVER	ANTERIOR RIGHT HEPATIC LESION	CT		18	
	SCREENING/11JUL2013	TL:3/LIVER	RIGHT HEPATIC LOBE NEAR DOME	CT		9	SLD = 61
	WEEK12/24OCT2013	TL:1/LIVER	LOBULATED MID RIGHT HEPATIC LESION	CT		31	
	WEEK12/24OCT2013	TL:2/LIVER	ANTERIOR RIGHT HEPATIC LESION	CT		18	
	WEEK12/24OCT2013	TL:3/LIVER	RIGHT HEPATIC LOBE NEAR DOME	CT		16	
	Summary:					.	SLD = 65, %CN = 6.56, TL: SD, NTL: NotAssessed, OR: SD, PD confirmed: No

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
104-0007 /89/M/A1	WEEK24/17JAN2014	TL:1/LIVER	LOBULATED MID RIGHT HEPATIC LESION	CT		30	
	WEEK24/17JAN2014	TL:2/LIVER	ANTERIOR RIGHT HEPATIC LESION	CT		17	
	WEEK24/17JAN2014	TL:3/LIVER	RIGHT HEPATIC LOBE NEAR DOME	CT		16	
	Summary:					.	SLD = 63, %CN = 36.96, TL: SD, NTL: NotAssessed, OR: SD, PD confirmed: No
	WEEK36/11APR2014	TL:1/LIVER	LOBULATED MID RIGHT HEPATIC LESION	CT		28	
	WEEK36/11APR2014	TL:2/LIVER	ANTERIOR RIGHT HEPATIC LESION	CT		19	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
104-0007 /89/M/A1	WEEK36/11APR2014	TL:3/LIVER	RIGHT HEPATIC LOBE NEAR DOME	CT		15	
	Summary:					.	SLD = 62, %CN = 34.78, TL: SD, NTL: NotAssessed, OR: SD, PD confirmed: No
	WEEK48/09JUL2014	TL:1/LIVER	LOBULATED MID RIGHT HEPATIC LESION	CT		30	
	WEEK48/09JUL2014	TL:2/LIVER	ANTERIOR RIGHT HEPATIC LESION	CT		17	
	WEEK48/09JUL2014	TL:3/LIVER	RIGHT HEPATIC LOBE NEAR DOME	CT		23	
	Summary:					.	SLD = 70, %CN = 52.17, TL: SD, NTL: NotAssessed, OR: SD, PD confirmed: No

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
104-0007 /89/M/A1	WEEK60/24SEP2014	TL:1/LIVER	LOBULATED MID RIGHT HEPATIC LESION	CT		27	
	WEEK60/24SEP2014	TL:2/LIVER	ANTERIOR RIGHT HEPATIC LESION	CT		17	
	WEEK60/24SEP2014	TL:3/LIVER	RIGHT HEPATIC LOBE NEAR DOME	CT		20	
	Summary:					.	SLD = 64, %CN = 39.13, TL: SD, NTL: NotAssessed, OR: SD, PD confirmed: No
	WEEK72/19DEC2014	TL:1/LIVER	LOBULATED MID RIGHT HEPATIC LESION	CT		27	
	WEEK72/19DEC2014	TL:2/LIVER	ANTERIOR RIGHT HEPATIC LESION	CT		17	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
104-0007 /89/M/A1	WEEK72/19DEC2014	TL:3/LIVER	RIGHT HEPATIC LOBE NEAR DOME	CT		10	
	Summary:					.	SLD = 54, %CN = 17.39, TL: SD, NTL: NotAssessed, OR: SD, PD confirmed: No
	WEEK84/17MAR2015	TL:1/LIVER	LOBULATED MID RIGHT HEPATIC LESION	CT		28	
	WEEK84/17MAR2015	TL:2/LIVER	ANTERIOR RIGHT HEPATIC LESION	CT		17	
	WEEK84/17MAR2015	TL:3/LIVER	RIGHT HEPATIC LOBE NEAR DOME	CT		8	
	Summary:					.	SLD = 53, %CN = 15.22, TL: SD, NTL: NotAssessed, OR: SD, PD confirmed: No

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
104-0007 /89/M/A1	WEEK96/05JUN2015	TL:1/LIVER	LOBULATED MID RIGHT HEPATIC LESION	CT		24	
	WEEK96/05JUN2015	TL:2/LIVER	ANTERIOR RIGHT HEPATIC LESION	CT		15	
	WEEK96/05JUN2015	TL:3/LIVER	RIGHT HEPATIC LOBE NEAR DOME	CT		7	
	Summary:					.	SLD = 46, %CN = 0, TL: SD, NTL: NotAssessed, OR: SD, PD confirmed: No
105-0003 /57/M/W2	SCREENING/11OCT2013	TL:1/LIVER	RIGHT LOBE SEGMENT 5 LESION (SE: 15001 IMAGE#44)	MRI		48	SLD = 48
	WEEK12/22JAN2014	TL:1/LIVER	RIGHT LOBE SEGMENT 5 LESION (SE: 27 IMAGE #12)	MRI		43	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
105-0003 /57/M/W2	Summary:					.	SLD = 43, %CN = -10.42, TL: SD, NTL: NotAssessed, OR: SD, PD confirmed: No
	WEEK24/24APR2014	TL:1/LIVER	RIGHT LOBE SEGMENT 5 LESION .STABLE DISEASE	MRI		43	
	Summary:					.	SLD = 43, %CN = 13.16, TL: SD, NTL: NotAssessed, OR: SD, PD confirmed: No
	WEEK36/08JUL2014	TL:1/LIVER	NO CHANGES	MRI		43	
	Summary:					.	SLD = 43, %CN = 13.16, TL: SD, NTL: NotEvaluable, OR: SD, PD confirmed: No
	WEEK48/03OCT2014	TL:1/LIVER	SIMILAR HIGH SIGNAL, ILL DEFINED AREAS. RT PV THROMBOSIS. SEG 5 LESION SLIGHTLY DECREASED IN SIZE ME	MRI		38	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
105-0003 /57/M/W2	Summary:					.	SLD = 38, %CN = 0, TL: SD, NTL: NotEvaluable, OR: SD, PD confirmed: No
105-0006 /60/F/BL	SCREENING/08DEC2014	TL:1/	SE3 IMAGE 20 (SEG. 8) 31MM	CT		31	
	SCREENING/08DEC2014	TL:2/	SE3 IMAGE 25 (SEG. 5) 14MM	CT		27	SLD = 58
	WEEK12/17MAR2015	TL:1/	SE2 IMAGE 17 (SEG. 8) 30MM	CT		30	
	WEEK12/17MAR2015	TL:2/	SE2 IMAGE 20 (SEG. 5) 27MM	CT		27	
	Summary:					.	SLD = 57, %CN = -1.72, TL: SD, NTL: NotAssessed, OR: SD, PD confirmed: No

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
105-0006 /60/F/BL	WEEK24/11JUN2015	TL:1/	SE4 IMAGE 18 (SEG. 8) 35MM	CT		35	
	WEEK24/11JUN2015	TL:2/	SE4 IMAGE 20 (SEG. 5) 25MM	CT		25	
	Summary:					.	SLD = 60, %CN = 5.26, TL: PD, NTL: NotAssessed, OR: PD, PD confirmed: Yes, 18JUN2015
108-0003 /85/M/W2	SCREENING/31OCT2012	TL:1/SOFTT	PARASPINAL MASS	CT		35	
	SCREENING/31OCT2012	TL:2/LIVER	LIVER SEGMENT 4 A/B	CT		57	
	SCREENING/31OCT2012	TL:3/LIVER	LIVER SEGMENT 3	CT		12	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
108-0003 /85/M/W2	SCREENING/31OCT2012	TL:4/LIVER	LIVER SEGMENT 4	CT		13	
	SCREENING/31OCT2012	TL:5/LIVER	LIVER SEGMENT 4 (2)	CT		16	SLD = 133
	SCREENING/31OCT2012	NTL:1/LIVE	MULTIPLE LIVER	CT		.	
	WEEK12/31DEC2012	TL:1/SOFTT	PARASPINAL MASS	CT		35	
	WEEK12/31DEC2012	TL:2/LIVER	LIVER SEGMENT 4 A/B	CT		81	
	WEEK12/31DEC2012	TL:3/LIVER	LIVER SEGMENT 3	CT		15	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
108-0003 /85/M/W2	WEEK12/31DEC2012	TL:4/LIVER	LIVER SEGMENT 4	CT		18	
	WEEK12/31DEC2012	TL:5/LIVER	LIVER SEGMENT 4 (2)	CT		19	
	WEEK12/31DEC2012	NTL:1/LIVE	MULTIPLE LIVER	CT	UP	.	
	Summary:					.	SLD = 168, %CN = 26.32, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 31DEC2012
109-0002 /63/M/W2	SCREENING/19MAR2013	TL:1/LIVER	SEGMENT 5 HEPATIC LESION	CT		38	
	SCREENING/19MAR2013	TL:2/LIVER	SEGMENT 5 HEPATIC LESION	CT		15	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
109-0002 /63/M/W2	SCREENING/19MAR2013	TL:3/NODES	PERICARDIAL LYMPH NODE	CT		18	SLD = 71
	SCREENING/19MAR2013	NTL:1/LIVE	TUMOR THROMBUS OF RIGHT SUPERIOR PORTAL VENOUS BRANCH	CT		.	
	SCREENING/19MAR2013	NTL:2/LIVE	PERIPORTAL LYMPH NODES	CT		.	
	WEEK12/07JUN2013	TL:1/LIVER	SEGMENT 5 HEPATIC LESION	CT		27	
	WEEK12/07JUN2013	TL:2/LIVER	SEGMENT 5 HEPATIC LESION	CT		21	
	WEEK12/07JUN2013	TL:3/NODES	PERICARDIAL LYMPH NODE	CT		22	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
109-0002 /63/M/W2	WEEK12/07JUN2013	NTL:1/LIVE	TUMOR THROMBUS OF RIGHT SUPERIOR PORTAL VENOUS BRANCH	CT	Present	.	
	WEEK12/07JUN2013	NTL:2/LIVE	PERIPORTAL LYMPH NODES	CT	Present	.	
	WEEK12/07JUN2013	NTL:3/LIVE	MULTIPLE HEPATIC LESIONS	CT	Present	.	
	Summary:					.	SLD = 70, %CN = -1.41, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK24/30AUG2013	TL:1/LIVER	SEGMENT 5 HEPATIC LESION	CT		42	
	WEEK24/30AUG2013	TL:2/LIVER	SEGMENT 5 HEPATIC LESION	CT		48	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
109-0002 /63/M/W2	WEEK24/30AUG2013	TL:3/NODES	PERICARDIAL LYMPH NODE	CT		21	
	WEEK24/30AUG2013	NTL:1/LIVE	TUMOR THROMBUS OF THE RIGHT SUPERIOR PORTAL VENOUS BRANCH	CT	Present	.	
	WEEK24/30AUG2013	NTL:2/LIVE	PERIPORTAL LYMPH NODES	CT	Present	.	
	WEEK24/30AUG2013	NTL:3/LIVE	MULTIPLE HEPATIC LESIONS	CT	UP	.	
	Summary:					.	SLD = 111, %CN = 58.57, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 30AUG2013
109-0005 /64/F/W2	SCREENING/24JUL2013	TL:1/LIVER	RIGHT LOWER LOBE	CT		30	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
109-0005 /64/F/W2	SCREENING/24JUL2013	TL:2/LIVER	LEFT LOWER LOBE	CT		12	
	SCREENING/24JUL2013	TL:3/LIVER	HEPATIC SEGMENT II	CT		50	
	SCREENING/24JUL2013	TL:4/LIVER	HEPATIC SEGMENT III	CT		17	SLD = 109
109-0012 /21/F/W2	SCREENING/18SEP2014	TL:1/LIVER	CAUDATE LESION	CT		11	SLD = 11
	SCREENING/18SEP2014	NTL:1/LIVE	SEGMENT 4 LESION	CT		.	
	SCREENING/18SEP2014	NTL:2/LUNG	LUNG NODULES	CT		.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
109-0012 /21/F/W2	UNSCHEDULED/18NOV2014	TL:1/LIVER	CAUDATE LESION	CT		16	
	UNSCHEDULED/18NOV2014	NTL:1/LIVE	SEGMENT 4 LESION	CT	Present	.	
	UNSCHEDULED/18NOV2014	NTL:2/LUNG	LUNG NODULES	CT	Present	.	
	Summary:					.	SLD = 16, %CN = 45.45, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
109-0014 /50/F/W2	SCREENING/12JAN2015	TL:1/LUNG	LEFT LOWER LOBE MASS	CT		33	
	SCREENING/12JAN2015	TL:2/HEAD&	PARATRACHEAL NODE	CT		25	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
109-0014 /50/F/W2	SCREENING/12JAN2015	TL:3/LUNG	RIGHT LOWER LOBE MASS	CT		29	
	SCREENING/12JAN2015	TL:4/GU	LEFT ADRENAL MASS	CT		129	
	SCREENING/12JAN2015	TL:5/LIVER	HEPATIC SEGMENT 3	CT		70	SLD = 286
	SCREENING/12JAN2015	NTL:1/LUNG	PULMONARY METASTASES	CT		.	
	SCREENING/12JAN2015	NTL:2/SOFT	MEDIASTINAL ADENOPATHY	CT		.	
	SCREENING/12JAN2015	NTL:3/LIVE	BILATERAL HILAR ADENOPATHY	CT		.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
109-0014 /50/F/W2	SCREENING/12JAN2015	NTL:4/GU	RIGHT ADRENAL METASTASIS	CT		.	
	SCREENING/12JAN2015	NTL:5/LIVE	MULTIPLE HEPATIC METASTASES	CT		.	
	SCREENING/12JAN2015	NTL:6/SOFT	RIGHT PELVIC SOFT TISSUE MASS	CT		.	
	SCREENING/12JAN2015	NTL:7/BONE	LYTIC METASTASES	CT		.	
	UNSCHEDULED/13MAR2015	TL:/HEAD&N	PARATRACHEAL NODE	CT		31	
	UNSCHEDULED/13MAR2015	TL:1/LUNG	LEFT LOWER LOBE MASS	CT		50	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
109-0014 /50/F/W2	UNSCHEDULED/13MAR2015	TL:3/LUNG	RIGHT LOWER LOBE MASS	CT		46	
	UNSCHEDULED/13MAR2015	TL:4/GU	LEFT ADRENAL MASS	CT		131	
	UNSCHEDULED/13MAR2015	TL:5/LIVER	HEPATIC SEGMENT 3	CT		90	
	UNSCHEDULED/13MAR2015	NTL:1/LUNG	PULMONARY METASTASES	CT	Present	.	
	UNSCHEDULED/13MAR2015	NTL:2/SOFT	MEDIASTINAL ADENOPATHY	CT	Present	.	
	UNSCHEDULED/13MAR2015	NTL:3/LIVE	BILATERAL HILAR ADENOPATHY	CT	Present	.	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
109-0014 /50/F/W2	UNSCHEDULED/13MAR2015	NTL:4/GU	RIGHT ADRENAL METASTASIS	CT	Present	.	
	UNSCHEDULED/13MAR2015	NTL:5/LIVE	MULTIPLE HEPATIC METASTASES	CT	Present	.	
	UNSCHEDULED/13MAR2015	NTL:6/SOFT	RIGHT PELVIC SOFT TISSUE MASS	CT	Present	.	
	UNSCHEDULED/13MAR2015	NTL:7/BONE	LYTIC METASTASES	CT	Present	.	
	Summary:					.	SLD = 348, %CN = 21.68, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 13MAR2015
111-0003 /37/M/A1	SCREENING/02JAN2013	TL:1/LUNG	RIGHT LOWER MEDIAL LOBE	CT		20	

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[3] UP=Unequivocally Progressed
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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
111-0003 /37/M/A1	SCREENING/02JAN2013	TL:2/LUNG	LEFT LOWER LOBE	CT		19	SLD = 39
	UNSCHEDULED/13MAR2013	TL:1/LUNG	RIGHT LOWER MEDIAL LOBE	CT		30	
	UNSCHEDULED/13MAR2013	TL:2/LUNG	LEFT LOWER LOBE	CT		27	
	UNSCHEDULED/13MAR2013	NTL:1/LUNG	RIGHT LOWER LOBE	CT	New	.	
	Summary:					.	SLD = 57, %CN = 46.15, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 13MAR2013
112-0010 /56/F/W2	SCREENING/27NOV2013	TL:1/LIVER	MASS BETWEEN RIGHT AND LEFT LIVER	CT		57	

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[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
112-0010 /56/F/W2	SCREENING/27NOV2013	TL:2/LIVER	LARGE RIGHT LOBE MASS	CT		121	
	SCREENING/27NOV2013	TL:3/NODES	NODE IN PORTA	CT		90	
	SCREENING/27NOV2013	TL:4/NODES	PRETRACHEAL NODE	CT		12	SLD = 280
	SCREENING/27NOV2013	NTL:1/BONE	LYTIC LESION LEFT ILIAC	CT		.	
	SCREENING/27NOV2013	NTL:2/LIVE	OTHER LIVER LESIONS	CT		.	
	WEEK12/21FEB2014	TL:1/LIVER	MASS BETWEEN RIGHT AND LEFT LIVER	CT		52	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
112-0010 /56/F/W2	WEEK12/21FEB2014	TL:2/LIVER	LARGE RIGHT LOBE MASS	CT		121	
	WEEK12/21FEB2014	TL:3/NODES	NODE IN PORTA	CT		116	
	WEEK12/21FEB2014	TL:4/NODES	PRETRACHEAL NODE	CT		18	
	WEEK12/21FEB2014	NTL:1/BONE	LYTIC LESION LEFT ILIAC	CT	Present	.	
	WEEK12/21FEB2014	NTL:2/LIVE	OTHER LIVER LESIONS	CT	Present	.	
	WEEK12/21FEB2014	NTL:3/LIVE	LOBE LESION LEFT LOBE	CT	New	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
112-0010 /56/F/W2	Summary:					.	SLD = 307, %CN = 9.64, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 21FEB2014
113-0007 /74/M/W2	SCREENING/16JAN2014	TL:1/LIVER	LIVER SEGMENT 4A	CT		29	
	SCREENING/16JAN2014	TL:2/LIVER	LIVER SEGMENT 5	CT		35	SLD = 64
	SCREENING/16JAN2014	NTL:1/LIVE	LIVER SEGMENT 7	CT		.	
	WEEK12/09APR2014	TL:1/LIVER	LIVER SEGMENT 4A	CT		30	
	WEEK12/09APR2014	TL:2/LIVER	LIVER SEGMENT 5	CT		38	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
113-0007 /74/M/W2	WEEK12/09APR2014	NTL:1/LIVE	LIVER SEGMENT 7	CT	Present	.	
	Summary:					.	SLD = 68, %CN = 6.25, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK24/02JUL2014	TL:1/LIVER	LIVER SEGMENT 4A	CT		28	
	WEEK24/02JUL2014	TL:2/LIVER	LIVER SEGMENT 5	CT		35	
	WEEK24/02JUL2014	NTL:1/LIVE	LIVER SEGMENT 7	CT	Present	.	
	Summary:					.	SLD = 63, %CN = 0, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No

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Listing 16.2.6.2
Tumor Assessment Summary Listing
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Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
113-0015 /58/F/BL	SCREENING/24OCT2014	TL:1/LIVER	LIVER SEGMENT 8 IMAGE NUMBER 12	CT		38	
	SCREENING/24OCT2014	TL:2/LIVER	LIVER SEGMENT 8 IMAGE NUMBER 6			30	SLD = 68
	SCREENING/24OCT2014	NTL:1/LIVE	LIVER SEGMENT 8 IMAGE NUMBER 10	CT		.	
114-0001 /25/F/OTH	SCREENING/10JUL2012	TL:1/LUNG	RIGHT LOWER LOBE	CT		33	
	SCREENING/10JUL2012	TL:2/LUNG	RIGHT UPPER LOBE	CT		18	
	SCREENING/10JUL2012	TL:3/LIVER	SEGMENT 3	CT		54	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
114-0001 /25/F/OTH	SCREENING/10JUL2012	TL:4/LIVER	SEGMENT 4	CT		31	SLD = 136
	SCREENING/10JUL2012	NTL:1/LUNG	VARIOUS	CT		.	
	SCREENING/10JUL2012	NTL:2/LUNG	RIGHT HILUM	CT		.	
	SCREENING/10JUL2012	NTL:3/LUNG	POSTERIOR MEDIASTINUM	CT		.	
	SCREENING/10JUL2012	NTL:4/LIVE	TREATED LESIONS	CT		.	
	WEEK12/27SEP2012	TL:1/LUNG	RIGHT LOWER LOBE	CT		38	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
114-0001 /25/F/OTH	WEEK12/27SEP2012	TL:2/LUNG	RIGHT UPPER LOBE	CT		22	
	WEEK12/27SEP2012	TL:3/LIVER	SEGMENT 3	CT		63	
	WEEK12/27SEP2012	TL:4/LIVER	SEGMENT 4	CT		50	
	WEEK12/27SEP2012	NTL:1/LUNG	VARIOUS	CT	Present	.	
	WEEK12/27SEP2012	NTL:2/LUNG	RIGHT HILUM	CT	Present	.	
	WEEK12/27SEP2012	NTL:3/LUNG	POSTERIOR MEDIASTINUM	CT	Present	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
114-0001 /25/F/OTH	WEEK12/27SEP2012	NTL:4/LIVE	TREATED LESIONS	CT	Present	.	
	WEEK12/27SEP2012	NTL:5/LIVE	LATERAL LOBE	CT	New	.	
	Summary:					.	SLD = 173, %CN = 27.21, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 27SEP2014
114-0004 /54/F/A1	SCREENING/05FEB2013	TL:1/LUNG	LEFT LOWER LOBE	CT		18	
	SCREENING/05FEB2013	TL:2/LUNG	RIGHT MIDDLE LOBE	CT		21	SLD = 39
	SCREENING/05FEB2013	NTL:1/LUNG	NODULES	CT		.	

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[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
114-0004 /54/F/A1	UNSCHEDULED/27MAR2013	TL:1/LUNG	LEFT LOWER LOBE	CT		20	
	UNSCHEDULED/27MAR2013	TL:2/LUNG	RIGHT MIDDLE LOBE	CT		22	
	UNSCHEDULED/27MAR2013	NTL:1/LUNG	LUNG NODULES	CT	Present	.	
	Summary:					.	SLD = 42, %CN = 7.69, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
115-0005 /60/M/W2	SCREENING/06MAR2013	TL:1/LIVER	HEPATIC MASS	CT		28	
	SCREENING/06MAR2013	TL:2/GI	ADRENAL METASTASIS	CT		75	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
115-0005 /60/M/W2	SCREENING/06MAR2013	TL:3/BONE	BONE METASTASIS	CT		111	SLD = 214
	SCREENING/06MAR2013	NTL:1/BONE	BONE METASTASIS 2	CT		.	
	SCREENING/06MAR2013	NTL:2/NODE	CELIAC	CT		.	
115-0006 /62/M/W2	SCREENING/08APR2013	TL:1/LIVER	RIGHT HEPATIC MASS	CT		98	
	SCREENING/08APR2013	TL:2/NODES	RT RETROPERITONEAL NODES	CT		54	
	SCREENING/08APR2013	TL:3/NODES	MEDIASTINAL NODE	CT		34	SLD = 186

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
115-0006 /62/M/W2	SCREENING/08APR2013	NTL:1/NODE	RETROCRURAL NODE	CT		.	
	SCREENING/08APR2013	NTL:2/NODE	CELIAC AXIS NODE	CT		.	
	SCREENING/08APR2013	NTL:3/GI	PARARENAL NODULE	CT		.	
	WEEK12/25JUN2013	TL:1/LIVER	RIGHT HEPATIC MASS	CT		101	
	WEEK12/25JUN2013	TL:2/NODES	RT RETROPERITONEAL NODES	CT		59	
	WEEK12/25JUN2013	TL:3/NODES	MEDIASTINAL NODE	CT		45	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
115-0006 /62/M/W2	WEEK12/25JUN2013	NTL:1/NODE	RETROCRURAL NODE	CT	Present	.	
	WEEK12/25JUN2013	NTL:2/NODE	CELIAC AXIS NODE	CT	Present	.	
	WEEK12/25JUN2013	NTL:3/GI	PARARENAL NODULE	CT	Present	.	
	Summary:					.	SLD = 205, %CN = 10.22, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
115-0007 /57/M/W2	SCREENING/10APR2013	TL:1/LIVER		MRI		38	
	SCREENING/10APR2013	TL:2/LIVER		MRI		29	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
115-0007 /57/M/W2	SCREENING/10APR2013	TL:3/NODES	PORTOCAVAL	MRI		39	SLD = 106
	SCREENING/10APR2013	NTL:1/LIVE		MRI		.	
	UNSCHEDULED/16MAY2013	TL:1/LIVER	LIVER TUMOR	MRI		42	
	UNSCHEDULED/16MAY2013	TL:2/LIVER	LIVER TUMOR 2	MRI		28	
	UNSCHEDULED/16MAY2013	TL:3/NODES	PORTOCAVAL LYMPHNODE	MRI		61	
	UNSCHEDULED/16MAY2013	NTL:1/LIVE	LIVER TUMOR 3	MRI	Present	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
115-0007 /57/M/W2	Summary:					.	SLD = 131, %CN = 23.58, TL: PD, NTL: IncompleteResponse/SD, OR: PD, PD confirmed: Yes, 16MAY2013
115-0010 /54/M/A4	SCREENING/18MAR2014	TL:1/LUNG	RIGHT UPPER LOBE LUNG NODULE	CT		16	
	SCREENING/18MAR2014	TL:2/LUNG	RIGHT LOWER LOBE NODULE	CT		18	SLD = 34
	SCREENING/18MAR2014	NTL:1/LUNG	LUNG NODULES	CT		.	
	WEEK12/20JUN2014	TL:1/LUNG	RIGHT UPPER LOBE LUNG NODULE	CT		23	
	WEEK12/20JUN2014	TL:2/LUNG	RIGHT LOWER LOBE NODULE	CT		26	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
115-0010 /54/M/A4	WEEK12/20JUN2014	NTL:1/LUNG	LUNG NODULES	CT	UP	.	
	Summary:					.	SLD = 49, %CN = 44.12, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 20JUN2014
121-0003 /65/M/BL	SCREENING/21JUN2014	TL:1/LIVER	LIVER SEGMENT VII	CT		46	
	SCREENING/21JUN2014	TL:2/LIVER	LIVER DOME	CT		129	SLD = 175
	UNSCHEDULED/27AUG2014	TL:1/LIVER	LIVER SEGMENT VII	CT		77	
	UNSCHEDULED/27AUG2014	TL:2/LIVER	LIVER DOME	CT		121	

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Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
121-0003 /65/M/BL	Summary:					.	SLD = 198, %CN = 13.14, TL: SD, NTL: NotAssessed, OR: SD, PD confirmed: No
201-0002 /76/M/W2	SCREENING/08MAR2012	TL:1/LIVER	VII LIVER SEGMENT	CT		46	
	SCREENING/08MAR2012	TL:2/LIVER	VI LIVER SEGMENT	CT		23	SLD = 69
	SCREENING/08MAR2012	NTL:1/LIVE	MULTIPLE LESIONS IN THE RIGHT LOBE	CT		.	
	WEEK12/04JUN2012	TL:1/LIVER	VII LIVER SEGMENT	CT		48	
	WEEK12/04JUN2012	TL:2/LIVER	VI LIVER SEGMENT	CT		25	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
201-0002 /76/M/W2	WEEK12/04JUN2012	NTL:1/LIVE	MULTIPLE LESIONS IN THE RIGHT LOBE	CT	Present	.	
	Summary:					.	SLD = 73, %CN = 5.8, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK24/24AUG2012	TL:1/LIVER	VII LIVER SEGMENT	CT		48	
	WEEK24/24AUG2012	TL:2/LIVER	VI LIVER SEGMENT	CT		24	
	WEEK24/24AUG2012	NTL:1/LIVE	MULTIPLE LESIONS IN THE RIGHT LOBE	CT	Present	.	
	Summary:					.	SLD = 72, %CN = 4.35, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
201-0002 /76/M/W2	WEEK36/16NOV2012	TL:1/LIVER	VII LIVER SEGMENT	CT		49	
	WEEK36/16NOV2012	TL:2/LIVER	VI LIVER SEGMENT	CT		25	
	WEEK36/16NOV2012	NTL:1/LIVE	MULTIPLE LESIONS IN THE RIGHT LOBE	CT	Present	.	
	Summary:					.	SLD = 74, %CN = 7.25, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK48/11FEB2013	TL:1/LIVER	VII LIVER SEGMENT	CT		50	
	WEEK48/11FEB2013	TL:2/LIVER	VI LIVER SEGMENT	CT		29	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
201-0002 /76/M/W2	WEEK48/11FEB2013	NTL:1/LIVE	MULTIPLE LESIONS IN THE RIGHT LOBE	CT	Present	.	
	WEEK48/11FEB2013	NTL:2/LIVE	EVIDENCE OF PERITONEAL CARCINOMATOSIS	CT	New	.	
	Summary:					.	SLD = 79, %CN = 14.49, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 11FEB2013
201-0006 /71/M/W2	SCREENING/02JUL2012	TL:1/LIVER	LESION BETWEN V-IVB LIVER SEGMENT	CT		32	
	SCREENING/02JUL2012	TL:2/LIVER	LESION AT IVA LIVER SEGMENT	CT		16	SLD = 48
	SCREENING/02JUL2012	NTL:1/LIVE	UNHOMOGENEOUS IMPREGNATION AREA AT LEFT LOBE	CT		.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
201-0006 /71/M/W2	WEEK12/28SEP2012	TL:1/LIVER	LESION BETWEN V-IVB LIVER SEGMENT	CT		35	
	WEEK12/28SEP2012	TL:2/LIVER	LESION AT IVA LIVER SEGMENT	CT		22	
	WEEK12/28SEP2012	NTL:1/LIVE	UNHOMOGENEOUS IMPREGNATION AREA AT LEFT LOBE	CT	Present	.	
	Summary:					.	SLD = 57, %CN = 18.75, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK24/19DEC2012	TL:1/LIVER	LESION BETWEN V-IVB LIVER SEGMENT	CT		40	
	WEEK24/19DEC2012	TL:2/LIVER	LESION AT IVA LIVER SEGMENT	CT		22	

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[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
201-0006 /71/M/W2	WEEK24/19DEC2012	NTL:1/LIVE	UNHOMOGENEOUS IMPREGNATION AREA AT LEFT LOBE	CT	Present	.	
	Summary:					.	SLD = 62, %CN = 29.17, TL: PD, NTL: IncompleteResponse/SD, OR: PD, PD confirmed: Yes, 21DEC2012
201-0007 /71/M/W2	SCREENING/13JUL2012	TL:1/LIVER	VII LIVER SEGMENT	CT		31	
	SCREENING/13JUL2012	TL:2/LIVER	LESION BETWEEN V AND VI LIVER SEGMENT	CT		25	SLD = 56
	WEEK12/12OCT2012	TL:1/LIVER	VII LIVER SEGMENT	CT		33	
	WEEK12/12OCT2012	TL:2/LIVER	LESION BETWEEN V AND VI LIVER SEGMENT	CT		33	

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[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
201-0007 /71/M/W2	Summary:					.	SLD = 66, %CN = 17.86, TL: SD, NTL: NotAssessed, OR: SD, PD confirmed: No
	WEEK24/04JAN2013	TL:1/LIVER	VII LIVER SEGMENT	CT		0	
	WEEK24/04JAN2013	TL:2/LIVER	LESION BETWEEN V AND VI LIVER SEGMENT	CT		32	
	Summary:					.	SLD = 32, %CN = 0, TL: PR, NTL: NotAssessed, OR: PR, PD confirmed: No
	WEEK36/29MAR2013	TL:1/LIVER	VII LIVER SEGMENT	CT		0	
	WEEK36/29MAR2013	TL:2/LIVER	LESION BETWEEN V AND VI LIVER SEGMENT	CT		32	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
201-0007 /71/M/W2	WEEK36/29MAR2013	NTL:1/LIVE	LESIONS	CT	New	.	
	WEEK36/29MAR2013	NTL:2/LIVE	II SEGMENT	CT	New	.	
	WEEK36/29MAR2013	NTL:3/LIVE	V - VI SEGMENT	CT	New	.	
	Summary:					.	SLD = 32, %CN = 0, TL: PR, NTL: PD, OR: PD, PD confirmed: Yes, 02APR2013
201-0009 /64/M/W2	SCREENING/27MAY2013	TL:1/LIVER	VII-VI SEGMENT	CT		35	
	SCREENING/27MAY2013	TL:2/LIVER	VIII SEGMENT	CT		52	SLD = 87

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
201-0009 /64/M/W2	SCREENING/27MAY2013	NTL:1/LIVE	II SEGMENT	CT		.	
	WEEK12/06SEP2013	TL:1/LIVER	VII-VI SEGMENT	CT		31	
	WEEK12/06SEP2013	TL:2/LIVER	VIII SEGMENT	CT		52	
	WEEK12/06SEP2013	NTL:1/LIVE	II SEGMENT	CT	Present	.	
	Summary:					.	SLD = 83, %CN = -4.6, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK24/29NOV2013	TL:1/LIVER	VII-VI SEGMENT	CT		31	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
201-0009 /64/M/W2	WEEK24/29NOV2013	TL:2/LIVER	VIII SEGMENT	CT		52	
	WEEK24/29NOV2013	NTL:1/LIVE	II SEGMENT	CT	Present	.	
	Summary:					.	SLD = 83, %CN = 10.67, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK36/21FEB2014	TL:1/LIVER	VII-VI SEGMENT	CT		31	
	WEEK36/21FEB2014	TL:2/LIVER	VIII SEGMENT	CT		51	
	WEEK36/21FEB2014	NTL:1/LIVE	II SEGMENT	CT	Present	.	

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[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
201-0009 /64/M/W2	Summary:					.	SLD = 82, %CN = 9.33, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK48/19MAY2014	TL:1/LIVER	VII-VI SEGMENT	CT		23	
	WEEK48/19MAY2014	TL:2/LIVER	VIII SEGMENT	CT		52	
	WEEK48/19MAY2014	NTL:1/LIVE	II SEGMENT	CT	Present	.	
	Summary:					.	SLD = 75, %CN = 0, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK60/04AUG2014	TL:1/LIVER	VII-VI SEGMENT	CT		27	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
201-0009 /64/M/W2	WEEK60/04AUG2014	TL:2/LIVER	VIII SEGMENT	CT		51	
	WEEK60/04AUG2014	NTL:1/LIVE	II SEGMENT	CT	Present	.	
	Summary:					.	SLD = 78, %CN = 4, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK72/04NOV2014	TL:1/LIVER	VII-VI SEGMENT	CT		27	
	WEEK72/04NOV2014	TL:2/LIVER	VIII SEGMENT	CT		53	
	WEEK72/04NOV2014	NTL:1/LIVE	II SEGMENT	CT	Present	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
201-0009 /64/M/W2	Summary:					.	SLD = 80, %CN = 6.67, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK84/26JAN2015	TL:1/LIVER	VII-VI SEGMENT	CT		27	
	WEEK84/26JAN2015	TL:2/LIVER	VIII SEGMENT	CT		53	
	WEEK84/26JAN2015	NTL:1/LIVE	II SEGMENT	CT	Present	.	
	Summary:					.	SLD = 80, %CN = 6.67, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK96/20APR2015	TL:1/LIVER	VII-VI SEGMENT	CT		27	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
201-0009 /64/M/W2	WEEK96/20APR2015	TL:2/LIVER	VIII SEGMENT	CT		53	
	WEEK96/20APR2015	NTL:1/LIVE	II SEGMENT	CT	Present	.	
	Summary:					.	SLD = 80, %CN = 6.67, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
201-0010 /81/F/W2	SCREENING/31MAY2013	TL:1/LIVER	VI SEGMENT	CT		22	
	SCREENING/31MAY2013	TL:2/LIVER	II SEGMENT	CT		16	SLD = 38
	SCREENING/31MAY2013	NTL:1/LIVE	MORE LESIONS V SEGMENT	CT		.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
201-0010 /81/F/W2	SCREENING/31MAY2013	NTL:3/LIVE	LESIONS II SEGMENT	CT		.	
	WEEK12/13SEP2013	TL:1/LIVER	VI SEGMENT	CT		23	
	WEEK12/13SEP2013	TL:2/LIVER	II SEGMENT	CT		22	
	WEEK12/13SEP2013	NTL:1/LIVE	MORE LESIONS V SEGMENT	CT	Present	.	
	WEEK12/13SEP2013	NTL:2/LIVE	LESIONS IV AND VIII SEGMENT	CT	New	.	
	WEEK12/13SEP2013	NTL:3/LIVE	LESIONS II SEGMENT	CT	Present	.	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
201-0010 /81/F/W2	Summary:					.	SLD = 45, %CN = 18.42, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 13SEP2013
201-0014 /73/M/W2	SCREENING/28JUN2013	TL:1/LIVER	III SEGMENT	CT		29	
	SCREENING/28JUN2013	TL:2/LIVER	IV SEGMENT	CT		27	SLD = 56
	SCREENING/28JUN2013	NTL:1/LIVE	HEPATIC LESIONS	CT		.	
	SCREENING/28JUN2013	NTL:2/GI	PERITONEAL SOLID NODULE	CT		.	
	WEEK12/04OCT2013	TL:1/LIVER	III SEGMENT	CT		35	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
201-0014 /73/M/W2	WEEK12/04OCT2013	TL:2/LIVER	IV SEGMENT	CT		54	
	WEEK12/04OCT2013	NTL:1/LIVE	HEPATIC LESIONS	CT	Present	.	
	WEEK12/04OCT2013	NTL:2/GI	PERITONEAL SOLID NODULE	CT	UP	.	
	WEEK12/04OCT2013	NTL:3/LIVE	HEPATIC LESIONS	CT	New	.	
	WEEK12/04OCT2013	NTL:4/ASCI	ASCITES	CT	New	.	
	Summary:					.	SLD = 89, %CN = 58.93, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 04OCT2013

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
201-0015 /49/M/W2	SCREENING/19JUL2013	TL:1/LIVER	II SEGMENT	CT		30	
	SCREENING/19JUL2013	TL:2/LIVER	VI LIVER SEGMENT	CT		26	SLD = 56
	SCREENING/19JUL2013	NTL:1/LIVE	LESION AT VIII SEGMENT	CT		.	
	WEEK12/25OCT2013	TL:1/LIVER	II SEGMENT	CT		31	
	WEEK12/25OCT2013	TL:2/LIVER	VI LIVER SEGMENT	CT		31	
	WEEK12/25OCT2013	NTL:1/LIVE	LESION AT VIII SEGMENT	CT	Present	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
201-0015 /49/M/W2	Summary:					.	SLD = 62, %CN = 10.71, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK24/17JAN2014	TL:1/LIVER	II SEGMENT	CT		20	
	WEEK24/17JAN2014	TL:2/LIVER	VI LIVER SEGMENT	CT		31	
	WEEK24/17JAN2014	NTL:1/LIVE	LESION AT VIII SEGMENT	CT	Present	.	
	Summary:					.	SLD = 51, %CN = 0, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK36/14MAR2014	TL:1/LIVER	II SEGMENT	CT		24	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
201-0015 /49/M/W2	WEEK36/14MAR2014	TL:2/LIVER	VI LIVER SEGMENT	CT		38	
	WEEK36/14MAR2014	NTL:1/LIVE	LESION AT VIII SEGMENT	CT	UP	.	
	WEEK36/14MAR2014	NTL:2/LIVE	LESIONS	CT	New	.	
	Summary:					.	SLD = 62, %CN = 21.57, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 17MAR2014
201-0022 /80/F/W2	SCREENING/28APR2014	TL:1/NODES	ONE ABDOMINAL LESION	CT		59	SLD = 59
	WEEK12/25JUL2014	TL:1/NODES	ONE ABDOMINAL LESION	CT		62	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
201-0022 /80/F/W2	Summary:					.	SLD = 62, %CN = 5.08, TL: SD, NTL: NotEvaluable, OR: SD, PD confirmed: No
	WEEK24/27OCT2014	TL:1/NODES	ONE ABDOMINAL LESION	CT		62	
	WEEK24/27OCT2014	NTL:1/LIVE	NEW LESION AT VI LIEVR SEGMENT	CT	New	.	
	WEEK24/27OCT2014	NTL:2/LIVE	LESION BETWEEN V AND VI SEGMENT (15MM)	CT	New	.	
	WEEK24/27OCT2014	NTL:3/LIVE	LESION BETWEEN V AND VI LIVER SEGMENT	CT	New	.	
	Summary:					.	SLD = 62, %CN = 5.08, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 28OCT2014

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
203-0004 /81/M/W2	SCREENING/22MAR2012	TL:1/LIVER	SEGMENT III	CT		24	
	SCREENING/22MAR2012	TL:2/LIVER	SEGMENT VI	CT		22	SLD = 46
	SCREENING/22MAR2012	NTL:1/NODE	MEDIASTINUM	CT		.	
	SCREENING/22MAR2012	NTL:2/NODE	HEPATIC HILUM	CT		.	
	WEEK12/28JUN2012	TL:1/LIVER	SEGMENT III	CT		31	
	WEEK12/28JUN2012	TL:2/LIVER	SEGMENT VI	CT		16	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
203-0004 /81/M/W2	WEEK12/28JUN2012	NTL:1/NODE	MEDIASTINUM	CT	Present	.	
	WEEK12/28JUN2012	NTL:2/NODE	HEPATIC HILUM	CT	Present	.	
	Summary:					.	SLD = 47, %CN = 2.17, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK24/20SEP2012	TL:1/LIVER	SEGMENT III	CT		24	
	WEEK24/20SEP2012	TL:2/LIVER	SEGMENT VI	CT		26	
	WEEK24/20SEP2012	NTL:1/NODE	MEDIASTINUM	CT	Present	.	

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Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
203-0004 /81/M/W2	WEEK24/20SEP2012	NTL:2/NODE	HEPATIC HILUM	CT	Present	.	
	Summary:					.	SLD = 50, %CN = 8.7, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK36/13DEC2012	TL:1/LIVER	SEGMENT III	CT		24	
	WEEK36/13DEC2012	TL:2/LIVER	SEGMENT VI	CT		26	
	WEEK36/13DEC2012	NTL:1/NODE	MEDIASTINUM	CT	Present	.	
	WEEK36/13DEC2012	NTL:2/NODE	HEPATIC HILUM	CT	Present	.	

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Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
203-0004 /81/M/W2	UNSCHEDULED/13DEC2012	NTL:3/LIVE	LEFT NEOPLASTIC THROMBOSIS	CT	New	.	
	Summary:					.	SLD = 50, %CN = 8.7, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 13DEC2012
203-0006 /76/M/W2	SCREENING/30MAR2012	TL:1/LIVER	SEGMENT V	CT		34	SLD = 34
	SCREENING/30MAR2012	NTL:1/LIVE	HEPATIC HILUM	CT		.	
203-0007 /59/M/W2	SCREENING/08MAY2012	TL:1/LIVER	VIII SEGMENT	CT		76	
	SCREENING/08MAY2012	TL:2/LIVER	VII SEGMENT	CT		52	

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Tumor Assessment Summary Listing
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Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
203-0007 /59/M/W2	SCREENING/08MAY2012	TL:3/LUNG	LINGULA	CT		16	
	SCREENING/08MAY2012	TL:4/LUNG	RIGH UPPER LOBE	CT		11	SLD = 155
	SCREENING/08MAY2012	NTL:1/LUNG	INFERIOR LOBE	CT		.	
203-0009 /73/M/W2	SCREENING/27AUG2012	TL:1/LIVER	SEGMENT IV-VIII	CT		70	
	SCREENING/27AUG2012	TL:2/LIVER	SEGMENT VII	CT		36	SLD = 106
	SCREENING/27AUG2012	NTL:1/NODE	HEPATIC HILUM	CT		.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
203-0009 /73/M/W2	SCREENING/27AUG2012	NTL:2/NODE	CELIAC	CT		.	
	SCREENING/27AUG2012	NTL:3/LIVE	CAUDATE LOBE	CT		.	
	WEEK12/20DEC2012	TL:1/LIVER	SEGMENT IV-VIII	CT		73	
	WEEK12/20DEC2012	TL:2/LIVER	SEGMENT VII	CT		38	
	WEEK12/20DEC2012	NTL:1/NODE	HEPATIC HILUM	CT	Present	.	
	WEEK12/20DEC2012	NTL:2/NODE	CELIAC	CT	Present	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
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Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
203-0009 /73/M/W2	WEEK12/20DEC2012	NTL:3/LIVE	CAUDATE LOBE	CT	Present	.	
	Summary:					.	SLD = 111, %CN = 4.72, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK24/04APR2013	TL:1/LIVER	SEGMENT IV-VIII	CT		78	
	WEEK24/04APR2013	TL:2/LIVER	SEGMENT VII	CT		43	
	WEEK24/04APR2013	NTL:1/NODE	HEPATIC HILUM	CT	Present	.	
	WEEK24/04APR2013	NTL:2/NODE	CELIAC	CT	Present	.	

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[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
203-0009 /73/M/W2	WEEK24/04APR2013	NTL:3/LIVE	CAUDATE LOBE	CT	Present	.	
	Summary:					.	SLD = 121, %CN = 14.15, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK36/01AUG2013	TL:1/LIVER	SEGMENT IV-VIII	CT		79	
	WEEK36/01AUG2013	TL:2/LIVER	SEGMENT VII	CT		40	
	WEEK36/01AUG2013	NTL:1/NODE	HEPATIC HILUM	CT	Present	.	
	WEEK36/01AUG2013	NTL:2/NODE	CELIAC	CT	Present	.	

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[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
203-0009 /73/M/W2	WEEK36/01AUG2013	NTL:3/LIVE	CAUDATE LOBE	CT	Present	.	
	Summary:					.	SLD = 119, %CN = 12.26, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK48/31OCT2013	TL:1/LIVER	SEGMENT IV-VIII	CT		78	
	WEEK48/31OCT2013	TL:2/LIVER	SEGMENT VII	CT		44	
	WEEK48/31OCT2013	NTL:1/NODE	HEPATIC HILUM	CT	Present	.	
	WEEK48/31OCT2013	NTL:2/NODE	CELIAC	CT	Present	.	

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[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
203-0009 /73/M/W2	WEEK48/31OCT2013	NTL:3/LIVE	CAUDATE LOBE	CT	UP	.	
	Summary:					.	SLD = 122, %CN = 15.09, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 31OCT2013
203-0010 /74/M/W2	SCREENING/17SEP2012	TL:1/LIVER	SEGMENT VII	CT		36	
	SCREENING/17SEP2012	TL:2/LIVER	SEGMENT VI	CT		37	
	SCREENING/17SEP2012	TL:3/	RIGHT SIDE (PERITONEAL SITE)	CT		33	SLD = 106
	WEEK12/13DEC2012	TL:1/LIVER	SEGMENT VII	CT		36	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
203-0010 /74/M/W2	WEEK12/13DEC2012	TL:2/LIVER	SEGMENT VI	CT		37	
	WEEK12/13DEC2012	TL:3/	RIGHT SIDE (PERITONEAL SITE)	CT		28	
	Summary:					.	SLD = 101, %CN = -4.72, TL: SD, NTL: NotAssessed, OR: SD, PD confirmed: No
	WEEK24/21MAR2013	TL:1/LIVER	SEGMENT VII	CT		32	
	WEEK24/21MAR2013	TL:2/LIVER	SEGMENT VI	CT		35	
	WEEK24/21MAR2013	TL:3/	RIGHT SIDE (PERITONEAL SITE)	CT		21	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
203-0010 /74/M/W2	Summary:					.	SLD = 88, %CN = 31.34, TL: SD, NTL: NotAssessed, OR: SD, PD confirmed: No
	WEEK36/20JUN2013	TL:1/LIVER	VII	CT		32	
	WEEK36/20JUN2013	TL:2/LIVER	SEGMENT VI	CT		35	
	WEEK36/20JUN2013	TL:3/	RIGHT SIDE (PERITONEAL SITE)	CT		21	
	Summary:					.	SLD = 88, %CN = 31.34, TL: SD, NTL: NotAssessed, OR: SD, PD confirmed: No
	WEEK48/26SEP2013	TL:1/LIVER	VII	CT		32	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
203-0010 /74/M/W2	WEEK48/26SEP2013	TL:2/LIVER	SEGMENT VI	CT		35	
	WEEK48/26SEP2013	TL:3/	RIGHT SIDE (PERITONEAL SITE)	CT		21	
	Summary:					.	SLD = 88, %CN = 31.34, TL: SD, NTL: NotAssessed, OR: SD, PD confirmed: No
	WEEK60/09JAN2014	TL:1/LIVER	VII	CT		25	
	WEEK60/09JAN2014	TL:2/LIVER	SEGMENT VI	CT		32	
	WEEK60/09JAN2014	TL:3/	RIGHT SIDE (PERITONEAL SITE)	CT		19	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
203-0010 /74/M/W2	Summary:					.	SLD = 76, %CN = 13.43, TL: SD, NTL: NotAssessed, OR: SD, PD confirmed: No
	WEEK72/17APR2014	TL:1/LIVER	VII	CT		24	
	WEEK72/17APR2014	TL:2/LIVER	SEGMENT VI	CT		30	
	WEEK72/17APR2014	TL:3/	RIGHT SIDE (PERITONEAL SITE)	CT		19	
	Summary:					.	SLD = 73, %CN = 8.96, TL: PR, NTL: NotAssessed, OR: PR, PD confirmed: No
	WEEK84/17JUL2014	TL:1/LIVER	VII	CT		20	

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[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
203-0010 /74/M/W2	WEEK84/17JUL2014	TL:2/LIVER	SEGMENT VI	CT		30	
	WEEK84/17JUL2014	TL:3/	RIGHT SIDE (PERITONEAL SITE)	CT		17	
	Summary:					.	SLD = 67, %CN = 0, TL: PR, NTL: NotEvaluable, OR: PR, PD confirmed: No
	WEEK96/02OCT2014	TL:1/LIVER	VII	CT		20	
	WEEK96/02OCT2014	TL:2/LIVER	SEGMENT VI	CT		30	
	WEEK96/02OCT2014	TL:3/	RIGHT SIDE (PERITONEAL SITE)	CT		17	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
203-0010 /74/M/W2	Summary:					.	SLD = 67, %CN = 0, TL: PR, NTL: NotEvaluable, OR: PR, PD confirmed: No
203-0014 /73/M/W2	SCREENING/10JAN2014	TL:1/LIVER	III SEGMENT	CT		26	SLD = 26
	SCREENING/10JAN2014	NTL:1/LIVE	VIII-IV SEGMENT	CT		.	
	SCREENING/10JAN2014	NTL:2/LIVE	VI SEGMENT	CT		.	
203-0016 /57/M/W2	SCREENING/23JAN2014	TL:1/LIVER		CT		19	SLD = 19
	SCREENING/23JAN2014	NTL:1/NODE		CT		.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
203-0016 /57/M/W2	WEEK12/22APR2014	NTL:1/NODE		CT	Present	.	
	WEEK12/24APR2014	TL:1/LIVER		CT		16	
	Summary:					.	SLD = 16, %CN = -15.79, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK24/31JUL2014	TL:1/LIVER		CT	UP	.	
	WEEK24/31JUL2014	NTL:1/NODE		CT	UP	.	
	Summary:					.	SLD = ., %CN = ., TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 31JUL2014

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
203-0019 /68/M/W2	SCREENING/29APR2014	TL:1/LIVER	IV SEGMENT	CT		80	SLD = 80
	SCREENING/29APR2014	NTL:1/LIVE	MULTIPLE LESIONS	CT		.	
	WEEK12/04JUL2014	TL:1/LIVER	IV SEGMENT	CT		80	
	WEEK12/04JUL2014	NTL:1/LIVE	MULTIPLE LESIONS	CT	UP	.	
	Summary:					.	SLD = 80, %CN = 0, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 04JUL2014
204-0003 /64/M/W2	SCREENING/27JUN2013	TL:1/LIVER	V-VI LIVER SEGMENT	CT		98	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
204-0003 /64/M/W2	SCREENING/27JUN2013	TL:2/LIVER	II-III LIVER SEGMENT	CT		72	
	SCREENING/27JUN2013	TL:3/GI	ONE NODULE IN ABDOMINAL WALL	CT		35	SLD = 205
	SCREENING/27JUN2013	NTL:1/LIVE	THREE ABDOMINAL NODULES WITH HYPERVASCULARIZATION	CT		.	
	WEEK12/26SEP2013	TL:1/LIVER	V-VI LIVER SEGMENT	CT		112	
	WEEK12/26SEP2013	TL:2/LIVER	II-III LIVER SEGMENT	CT		85	
	WEEK12/26SEP2013	TL:3/GI	ONE NODULE IN ABDOMINAL WALL	CT		58	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
204-0003 /64/M/W2	WEEK12/26SEP2013	NTL:1/LIVE	THREE ABDOMINAL NODULES WITH HYPERVASCULARIZ ATION	CT	UP	.	
	Summary:					.	SLD = 255, %CN = 24.39, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 26SEP2013
204-0004 /76/F/W2	SCREENING/20AUG2013	TL:1/LIVER	AT SEGMENT 3	CT		75	
	SCREENING/20AUG2013	TL:2/LIVER	BETWEEN SEGMENT 5 AND 6	CT		72	SLD = 147
	SCREENING/20AUG2013	NTL:1/LIVE	IN LIVER PARENCHYMA	CT		.	
	SCREENING/20AUG2013	NTL:2/LIVE	IN LIVER PARENCHYMA	CT		.	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
204-0004 /76/F/W2	SCREENING/20AUG2013	NTL:3/LIVE	IN LIVER PARENCHYMA	CT		.	
	SCREENING/20AUG2013	NTL:4/LUNG	NODULE OF 5 MM	CT		.	
	WEEK12/17DEC2013	TL:1/LIVER	AT SEGMENT 3	CT		90	
	WEEK12/17DEC2013	TL:2/LIVER	BETWEEN SEGMENT 5 AND 6	CT		89	
	WEEK12/17DEC2013	NTL:1/LIVE	IN LIVER PARENCHYMA	CT	UP	.	
	WEEK12/17DEC2013	NTL:2/LIVE	IN LIVER PARENCHYMA	CT	UP	.	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
204-0004 /76/F/W2	WEEK12/17DEC2013	NTL:3/LIVE	IN LIVER PARENCHYMA	CT	UP	.	
	WEEK12/17DEC2013	NTL:4/LUNG	NODULE	CT	UP	.	
	WEEK12/17DEC2013	NTL:5/LUNG	LESIONS	CT	New	.	
	Summary:					.	SLD = 179, %CN = 21.77, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 17DEC2013
205-0002 /71/M/W2	SCREENING/14FEB2012	TL:1/LIVER	S3	CT		35	
	SCREENING/14FEB2012	TL:2/LIVER	S3	CT		90	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
205-0002 /71/M/W2	SCREENING/14FEB2012	TL:3/NODES	LIVER LYMPHNODES	CT		18	
	SCREENING/14FEB2012	TL:4/NODES	LOMBOAORTIC REGION	CT		16	SLD = 159
	WEEK12/08MAY2012	TL:1/LIVER	S3	CT		50	
	WEEK12/08MAY2012	TL:2/LIVER	S3	CT		130	
	WEEK12/08MAY2012	TL:3/NODES	LIVER LYMPHNODES	CT	NE	.	
	WEEK12/08MAY2012	TL:4/NODES	LOMBOAORTIC REGION	CT	NE	.	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
205-0002 /71/M/W2	WEEK12/08MAY2012	NTL:1/LUNG	RIGHT SUPERIOR LOBE	CT	New	.	
	WEEK12/08MAY2012	NTL:2/LIVE	LEFT PORTAL BRANCH THROMBOSIS	CT	New	.	
	Summary:					.	SLD = ., %CN = ., TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 08MAY2012
205-0003 /79/M/W2	SCREENING/06MAR2012	TL:1/LIVER	S2-S3	CT		52	
	SCREENING/06MAR2012	TL:2/LIVER	S1	CT		33	
	SCREENING/06MAR2012	TL:3/LUNG	RIGHT SUPERIOR LOBE	CT		19	SLD = 104

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
205-0003 /79/M/W2	SCREENING/06MAR2012	NTL:1/LIVE	S2	CT		.	
	WEEK12/12JUN2012	TL:1/LIVER	S2-S3	CT		52	
	WEEK12/12JUN2012	TL:2/LIVER	S1	CT		35	
	WEEK12/12JUN2012	TL:3/LUNG	RIGHT SUPERIOR LOBE	CT		19	
	WEEK12/12JUN2012	NTL:1/LIVE	S2	CT	Present	.	
	Summary:					.	SLD = 106, %CN = 1.92, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
205-0003 /79/M/W2	WEEK24/11SEP2012	TL:1/LIVER	S2-S3	CT		58	
	WEEK24/11SEP2012	TL:2/LIVER	S1	CT		33	
	WEEK24/11SEP2012	TL:3/LUNG	RIGHT SUPERIOR LOBE	CT		19	
	WEEK24/11SEP2012	NTL:1/LIVE	S2	CT	Present	.	
	Summary:					.	SLD = 110, %CN = 5.77, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK36/04DEC2012	TL:1/LIVER	S2-S3	CT		58	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
205-0003 /79/M/W2	WEEK36/04DEC2012	TL:2/LIVER	S1	CT		63	
	WEEK36/04DEC2012	TL:3/LUNG	RIGHT SUPERIOR LOBE	CT		19	
	WEEK36/04DEC2012	NTL:1/LIVE	S2	CT	UP	.	
	Summary:					.	SLD = 140, %CN = 34.62, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 04DEC2012
205-0005 /71/M/W2	SCREENING/21FEB2012	TL:1/LIVER	S8	CT		51	
	SCREENING/21FEB2012	TL:2/LIVER	S8	CT		50	SLD = 101

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
205-0005 /71/M/W2	SCREENING/21FEB2012	NTL:1/LIVE	S5-S6	CT		.	
	SCREENING/21FEB2012	NTL:2/LIVE	S6	CT		.	
	SCREENING/21FEB2012	NTL:3/LIVE	S6	CT		.	
	WEEK12/05JUN2012	TL:1/LIVER	S8	CT		65	
	WEEK12/05JUN2012	TL:2/LIVER	S8	CT		70	
	WEEK12/05JUN2012	NTL:1/LIVE	S5-S6	CT	UP	.	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
205-0005 /71/M/W2	WEEK12/05JUN2012	NTL:2/LIVE	S6	CT	Present	.	
	WEEK12/05JUN2012	NTL:3/LIVE	S6	CT	Present	.	
	Summary:					.	SLD = 135, %CN = 33.66, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 11JUN2012
205-0014 /70/M/W2	SCREENING/11JUN2013	TL:1/LIVER	IV, VIII, VII	CT		100	
	SCREENING/11JUN2013	TL:2/LIVER	VII	CT		81	SLD = 181
205-0023 /72/M/W2	SCREENING/03OCT2013	TL:1/LIVER	HEPATIC DOME	CT		34	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
205-0023 /72/M/W2	SCREENING/03OCT2013	TL:2/GU	RIGHT ADRENAL GLAND	CT		53	SLD = 87
	WEEK12/21JAN2014	TL:1/LIVER	HEPATIC DOME	CT		105	
	WEEK12/21JAN2014	TL:2/GU	RIGHT ADRENAL GLAND	CT		62	
	Summary:					.	SLD = 167, %CN = 91.95, TL: PD, NTL: NotAssessed, OR: PD, PD confirmed: Yes, 30JAN2014
205-0026 /61/F/W2	SCREENING/03FEB2015	TL:1/SOFTT	RIGHT ADRENAL GLAND	CT		34	
	SCREENING/03FEB2015	TL:2/SOFTT	LEFT ADRENAL GLAND	CT		120	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
205-0026 /61/F/W2	SCREENING/03FEB2015	TL:3/LIVER	RIGHT LOBE	CT		41	SLD = 195
	SCREENING/03FEB2015	NTL:1/LIVE	13 LESIONS IN THE LEFT LOBE	CT		.	
	WEEK12/28APR2015	TL:1/SOFTT	RIGHT ADRENAL GLAND	CT		51	
	WEEK12/28APR2015	TL:2/SOFTT	LEFT ADRENAL GLAND	CT		124	
	WEEK12/28APR2015	TL:3/LIVER	RIGHT LOBE	CT		41	
	WEEK12/28APR2015	NTL:1/LIVE	13 LESIONS IN THE LEFT LOBE	CT	UP	.	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
205-0026 /61/F/W2	WEEK12/28APR2015	NTL:2/LIVE	RIGHT LOBE	CT	New	.	
	Summary:					.	SLD = 216, %CN = 10.77, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 05MAY2015
205-0028 /73/F/W2	SCREENING/20JAN2015	TL:1/LIVER	S8	CT		50	
	SCREENING/20JAN2015	TL:2/LIVER	HEPATIC PERILAR SEGMENT	CT		27	SLD = 77
207-0002 /71/M/W2	SCREENING/28FEB2012	TL:1/LIVER	RIGHT HEPATIC LOBE	CT		35	
	SCREENING/28FEB2012	TL:2/	BETWEEN INFERIOR CAVA AND RIGHT PSOAS MUSCLE	CT		45	SLD = 80

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
207-0002 /71/M/W2	SCREENING/28FEB2012	NTL:1/LUNG	RIGHT INFERIOR SUBPLEURIC LOBE	CT		.	
	SCREENING/28FEB2012	NTL:2/LUNG	LUNG LOBES	CT		.	
	SCREENING/28FEB2012	NTL:3/LUNG	LYMPHONODES	CT		.	
	SCREENING/28FEB2012	NTL:4/GI	LYMPHONODES IN EPATIC ILO, MESENTERIAL AND LOMBOAORTIC SITE	CT		.	
	WEEK12/07JUN2012	TL:1/LIVER	RIGHT HEPATIC LOBE	CT		48	
	WEEK12/07JUN2012	TL:2/	BETWEEN INFERIOR CAVA AND RIGHT PSOAS MUSCLE	CT		45	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
207-0002 /71/M/W2	WEEK12/07JUN2012	NTL:1/LUNG	RIGHT INFERIOR SUBPLEURIC LOBE	CT	Present	.	
	WEEK12/07JUN2012	NTL:2/LUNG	LUNG LOBES	CT	Present	.	
	WEEK12/07JUN2012	NTL:3/LUNG	LYMPHONODES	CT	Present	.	
	WEEK12/07JUN2012	NTL:4/GI	LYMPHONODES IN EPATIC ILO, MESENTERIAL AND LOMBOAORTIC SITE	CT	UP	.	
	Summary:					.	SLD = 93, %CN = 16.25, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 20JUN2012
207-0007 /71/M/W2	SCREENING/25JUN2012	TL:1/LIVER	CAUDATE LOBE	CT		69	SLD = 69

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
207-0007 /71/M/W2	SCREENING/25JUN2012	NTL:1/NODE	MULTIPLE LYMPHNODES IN ABDOMEN	CT		.	
	WEEK12/18SEP2012	TL:1/LIVER	CAUDATE LOBE	CT		79	
	WEEK12/18SEP2012	NTL:1/NODE	MULTIPLE LYMPHNODES IN ABDOMEN	CT	Present	.	
	WEEK12/18SEP2012	NTL:2/LIVE	CAUDATE LOBE	CT	New	.	
	Summary:					.	SLD = 79, %CN = 14.49, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 18SEP2012
207-0012 /66/M/W2	SCREENING/18MAR2013	TL:1/LIVER	VII SEGMENT	CT		40	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
207-0012 /66/M/W2	SCREENING/18MAR2013	TL:2/LUNG	MULTIPLE LESIONS	CT		28	
	SCREENING/18MAR2013	TL:3/NODES	PARATRACHEAL	CT		30	
	SCREENING/18MAR2013	TL:4/NODES	SUBCARINAL	CT		50	
	SCREENING/18MAR2013	TL:5/LUNG	UPPER CAVA	CT		50	SLD = 198
	SCREENING/18MAR2013	NTL:1/NODE	EPATIC ILAR, LEFT PARAORTIC, INTER-AORTIC-CA VAL	CT		.	
	SCREENING/18MAR2013	NTL:2/NODE	BILATERAL MEDIASTINIC AND ILAR (LUNG)	CT		.	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
207-0012 /66/M/W2	WEEK12/13JUN2013	TL:1/LIVER	VII SEGMENT	CT		40	
	WEEK12/13JUN2013	TL:2/LUNG	MULTIPLE LESIONS	CT		25	
	WEEK12/13JUN2013	TL:3/NODES	PARATRACHEAL	CT		30	
	WEEK12/13JUN2013	TL:4/NODES	SUBCARINAL	CT		50	
	WEEK12/13JUN2013	TL:5/LUNG	UPPER CAVA	CT		30	
	WEEK12/13JUN2013	NTL:1/NODE	EPATIC ILAR, LEFT PARAORTIC, INTER-AORTIC-CA VAL	CT	Present	.	

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[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
207-0012 /66/M/W2	WEEK12/13JUN2013	NTL:2/NODE	BILATERAL MEDIASTINIC AND ILAR (LUNG)	CT	Present	.	
	Summary:					.	SLD = 175, %CN = -11.62, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK24/05SEP2013	TL:1/LIVER	VII SEGMENT	CT		40	
	WEEK24/05SEP2013	TL:2/LUNG	MULTIPLE LESION	CT		23	
	WEEK24/05SEP2013	TL:3/NODES	PARATRACHEAL	CT		30	
	WEEK24/05SEP2013	TL:4/NODES	SUBCARINAL	CT		50	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
207-0012 /66/M/W2	WEEK24/05SEP2013	TL:5/LUNG	UPPER CAVA	CT		30	
	WEEK24/05SEP2013	NTL:1/NODE	EPATIC ILAR, LEFT PARAORTIC, INTER-AORTIC-CA VAL	CT	Present	.	
	WEEK24/05SEP2013	NTL:2/NODE	BILATERAL MEDIASTINIC AND ILAR (LUNG)	CT	Present	.	
	Summary:					.	SLD = 173, %CN = 0, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK36/29NOV2013	TL:1/LIVER	VII SEGMENT	CT		40	
	WEEK36/29NOV2013	TL:2/LUNG	MULTIPLE LESION	CT		23	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
207-0012 /66/M/W2	WEEK36/29NOV2013	TL:3/NODES	PARATRACHEAL	CT		30	
	WEEK36/29NOV2013	TL:4/NODES	SUBCARINAL	CT		50	
	WEEK36/29NOV2013	TL:5/LUNG	UPPER CAVA	CT		30	
	WEEK36/29NOV2013	NTL:1/NODE	EPATIC ILAR, LEFT PARAORTIC, INTER-AORTIC-CA VAL	CT	Present	.	
	WEEK36/29NOV2013	NTL:2/NODE	BILATERAL MEDIASTINIC AND ILAR (LUNG)	CT	Present	.	
	Summary:					.	SLD = 173, %CN = 0, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
207-0012 /66/M/W2	WEEK48/19FEB2014	TL:1/LIVER	VII SEGMENT	CT		45	
	WEEK48/19FEB2014	TL:2/LUNG	MULTIPLE LESION	CT		27	
	WEEK48/19FEB2014	TL:3/NODES	PARATRACHEAL	CT		30	
	WEEK48/19FEB2014	TL:4/NODES	SUBCARINAL	CT		50	
	WEEK48/19FEB2014	TL:5/LUNG	UPPER CAVA	CT		30	
	WEEK48/19FEB2014	NTL:1/NODE	EPATIC ILAR, LEFT PARAORTIC, INTER-AORTIC-CA VAL	CT	Present	.	

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[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
207-0012 /66/M/W2	WEEK48/19FEB2014	NTL:2/NODE	BILATERAL MEDIASTINIC AND ILAR (LUNG)	CT	Present	.	
	WEEK48/19FEB2014	NTL:3/LUNG	LUNG LESIONS	CT	New	.	
	WEEK48/19FEB2014	NTL:4/LIVE	HEPATIC LESIONS	CT	New	.	
	Summary:					.	SLD = 182, %CN = 5.2, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 19FEB2014
207-0016 /82/F/W2	SCREENING/03OCT2013	TL:1/LIVER	VI SEGMENT	CT		45	
	SCREENING/03OCT2013	TL:2/NODES	CELIAC	CT		20	SLD = 65

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[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
207-0016 /82/F/W2	SCREENING/03OCT2013	NTL:1/LUNG	MULTIPLE LESIONS	CT		.	
	SCREENING/03OCT2013	NTL:2/LIVE	MULTIPLE LESIONS	CT		.	
	SCREENING/03OCT2013	NTL:3/NODE	CELIAC AND EPATIC ILO	CT		.	
	WEEK12/03JAN2014	TL:1/LIVER	VI SEGMENT	CT		50	
	WEEK12/03JAN2014	TL:2/NODES	CELIAC	CT		20	
	WEEK12/03JAN2014	NTL:1/LUNG	MULTIPLE LESIONS	CT	Present	.	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
207-0016 /82/F/W2	WEEK12/03JAN2014	NTL:2/LIVE	MULTIPLE LESIONS	CT	Present	.	
	WEEK12/03JAN2014	NTL:3/NODE	CELIAC AND EPATIC ILO	CT	Present	.	
	Summary:					.	SLD = 70, %CN = 7.69, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
207-0017 /81/F/W2	SCREENING/05NOV2013	TL:1/LIVER	SEGMENT VII	MRI		46	
	SCREENING/05NOV2013	TL:2/LIVER	SEGMENT VII	MRI		30	
	SCREENING/05NOV2013	TL:3/LIVER	LEFT LOBE	MRI		50	SLD = 126

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[3] UP=Unequivocally Progressed
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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
207-0017 /81/F/W2	SCREENING/05NOV2013	NTL:1/LIVE	MULTIPLE LESIONS	MRI		.	
	SCREENING/05NOV2013	NTL:2/ASCI		MRI		.	
	WEEK12/19FEB2014	TL:1/LIVER	SEGMENT VII	MRI		47	
	WEEK12/19FEB2014	TL:2/LIVER	SEGMENT VII	MRI		37	
	WEEK12/19FEB2014	TL:3/LIVER	LEFT LOBE	MRI		60	
	WEEK12/19FEB2014	NTL:1/LIVE	MULTIPLE LESIONS	MRI	Present	.	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
207-0017 /81/F/W2	WEEK12/19FEB2014	NTL:2/ASCI		MRI	Present	.	
	WEEK12/19FEB2014	NTL:3/PLEU		MRI	New	.	
	WEEK12/19FEB2014	NTL:4/SOFT	SUBCUTANEUS OEDEMA	MRI	New	.	
	WEEK12/19FEB2014	NTL:5/GI	PORTAL VEIN THROMBOSIS (RIGHT)	MRI	New	.	
	Summary:					.	SLD = 144, %CN = 14.29, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 19FEB2014
207-0019 /55/M/W2	SCREENING/09MAY2014	TL:1/GI	PERITONEUM	CT		20	

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Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

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207-0019 /55/M/W2	SCREENING/09MAY2014	TL:2/LIVER		CT		130	SLD = 150
	SCREENING/09MAY2014	NTL:1/LUNG	PARENCHYMA	CT		.	
209-0006 /68/M/W2	SCREENING/02MAY2013	TL:1/LIVER	NODULE IN SVII	CT		90	
	SCREENING/02MAY2013	TL:2/LIVER	NODULE IN SIX HEPATIC SEGMENT	CT		60	SLD = 150
	SCREENING/02MAY2013	NTL:1/LIVE	NODULE AT CUPOLA HEPATICA 31X28 MM	CT		.	
	SCREENING/02MAY2013	NTL:2/LIVE	NODULE IN SECOND HEPATIC SEGMENT 16 MM	CT		.	

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Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

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209-0006 /68/M/W2	SCREENING/02MAY2013	NTL:3/LIVE	NODULE IN SEVENTH HEPATIC SEGMENT 14 MM	CT		.	
	WEEK12/19JUL2013	TL:1/LIVER	NODULE IN SVII	CT		92	
	WEEK12/19JUL2013	TL:2/LIVER	NODULE IN SIX HEPATIC SEGMENT	CT		65	
	WEEK12/19JUL2013	NTL:1/LIVE	NODULE AT CUPOLA HEPATICA 33X33 MM	CT	Present	.	
	WEEK12/19JUL2013	NTL:2/LIVE	NODULE IN SECOND HEPATIC SEGMENT 18 MM	CT	Present	.	
	WEEK12/19JUL2013	NTL:3/LIVE	NODULE IN SEVENTH HEPATIC SEGMENT 14 MM	CT	Present	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
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Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
209-0006 /68/M/W2	Summary:					.	SLD = 157, %CN = 4.67, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK24/10OCT2013	TL:1/LIVER	NODULE IN SVII	CT		103	
	WEEK24/10OCT2013	TL:2/LIVER	NODULE IN SIX HEPATIC SEGMENT	CT		67	
	WEEK24/10OCT2013	NTL:1/LIVE	NODULE AT CUPOLA HEPATICA	CT	Present	.	
	WEEK24/10OCT2013	NTL:2/LIVE	NODULE IN SECOND HEPATIC	CT	Present	.	
	WEEK24/10OCT2013	NTL:3/LIVE	NODULE IN SEVENTH HEPATIC	CT	Present	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
209-0006 /68/M/W2	Summary:					.	SLD = 170, %CN = 13.33, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK36/08JAN2014	TL:1/LIVER	NODULE IN SVII	CT		108	
	WEEK36/08JAN2014	TL:2/LIVER	NODULE IN SIX HEPATIC SEGMENT	CT		75	
	WEEK36/08JAN2014	NTL:1/LIVE	NODULE AT CUPOLA HEPATICA	CT	Present	.	
	WEEK36/08JAN2014	NTL:2/LIVE	NODULE IN SECOND HEPATIC	CT	Present	.	
	WEEK36/08JAN2014	NTL:3/LIVE	NODULE IN SEVENTH HEPATIC	CT	Present	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
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Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
209-0006 /68/M/W2	WEEK36/08JAN2014	NTL:4/LIVE	NEOPLASTIC PORTAL VEIN THROMBOSIS	CT	New	.	
	Summary:					.	SLD = 183, %CN = 22, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 08JAN2014
209-0011 /69/M/W2	SCREENING/29NOV2013	TL:1/LIVER	HCC IN UPPER HEPATIC SEGMENTS (S4 - S8)	CT		91	
	SCREENING/29NOV2013	TL:2/LIVER	HCC IN S5 - S6	CT		45	SLD = 136
	SCREENING/29NOV2013	NTL:1/LIVE	MULTIPLE HCC NODULES	CT		.	
	WEEK12/17FEB2014	TL:1/LIVER	HCC IN UPPER HEPATIC SEGMENTS (S4 - S8)	CT		100	

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209-0011 /69/M/W2	WEEK12/17FEB2014	TL:2/LIVER	HCC IN S5 - S6	CT		62	
	WEEK12/17FEB2014	NTL:1/LIVE	MULTIPLE HCC NODULES	CT	Present	.	
	WEEK12/17FEB2014	NTL:2/BONE	MULTIPLE BONE HCC METASTATIC LESIONS	CT	New	.	
	Summary:					.	SLD = 162, %CN = 19.12, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 17FEB2014
209-0014 /79/M/W2	SCREENING/14MAR2014	TL:1/LIVER	HCC IN S4	CT		28	
	SCREENING/14MAR2014	TL:2/BONE	VERTEBRAL METASTASIS IN D9 WITH 9TH RIB INFILTRATION	CT		30	

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Tumor Assessment Summary Listing
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209-0014 /79/M/W2	SCREENING/14MAR2014	TL:3/LIVER	HCC S2 - S4	CT		22	SLD = 80
	SCREENING/14MAR2014	NTL:1/LIVE	MULTIPLE HCC NODULES	CT		.	
	WEEK12/03JUN2014	TL:1/LIVER	HCC IN S4	CT		28	
	WEEK12/03JUN2014	TL:2/BONE	VERTEBRAL METASTASIS IN D9 WITH 9TH RIB INFILTRATION	CT		38	
	WEEK12/03JUN2014	TL:3/LIVER	HCC S2 - S4	CT		22	
	WEEK12/03JUN2014	NTL:1/LIVE	MULTIPLE HCC NODULES	CT	Present	.	

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209-0014 /79/M/W2	Summary:					.	SLD = 88, %CN = 10, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK24/25AUG2014	TL:1/LIVER	HCC IN S4	CT		28	
	WEEK24/25AUG2014	TL:2/BONE	VERTEBRAL METASTASIS IN D9 WITH 9TH RIB INFILTRATION	CT		51	
	WEEK24/25AUG2014	TL:3/LIVER	HCC S2 - S4	CT		20	
	WEEK24/25AUG2014	NTL:1/LIVE	MULTIPLE HCC NODULES	CT	Present	.	
	Summary:					.	SLD = 99, %CN = 23.75, TL: PD, NTL: IncompleteResponse/SD, OR: PD, PD confirmed: Yes, 01SEP2014

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210-0003 /74/M/W2	SCREENING/21OCT2013	TL:1/LIVER	RIGHT LOBE	CT		10	SLD = 10
	SCREENING/21OCT2013	NTL:1/BONE	LESION IN THE RIGHT INTERCOSTAL SITE	CT		.	
210-0004 /71/M/W2	SCREENING/19DEC2013	TL:1/LIVER	SEGMENT VIII OVALAR AREA	CT		60	
	SCREENING/19DEC2013	TL:2/NODES	ADENOPATHY IN THE AREA OF RIGHT CARDIOPHRENIC SINUS	CT		20	
	SCREENING/19DEC2013	TL:3/NODES	ADENOPATHY IN THE CELIAC TRUNK	CT		35	
	SCREENING/19DEC2013	TL:4/NODES	HEPATIC HILAR ADENOPATHY	CT		50	SLD = 165

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Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
210-0004 /71/M/W2	SCREENING/19DEC2013	NTL:1/NODE	ADENOPATHY IN THE MESOGASTRIC AREA	CT		.	
	WEEK12/27MAR2014	TL:1/LIVER	SEGMENT VIII OVALAR AREA	CT	UP	.	
	WEEK12/27MAR2014	TL:2/NODES	ADENOPATHY IN THE AREA OF RIGHT CARDIOPHRENIC SINUS	CT		23	
	WEEK12/27MAR2014	TL:3/NODES	ADENOPATHY IN THE CELIAC TRUNK	CT		45	
	WEEK12/27MAR2014	TL:4/NODES	HEPATIC HILAR ADENOPATHY	CT		65	
	WEEK12/27MAR2014	NTL:1/NODE	ADENOPATHY IN THE MESOGASTRIC AREA	CT	UP	.	

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210-0004 /71/M/W2	WEEK12/27MAR2014	NTL:2/NODE	LATEROBASAL LEFT PULMUNARY NODES	CT	New	.	
	WEEK12/27MAR2014	NTL:3/NODE	HOMOLATERAL PARACARDIAC ADENOPATHY	CT	New	.	
	Summary:					.	SLD = ., %CN = ., TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 28MAR2014
210-0005 /53/M/W2	SCREENING/13FEB2014	TL:1/LIVER	LESION V-VIII SEGMENT	CT		58	SLD = 58
	SCREENING/13FEB2014	NTL:1/LIVE	LYNPHONODE PARA AORTIC LEFT	CT		.	
	SCREENING/13FEB2014	NTL:2/LIVE	LYNPHONODE IN HEPATIC HILUM	CT		.	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
210-0005 /53/M/W2	WEEK12/07MAY2014	TL:1/LIVER	LESION V-VIII SEGMENT	CT		85	
	WEEK12/07MAY2014	NTL:1/LIVE	LYNPHONODE PARA AORTIC LEFT	CT	Present	.	
	WEEK12/07MAY2014	NTL:2/LIVE	LYNPHONODE IN HEPATIC HILUM	CT	UP	.	
	Summary:					.	SLD = 85, %CN = 46.55, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 07MAY2014
210-0006 /45/M/W2	SCREENING/26MAY2014	TL:1/LIVER	LESION BETWEEN 6-7 SEGMENTS	CT		65	SLD = 65
	SCREENING/26MAY2014	NTL:1/LIVE	SPACE OCCUPYING LESIONS OF LIVER	CT		.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
210-0006 /45/M/W2	WEEK12/18SEP2014	TL:1/LIVER	LESION BETWEEN 6-7 SEGMENTS	CT		56	
	WEEK12/18SEP2014	NTL:1/LIVE	SPACE OCCUPYING LESIONS OF LIVER	CT	UP	.	
	WEEK12/18SEP2014	NTL:2/NODE	RETROPERITONEAL AND INTRA PORTAL CAVAL	CT	New	.	
	WEEK12/18SEP2014	NTL:3/NODE	MESENTERIC LYMPH NODE	CT	New	.	
	Summary:					.	SLD = 56, %CN = -13.85, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 29SEP2014
251-0002 /69/M/W2	SCREENING/06AUG2013	TL:1/LIVER	SEGMENT IV	CT		106	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
251-0002 /69/M/W2	SCREENING/06AUG2013	TL:2/LIVER	SEGMENT V	CT		66	SLD = 172
	SCREENING/06AUG2013	NTL:1/LIVE	SEGMENT IV	CT		.	
	WEEK12/16OCT2013	TL:1/LIVER	SEGMENT IV	CT		106	
	WEEK12/16OCT2013	TL:2/LIVER	SEGMENT V	CT		106	
	WEEK12/16OCT2013	NTL:1/LIVE	SEGMENT IV	CT	UP	.	
	Summary:					.	SLD = 212, %CN = 23.26, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 16OCT2013

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
251-0003 /68/M/W2	SCREENING/18OCT2013	TL:1/LIVER	R HEPATIC LESION	CT		107	
	SCREENING/18OCT2013	TL:2/NODES	PERIPORTAL	CT		11	
	SCREENING/18OCT2013	TL:3/NODES	PRECAVAL NODE	CT		12	SLD = 130
	SCREENING/18OCT2013	NTL:1/NODE	RIGHT HILAR NODE	CT		.	
	WEEK12/21JAN2014	TL:1/LIVER	R HEPATIC LESION	CT		111	
	WEEK12/21JAN2014	TL:2/NODES	PERIPORTAL	CT		16	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
251-0003 /68/M/W2	WEEK12/21JAN2014	TL:3/NODES	PRECACAL NODE	CT		18	
	WEEK12/21JAN2014	NTL:1/NODE	RIGHT HILAR NODE	CT	Present	.	
	Summary:					.	SLD = 145, %CN = 11.54, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK24/15APR2014	TL:1/LIVER	R HEPATIC LESION	CT		112	
	WEEK24/15APR2014	TL:2/NODES	PERIPORTAL	CT		16	
	WEEK24/15APR2014	TL:3/NODES	PRECAVAL	CT		18	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
251-0003 /68/M/W2	WEEK24/15APR2014	NTL:1/NODE	RIGHT HILAR NODE	CT	Present	.	
	WEEK24/15APR2014	NTL:2/LUNG	RIGHT	CT	New	.	
	WEEK24/15APR2014	NTL:3/LIVE	INFILTRATION INTO MAIN PORTAL VEIN	CT	New	.	
	Summary:					.	SLD = 146, %CN = 12.31, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 15APR2014
252-0001 /65/M/A3	SCREENING/01MAY2012	TL:1/GI	LEFT T4 VERTEBRAL/RIB MASS	CT		72	
	SCREENING/01MAY2012	TL:2/GI	LEFT POSTERIOR EIGHTH RIB MASS	CT		38	

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Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
252-0001 /65/M/A3	SCREENING/01MAY2012	TL:3/GI	SUPERIOR LIVER MASS	CT		48	
	SCREENING/01MAY2012	TL:4/GI	INFERIOR LIVER MASS	CT		61	
	SCREENING/01MAY2012	TL:5/GI	RIGHT LOWER LOBE LUNG NODULE	CT		11	SLD = 230
252-0004 /50/M/A1	SCREENING/21MAY2013	TL:1/LIVER	SEGMENT 8 LESION	CT		25	
	SCREENING/21MAY2013	TL:2/LIVER	SEGMENT 6 LESION INFILTRATING THE HEPATIC FLEXURE	CT		96	SLD = 121
	SCREENING/21MAY2013	NTL:1/LIVE	SEGMENT 7	CT		.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
252-0004 /50/M/A1	UNSCHEDULED/25JUL2013	TL:1/LIVER	SEGMENT 8 LESION	CT		25	
	UNSCHEDULED/25JUL2013	TL:2/LIVER	SEGMENT 6 LESION INFILTRATING THE HEPATIC FLEXURE	CT		91	
	UNSCHEDULED/25JUL2013	NTL:1/LIVE	SEGMENT 7	CT	Present	.	
	UNSCHEDULED/25JUL2013	NTL:2/LIVE	NEW LIVER METS	CT	New	.	
	UNSCHEDULED/25JUL2013	NTL:3/GI	NEW OMENTAL MET	CT	New	.	
	Summary:					.	SLD = 116, %CN = 0, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 25JUL2013

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Tumor Assessment Summary Listing
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Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
252-0006 /64/M/W2	SCREENING/17SEP2013	TL:1/LIVER	SEGMENT 4 LESION	CT		90	
	SCREENING/17SEP2013	TL:2/LIVER	SEGMENT 7 METASTASIS	CT		45	SLD = 135
	WEEK12/17DEC2013	TL:1/LIVER	SEGMENT 4 LESION	CT		98	
	WEEK12/17DEC2013	TL:2/LIVER	SEGMENT 7 METASTASIS	CT		50	
	Summary:					.	SLD = 148, %CN = 9.63, TL: SD, NTL: NotAssessed, OR: SD, PD confirmed: No
	WEEK24/11MAR2014	TL:1/LIVER	SEGMENT 4	CT		95	

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Tumor Assessment Summary Listing
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Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
252-0006 /64/M/W2	WEEK24/11MAR2014	TL:2/LIVER	SEGMENT 7 METASTASIS	CT		51	
	Summary:					.	SLD = 146, %CN = 8.15, TL: SD, NTL: NotAssessed, OR: SD, PD confirmed: No
252-0008 /76/M/W2	SCREENING/20MAY2014	TL:1/LIVER	LIVER SEG 8	CT		41	
	SCREENING/20MAY2014	TL:2/LIVER	LIVER SEG 6	CT		22	
	SCREENING/20MAY2014	TL:3/NODES	PORTACAVAL LYMPH NODE	CT		46	SLD = 109
	WEEK12/12AUG2014	TL:1/LIVER	LIVER SEG 8	CT		56	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
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Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
252-0008 /76/M/W2	WEEK12/12AUG2014	TL:2/LIVER	LIVER SEG 6	CT		17	
	WEEK12/12AUG2014	TL:3/NODES	PORTACAVAL LYMPH NODE	CT		46	
	WEEK12/12AUG2014	NTL:1/HEAD	NEW LEFT LEVEL 3 NECK NODE	CT	New	.	
	WEEK12/12AUG2014	NTL:2/BONE	NEW L2 BONE METASTASIS	CT	New	.	
	Summary:					.	SLD = 119, %CN = 9.17, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 12AUG2014
252-0010 /56/F/W2	SCREENING/28OCT2014	TL:1/LIVER	SEGMENT 2	MRI		31	

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Tumor Assessment Summary Listing
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Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
252-0010 /56/F/W2	SCREENING/28OCT2014	TL:2/LIVER	SEGMENT 3	MRI		32	
	SCREENING/28OCT2014	TL:3/NODES	RIGHT POSTERIOR PERIRENAL NODULE	MRI		17	SLD = 80
	WEEK12/20JAN2015	TL:1/LIVER	SEGMENT 2	MRI		41	
	WEEK12/20JAN2015	TL:2/LIVER	SEGMENT 3	MRI		38	
	WEEK12/20JAN2015	TL:3/NODES	RIGHT POSTERIOR PERIRENAL NODULE	MRI		17	
	Summary:					.	SLD = 96, %CN = 20, TL: PD, NTL: NotAssessed, OR: PD, PD confirmed: Yes, 20JAN2015

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(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
253-0003 /75/M/W2	SCREENING/09JUN2012	TL:1/LIVER	SEGMENT 4A LESION	CT		38	
	SCREENING/09JUN2012	TL:2/LIVER	SEGMENT 4B LESION	CT		17	
	SCREENING/09JUN2012	TL:3/NODES	PERIPORTAL LYMPH NODE	CT		44	
	SCREENING/09JUN2012	TL:4/NODES	SUPERIOR PERIPORTAL NODE	CT		25	SLD = 124
	WEEK12/31AUG2012	TL:1/LIVER	SEGMENT 4A LESION	CT		36	
	WEEK12/31AUG2012	TL:2/LIVER	SEGMENT 4B LESION	CT		16	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
253-0003 /75/M/W2	WEEK12/31AUG2012	TL:3/NODES	PERIPORTAL LYMPH NODE	CT		44	
	WEEK12/31AUG2012	TL:4/NODES	SUPERIOR PERIPORTAL NODE	CT		24	
	Summary:					.	SLD = 120, %CN = -3.23, TL: SD, NTL: NotAssessed, OR: SD, PD confirmed: No
	WEEK24/16NOV2012	TL:1/LIVER	SEGMENT 4A LESION	CT		35	
	WEEK24/16NOV2012	TL:2/LIVER	SEGMENT 4B LESION	CT		18	
	WEEK24/16NOV2012	TL:3/NODES	PERIPORTAL LYMPH NODE	CT		46	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
253-0003 /75/M/W2	WEEK24/16NOV2012	TL:4/NODES	SUPERIOR PERIPORTAL NODE	CT		23	
	Summary:					.	SLD = 122, %CN = 1.67, TL: SD, NTL: NotAssessed, OR: SD, PD confirmed: No
	WEEK36/13FEB2013	TL:1/LIVER	SEGEMNT 4A LESION	CT		61	
	WEEK36/13FEB2013	TL:2/LIVER	SEGMENT 4B LESION	CT		35	
	WEEK36/13FEB2013	TL:3/NODES	PERIPORTAL NODE	CT		46	
	WEEK36/13FEB2013	TL:4/NODES	SUPERIOR PORTAL NODES	CT		24	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
253-0003 /75/M/W2	Summary:					.	SLD = 166, %CN = 38.33, TL: PD, NTL: NotAssessed, OR: PD, PD confirmed: Yes, 13FEB2013
253-0004 /79/M/W2	SCREENING/13AUG2012	TL:1/LIVER	LESION SEGMENTS 2/3	CT		39	
	SCREENING/13AUG2012	TL:2/LIVER	LESION SEGMENT 2	CT		16	
	SCREENING/13AUG2012	TL:3/LUNG	RIGHT MIDDLE LOBE	CT		21	
	SCREENING/13AUG2012	TL:4/LUNG	RIGHT LOWER LOBE	CT		23	
	SCREENING/13AUG2012	TL:5/PLEUR	RIGHT CHEST WALL	CT		28	SLD = 127

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
253-0004 /79/M/W2	SCREENING/13AUG2012	NTL:1/LUNG	MULTIPLE PULMONARY METS	CT		.	
	WEEK12/19NOV2012	TL:1/LIVER	LESION SEGMENTS 2/3	CT		60	
	WEEK12/19NOV2012	TL:2/LIVER	LESION SEGMENT 2	CT		27	
	WEEK12/19NOV2012	TL:3/LUNG	RIGHT MIDDLE LOBE	CT		30	
	WEEK12/19NOV2012	TL:4/LUNG	RIGHT LOWER LOBE	CT		33	
	WEEK12/19NOV2012	TL:5/PLEUR	RIGHT CHEST WALL	CT		38	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
253-0004 /79/M/W2	WEEK12/19NOV2012	NTL:1/LUNG	MULTIPLE PULMONARY METS	CT	UP	.	
	Summary:					.	SLD = 188, %CN = 48.03, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 19NOV2012
253-0005 /74/F/W2	SCREENING/15OCT2012	TL:1/LIVER	SEGMENT 4 LESION	CT		40	
	SCREENING/15OCT2012	TL:2/LIVER	SEGEMNT 3 LESION	CT		77	SLD = 117
253-0006 /63/M/A3	SCREENING/21DEC2012	TL:1/LIVER	HCC	CT		91	SLD = 91
	SCREENING/21DEC2012	NTL:1/LUNG	LINGULA NODULE	CT		.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
253-0006 /63/M/A3	SCREENING/21DEC2012	NTL:2/LUNG	SUB-CENTIMETRE PULMONARY NODULES	CT		.	
	WEEK12/15MAR2013	TL:1/LIVER	HCC RIGHT LOBE	CT		103	
	WEEK12/15MAR2013	NTL:1/LUNG	LINGULA NODULE	CT	Present	.	
	WEEK12/15MAR2013	NTL:2/LUNG	SEVERAL PULMONARY NODULES	CT	Present	.	
	Summary:					.	SLD = 103, %CN = 13.19, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	UNSCHEDULED/17MAY2013	TL:/LIVER	LIVER RIGHT	CT		104	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
253-0006 /63/M/A3	UNSCHEDULED/17MAY2013	NTL:/LUNG	SEVERAL PULMONARY	CT	UP	.	
	UNSCHEDULED/17MAY2013	NTL:1/LUNG	LINGULA NODULE	CT	Present	.	
	Summary:					.	SLD = 104, %CN = 14.29, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 17MAY2013
253-0011 /67/M/W2	SCREENING/22SEP2014	TL:1/LIVER	SEGMENT 8	CT		48	SLD = 48
	SCREENING/22SEP2014	NTL:1/LIVE	MULTIPLE ARTERIALISED HEPATIC LESIONS	CT		.	
	SCREENING/22SEP2014	NTL:2/LIVE	LEFT PORTAL VEIN THROMBUS	CT		.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
253-0011 /67/M/W2	WEEK12/22DEC2014	TL:1/LIVER	SEGMENT 8	CT		37	
	WEEK12/22DEC2014	NTL:1/LIVE	MULTIPLE ARTERIALISED HEPATIC LESIONS	CT	Present	.	
	WEEK12/22DEC2014	NTL:2/LIVE	LEFT PORTAL VEIN THROMBUS	CT	Present	.	
	Summary:					.	SLD = 37, %CN = -22.92, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK24/16MAR2015	TL:1/LIVER	SEGMENT 8	CT		27	
	WEEK24/16MAR2015	NTL:1/LIVE	MULTIPLE ARTERIALISED HEPATIC LESIONS	CT	Present	.	

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Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
253-0011 /67/M/W2	WEEK24/16MAR2015	NTL:2/LIVE	LEFT PORTAL VEIN THROMBUS	CT	Present	.	
	Summary:					.	SLD = 27, %CN = 0, TL: PR, NTL: IncompleteResponse/SD, OR: PR, PD confirmed: No
	WEEK36/08JUN2015	TL:1/LIVER	SEGMENT 8	CT		29	
	WEEK36/08JUN2015	NTL:1/LIVE	MULTIPLE ARTERIALISED HEPATIC LESIONS	CT	Present	.	
	WEEK36/08JUN2015	NTL:2/LIVE	LEFT PORTAL VEIN THROMBUS	CT	Present	.	
	Summary:					.	SLD = 29, %CN = 7.41, TL: PR, NTL: IncompleteResponse/SD, OR: PR, PD confirmed: No

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Tumor Assessment Summary Listing
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Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
253-0012 /67/M/W2	SCREENING/12NOV2014	TL:1/LIVER	SEGMENT IVB	CT		36	
	SCREENING/12NOV2014	TL:2/LIVER	SEGMENT V/VIII	CT		45	SLD = 81
257-0005 /66/M/W2	SCREENING/05DEC2012	TL:1/LIVER	SEGMENT 7	CT		100	SLD = 100
	SCREENING/05DEC2012	NTL:1/LUNG	MULTIPLE PULMONARY METASTASIS	CT		.	
	SCREENING/05DEC2012	NTL:2/LIVE	PORTAL VEIN THROMBOSIS	CT		.	
	WEEK12/18MAR2013	TL:1/LIVER	SEGMENT 7	CT		100	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
257-0005 /66/M/W2	WEEK12/18MAR2013	NTL:1/LUNG	MULTIPLE PULMONARY METASTASIS	CT	UP	.	
	WEEK12/18MAR2013	NTL:2/LIVE	PORTAL VEIN THROMBOSIS	CT	UP	.	
	Summary:					.	SLD = 100, %CN = 0, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 21MAR2013
257-0013 /63/M/W2	SCREENING/02MAY2013	TL:1/NODES	SUPRACOELIAC	CT		21	SLD = 21
	SCREENING/02MAY2013	NTL:1/LIVE	SEGMENT 4	CT		.	
	SCREENING/02MAY2013	NTL:2/LIVE	SEGMENT 2	CT		.	

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Tumor Assessment Summary Listing
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Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
257-0020 /72/M/A1	SCREENING/22OCT2014	TL:1/LIVER	SEGMENT 2	CT		27	
	SCREENING/22OCT2014	TL:2/LIVER	SEGMENT 4B	CT		22	SLD = 49
	UNSCHEDULED/20NOV2014	TL:1/LIVER	SEGMENT 2	CT		35	
	UNSCHEDULED/20NOV2014	TL:2/LIVER	SEGMENT 4B	CT		22	
	UNSCHEDULED/20NOV2014	NTL:1/NODE	LYPHADENOPATHY	CT	New	.	
	Summary:					.	SLD = 57, %CN = 16.33, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 22NOV2014

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
258-0002 /69/F/W2	SCREENING/27MAR2013	TL:1/LIVER	RIGHT LOBE	CT		152	
	SCREENING/27MAR2013	TL:2/LIVER	SEGMENT 4/5/8	CT		27	SLD = 179
	SCREENING/27MAR2013	NTL:1/LUNG	SOFT TISSUE NODULE IN THE LEFT LUNG UPPER ZONE	CT		.	
	SCREENING/27MAR2013	NTL:2/LIVE	SEGMENT 4	CT		.	
	SCREENING/27MAR2013	NTL:3/LIVE	SEGMENT 8	CT		.	
	WEEK12/26JUN2013	TL:1/LIVER	RIGHT LOBE	CT		161	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
258-0002 /69/F/W2	WEEK12/26JUN2013	TL:2/LIVER	SEGMENT 4/5/8	CT		33	
	WEEK12/26JUN2013	NTL:1/LUNG	UPPER ZONE	CT	Present	.	
	WEEK12/26JUN2013	NTL:2/LIVE	SEGMENT 4	CT	Present	.	
	WEEK12/26JUN2013	NTL:3/LIVE	SEGMENT 8	CT	Present	.	
	Summary:					.	SLD = 194, %CN = 8.38, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK24/18SEP2013	TL:1/LIVER	RIGHT LOBE	CT		171	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
258-0002 /69/F/W2	WEEK24/18SEP2013	TL:2/LIVER	SEGMENT 4/5/8	CT		34	
	WEEK24/18SEP2013	NTL:1/LUNG	UPPER ZONE	CT	Present	.	
	WEEK24/18SEP2013	NTL:2/LIVE	SEGMENT 4	CT	Present	.	
	WEEK24/18SEP2013	NTL:3/LIVE	SEGMENT 8	CT	Present	.	
	Summary:					.	SLD = 205, %CN = 14.53, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK36/11DEC2013	TL:1/LIVER	RIGHT LOBE	CT		179	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
258-0002 /69/F/W2	WEEK36/11DEC2013	TL:2/LIVER	SEGMENT 4/5/8	CT		37	
	WEEK36/11DEC2013	NTL:1/LUNG	UPPER ZONE	CT	Present	.	
	WEEK36/11DEC2013	NTL:2/LIVE	SEGMENT 4	CT	Present	.	
	WEEK36/11DEC2013	NTL:3/LIVE	SEGMENT 8	CT	UP	.	
	Summary:					.	SLD = 216, %CN = 20.67, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 11DEC2013
258-0003 /67/F/W2	SCREENING/09MAY2013	TL:1/LUNG	RIGHT HILUM	CT		10	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
258-0003 /67/F/W2	SCREENING/09MAY2013	TL:2/LUNG	BEHIND DESCENDING AORTA	CT		10	
	SCREENING/09MAY2013	TL:3/LIVER	ADJACNT TO CUT SURFACE	CT		930	
	SCREENING/09MAY2013	TL:4/LIVER	POSTEROLATERALLY IN SEGMENT 2/3	CT		240	SLD = 1190
	SCREENING/09MAY2013	NTL:1/LUNG	NODULE PERIPHERAL OF RIGHT LUNG, SUB PLEURAL	CT		.	
	WEEK12/31JUL2013	TL:1/LUNG	RIGHT HILUM	CT		13	
	WEEK12/31JUL2013	TL:2/LUNG	BEHIND DESCENDING AORTA	CT		12	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
258-0003 /67/F/W2	WEEK12/31JUL2013	TL:3/LIVER	ADJACNT TO CUT SURFACE	CT		950	
	WEEK12/31JUL2013	TL:4/LIVER	POSTEROLATERALLY IN SEGMENT 2/3	CT		290	
	WEEK12/31JUL2013	NTL:1/LUNG	NODULE PERIPHERAL OF RIGHT LUNG, SUB PLEURAL	CT	Present	.	
	Summary:					.	SLD = 1265, %CN = 6.3, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK24/23OCT2013	TL:1/LUNG	RIGHT HILUM	CT		16	
	WEEK24/23OCT2013	TL:2/LUNG	BEHIND DESCENDING AORTA	CT		12	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
258-0003 /67/F/W2	WEEK24/23OCT2013	TL:3/LIVER	ADJACNT TO CUT SURFACE	CT	UP	.	
	WEEK24/23OCT2013	TL:4/LIVER	POSTEROLATERALLY IN SEGMENT 2/3	CT		310	
	WEEK24/23OCT2013	NTL:1/LUNG	NODULE PERIPHERAL OF RIGHT LUNG, SUB PLEURAL	CT	UP	.	
	Summary:					.	SLD = ., %CN = ., TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 28OCT2013
258-0004 /65/M/W2	SCREENING/09MAY2013	TL:1/LIVER	SEGMENT 8	CT		24	SLD = 24
	SCREENING/09JUN2013	NTL:1/LIVE	SEGMENT 2/4	CT		.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
258-0004 /65/M/W2	SCREENING/09JUN2013	NTL:2/LIVE	SEGMENT 8	CT		.	
258-0006 /69/M/W2	SCREENING/02OCT2013	TL:1/LIVER	SEGMENT 7/8	CT		72	
	SCREENING/02OCT2013	TL:2/LIVER	ADJACENT TO RIGHT PORTAL VEIN	CT		41	SLD = 113
258-0013 /59/M/W2	SCREENING/05NOV2014	TL:1/LIVER	SUPERIOR ANTERIOR ASPECT OF THE RIGHT LOBE	CT		26	
	SCREENING/05NOV2014	TL:2/LIVER	LEFT LOBE OF LIVER	CT		28	SLD = 54
	WEEK12/28JAN2015	TL:1/LIVER	SUPERIOR ANTERIOR ASPECT OF THE RIGHT LOBE	CT		28	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
258-0013 /59/M/W2	WEEK12/28JAN2015	TL:2/LIVER	LEFT LOBE OF LIVER	CT		30	
	WEEK12/28JAN2015	NTL:1/LIVE	LEFT LOBE OF LIVER	CT	New	.	
	Summary:					.	SLD = 58, %CN = 7.41, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 28JAN2015
259-0003 /73/M/W2	SCREENING/09JUN2014	TL:1/LIVER	RIGHT LOBE OF LIVER	CT		127	
	SCREENING/09JUN2014	TL:2/LIVER	LIVER MASS IN SEGMENT 6	CT		80	SLD = 207
	SCREENING/09JUN2014	NTL:1/LUNG	RIGHT PLEURAL EFFUSION	CT		.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
259-0003 /73/M/W2	SCREENING/09JUN2014	NTL:2/LIVE	LEFT LOBE OF THE LIVER	CT		.	
	SCREENING/09JUN2014	NTL:3/NODE	EPIGASTRIC LYMPH NODE	CT		.	
	SCREENING/09JUN2014	NTL:4/NODE	PRECAVAL LYMPH NODE	CT		.	
	SCREENING/09JUN2014	NTL:5/LIVE	SEGMENT 4	CT		.	
	WEEK12/20AUG2014	TL:1/LIVER	RIGHT LOBE OF LIVER	CT		114	
	WEEK12/20AUG2014	TL:2/LIVER	LIVER MASS IN SEGMENT 6	CT		86	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
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Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
259-0003 /73/M/W2	WEEK12/20AUG2014	NTL:1/LUNG	RIGHT PLEURAL EFFUSION	CT	Present	.	
	WEEK12/20AUG2014	NTL:2/LIVE	LEFT LOBE OF THE LIVER	CT	Present	.	
	WEEK12/20AUG2014	NTL:3/NODE	EPIGASTRIC LYMPH NODE	CT	Present	.	
	WEEK12/20AUG2014	NTL:4/NODE	PRECAVAL LYMPH NODE	CT	Present	.	
	WEEK12/20AUG2014	NTL:5/LIVE	SEGMENT 4	CT	Present	.	
	Summary:					.	SLD = 200, %CN = -3.38, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No

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Listing 16.2.6.2
Tumor Assessment Summary Listing
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Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
259-0003 /73/M/W2	WEEK24/12NOV2014	TL:1/LIVER	RIGHT LOBE OF LIVER	CT		114	
	WEEK24/12NOV2014	TL:2/LIVER	LIVER MASS IN SEGMENT 6	CT		86	
	WEEK24/12NOV2014	NTL:1/LUNG	RIGHT PLEURAL EFFUSION	CT	Present	.	
	WEEK24/12NOV2014	NTL:2/LIVE	LEFT LOBD OF LIVER	CT	Present	.	
	WEEK24/12NOV2014	NTL:3/NODE	EPIGASTRIC LYMPH NODE	CT	Present	.	
	WEEK24/12NOV2014	NTL:4/NODE	PRECAVAL LYMPH NODE	CT	Present	.	

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Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
259-0003 /73/M/W2	Summary:					.	SLD = 200, %CN = 0, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK36/04FEB2015	TL:1/LIVER	RIGHT LOBE OF LIVER	CT		110	
	WEEK36/04FEB2015	TL:2/LIVER	LIVER MASS IN SEGMENT 6	CT		95	
	WEEK36/04FEB2015	NTL:1/LUNG	RIGHT PLEURAL EFFUSION	CT	Present	.	
	WEEK36/04FEB2015	NTL:2/LIVE	LEFT LOBE OF THE LIVER	CT	Present	.	
	WEEK36/04FEB2015	NTL:3/NODE	EPIGASTRIC LYMPH NODE	CT	Present	.	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
259-0003 /73/M/W2	WEEK36/04FEB2015	NTL:4/NODE	PRECAVAL LYMPH NODE	CT	Present	.	
	WEEK36/04FEB2015	NTL:5/LIVE	SEGMENT 4	CT	Present	.	
	Summary:					.	SLD = 205, %CN = 2.5, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK48/29APR2015	TL:1/LIVER	RIGHT LOBE OF LIVER	CT		111	
	WEEK48/29APR2015	TL:2/LIVER	LIVER MASS IN SEGMENT 6	CT		93	
	WEEK48/29APR2015	NTL:1/LUNG	RIGHT PLEURAL EFFUSION	CT	Present	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
259-0003 /73/M/W2	WEEK48/29APR2015	NTL:2/LIVE	LEFT LOBE OF THE LIVER	CT	Present	.	
	WEEK48/29APR2015	NTL:3/NODE	EPIGASTRIC LYMPH NODE	CT	Present	.	
	WEEK48/29APR2015	NTL:4/NODE	PRECAVAL LYMPH NODE	CT	Present	.	
	WEEK48/29APR2015	NTL:5/LIVE	SEGMENT 4	CT	Present	.	
	Summary:					.	SLD = 204, %CN = 2, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
259-0004 /52/M/W2	SCREENING/16JUL2014	TL:1/NODES	RIGHT HILAR NODE	CT		16	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
259-0004 /52/M/W2	SCREENING/16JUL2014	TL:2/NODES	AORTA PULMONARY WINDOW	CT		22	
	SCREENING/16JUL2014	TL:3/LIVER	HYPERVASCULAR MASS ANTERIOR TO THE LEFT LOBE OF THE LIVER	CT		79	
	SCREENING/16JUL2014	TL:4/LIVER	SEGMENT 7	CT		14	
	SCREENING/16JUL2014	TL:5/LIVER	LIVER LESION	CT		40	SLD = 171
	SCREENING/16JUL2014	NTL:1/LUNG	BILATERAL INTRAPULMONARY NODULE	CT		.	
	SCREENING/16JUL2014	NTL:2/NODE	MEDIASTINAL LYMPH NODES	CT		.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
259-0004 /52/M/W2	SCREENING/16JUL2014	NTL:3/GI	OMENTAL STREAKING	CT		.	
	SCREENING/16JUL2014	NTL:4/ASCI	SMALL VOLUME ASCITIC FLUID	CT		.	
	SCREENING/16JUL2014	NTL:5/GI	PORTAL HYPERTENSION	CT		.	
260-0002 /66/M/W2	SCREENING/23SEP2013	TL:1/LIVER	SEGMENT 2	CT		58	SLD = 58
	UNSCHEDULED/15NOV2013	TL:1/LIVER	SEGMENT 2	CT		74	
	Summary:					.	SLD = 74, %CN = 27.59, TL: PD, NTL: NotEvaluable, OR: PD, PD confirmed: Yes, 20NOV2013

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
301-0001 /47/F/A2	SCREENING/27OCT2011	TL:1/LUNG	RLL	CT		32	
	SCREENING/27OCT2011	TL:2/LUNG	LLL	CT		20	
	SCREENING/27OCT2011	TL:4/PLEUR	RIGHT PLEURAL HILAR LAP	CT		32	SLD = 120
	SCREENING/27OCT2011	NTL:1/LUNG	LUL LINGUAL LOBES	CT		.	
	WEEK12/17JAN2012	TL:1/LUNG	RLL	CT		38	
	WEEK12/17JAN2012	TL:2/LUNG	LLL	CT		23	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
301-0001 /47/F/A2	WEEK12/17JAN2012	TL:3/NODES	MEDIASTINAL LAP	CT		53	
	WEEK12/17JAN2012	TL:4/PLEUR	RIGHT PLEURAL HILAR LAP	CT		40	
	WEEK12/17JAN2012	NTL:1/LUNG	LUL LINGUAL LOBES	CT	UP	.	
	WEEK12/17JAN2012	NTL:2/NODE	MEDDIASTINAL	CT	New	.	
	WEEK12/17JAN2012	NTL:3/NODE	MEDIASTINAL	CT	New	.	
	Summary:					.	SLD = 154, %CN = 28.33, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 19JAN2012

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Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
301-0001 /47/F/A2	SCREENING/27OCT2012	TL:3/NODES	MEDIASTINAL LAP	CT		36	
301-0003 /61/F/A2	SCREENING/16FEB2012	TL:1/LUNG	LUL	CT		12	
	SCREENING/16FEB2012	TL:2/LIVER	S8	CT		75	
	SCREENING/16FEB2012	TL:3/LIVER	S7	CT		92	SLD = 179
	SCREENING/16FEB2012	NTL:1/NODE		CT		.	
	WEEK12/17MAY2012	TL:1/LUNG	LUL	CT		13	

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Tumor Assessment Summary Listing
(Intent-to-Treat Population)

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Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
301-0003 /61/F/A2	WEEK12/17MAY2012	TL:2/LIVER	S8	CT		84	
	WEEK12/17MAY2012	TL:3/LIVER	S7	CT		93	
	WEEK12/17MAY2012	NTL:1/NODE		CT	UP	.	
	Summary:					.	SLD = 190, %CN = 6.15, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 24MAY2012
301-0008 /53/M/A2	SCREENING/02JAN2013	TL:1/SOFTT	RIGHT ADRENAL NODULE	CT		38	
	SCREENING/02JAN2013	TL:2/SOFTT	LEFT ADRENAL NODULE	CT		18	SLD = 56

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Tumor Assessment Summary Listing
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Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
301-0008 /53/M/A2	WEEK12/22MAR2013	TL:1/SOFTT	RIGHT ADRENAL NODULE	CT		60	
	WEEK12/22MAR2013	TL:2/SOFTT	LEFT ADRENAL NODULE	CT		26	
	WEEK12/22MAR2013	NTL:1/LIVE	MULTIPLE INFILTRATIVE	CT	New	.	
	WEEK12/22MAR2013	NTL:2/LUNG	MULTIPLE NODULE INFILTRATIVE	CT	New	.	
	Summary:					.	SLD = 86, %CN = 53.57, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 23MAR2013
302-0006 /49/M/A2	SCREENING/04JAN2012	TL:1/LIVER	SUBHEPATIC SPACE	CT		67	SLD = 67

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Tumor Assessment Summary Listing
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Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
302-0006 /49/M/A2	SCREENING/04JAN2012	NTL:1/	RIGHT PORTAL VEIN THROMBOSIS	CT		.	
302-0009 /73/M/A2	SCREENING/03APR2012	TL:1/LIVER	SEGMENT 5-6	CT		40	
	SCREENING/03APR2012	TL:2/LIVER	SEGMENT 2-3	CT		28	SLD = 68
	SCREENING/03APR2012	NTL:1/LIVE		CT		.	
	SCREENING/03APR2012	NTL:2/LIVE	PORTAL VEIN THROMBOSIS	CT		.	
	SCREENING/03APR2012	NTL:3/LIVE	ASCITES	CT		.	

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Tumor Assessment Summary Listing
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Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
302-0012 /62/M/A2	SCREENING/18APR2012	TL:1/LIVER	SEGMENT 7-8	CT		63	
	SCREENING/18APR2012	TL:2/LIVER	SEGMENT 6-ADRENAL	CT		48	
	SCREENING/18APR2012	TL:3/LUNG	RIGHT UPPER LOBE	CT		21	
	SCREENING/18APR2012	TL:4/LUNG	RIGHT UPPER LOBE	CT		28	SLD = 160
	SCREENING/18APR2012	NTL:1/LIVE	ASCITES	CT		.	
	SCREENING/18APR2012	NTL:2/LUNG		CT		.	

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Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
302-0012 /62/M/A2	SCREENING/18APR2012	NTL:3/LIVE		CT		.	
	SCREENING/18APR2012	NTL:4/LUNG	INFERIOR VENA CAVA TRROMBOSIS	CT		.	
	SCREENING/18APR2012	NTL:5/LIVE	RIGHT PORTAL VEIN THROMBOSIS	CT		.	
	WEEK12/12JUL2012	TL:1/LIVER	SEGMENT 7-8	CT		105	
	WEEK12/12JUL2012	TL:2/LIVER	SEGMENT 6-ADRENAL	CT		51	
	WEEK12/12JUL2012	TL:3/LUNG	RIGHT UPPER LOBE	CT		55	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
302-0012 /62/M/A2	WEEK12/12JUL2012	TL:4/LUNG	RIGHT UPPER LOBE	CT		40	
	WEEK12/12JUL2012	NTL:1/LIVE	ASCITES	CT	UP	.	
	WEEK12/12JUL2012	NTL:2/LUNG		CT	UP	.	
	WEEK12/12JUL2012	NTL:3/LIVE		CT	UP	.	
	WEEK12/12JUL2012	NTL:4/LUNG	INFERIOR VENA CAVA TRROMBOSIS	CT	UP	.	
	WEEK12/12JUL2012	NTL:5/LIVE	RIGHT PORTAL VEIN THROMBOSIS	CT	UP	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
302-0012 /62/M/A2	Summary:					.	SLD = 251, %CN = 56.88, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 19JUL2012
302-0013 /62/M/A2	SCREENING/21MAR2013	TL:1/LUNG	LEFT UPPER LOBE	CT		30	
	SCREENING/21MAR2013	TL:2/LUNG	RIGHT UPPER LOBE	CT		16	SLD = 46
	SCREENING/21MAR2013	NTL:1/LUNG	BILATERAL LUNG	CT		.	
302-0020 /52/M/A2	SCREENING/16MAY2013	TL:1/LIVER	SEGMENT 4	CT		59	
	SCREENING/16MAY2013	TL:2/NODES	PARACAVAL	CT		19	SLD = 78

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
302-0021 /75/F/A2	SCREENING/06JUN2013	TL:1/NODES	LEFT AORTIC	CT		29	
	SCREENING/06JUN2013	TL:2/NODES	PORTAL CAVAL	CT		20	SLD = 49
	SCREENING/06JUN2013	NTL:1/LIVE	PORTAL VEIN THROMBOSIS	CT		.	
	WEEK12/27AUG2013	TL:1/NODES	LEFT AORTIC	CT		26	
	WEEK12/27AUG2013	TL:2/NODES	PORTAL CAVAL	CT		28	
	WEEK12/27AUG2013	NTL:1/LIVE	PORTAL VEIN THROMBOSIS	CT	Present	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
302-0021 /75/F/A2	Summary:					.	SLD = 54, %CN = 10.2, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK24/19NOV2013	TL:1/NODES	LEFT AORTIC	CT		32	
	WEEK24/19NOV2013	TL:2/NODES	PORTAL CAVAL	CT		43	
	WEEK24/19NOV2013	NTL:1/LIVE	PORTAL VEIN THROMBOSIS	CT	UP	.	
	WEEK24/19NOV2013	NTL:2/LIVE	ASCITES	CT	New	.	
	Summary:					.	SLD = 75, %CN = 53.06, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 25NOV2013

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
304-0003 /56/F/A2	SCREENING/11MAR2013	TL:1/LIVER	SEGMENT 7	CT		33	
	SCREENING/11MAR2013	TL:2/LIVER	SEGMENT 4	CT		40	
	SCREENING/11MAR2013	TL:3/LUNG	LEFT UPPER LOBE OF NODULE	CT		12	
	SCREENING/11MAR2013	TL:4/LUNG	RIGHT LOWER LOBE OF NODULE	CT		20	SLD = 105
	SCREENING/11MAR2013	NTL:1/LUNG	MULTIPLE NODULES IN LEFT UPPER LOBE AND RIGHT LOWER LOBE	CT		.	
	SCREENING/11MAR2013	NTL:2/LUNG	SMALL GROUND GLASS OPACITIES IN RIGHT UPPER AND LEFT LOWER LUNGS.	CT		.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
304-0003 /56/F/A2	SCREENING/11MAR2013	NTL:3/LIVE	MULTIPLE LIVER HEPATOMA IN BOTH LOBES OF LIVER.	CT		.	
	WEEK12/03JUN2013	TL:1/LIVER	SEGMENT 7	CT		38	
	WEEK12/03JUN2013	TL:2/LIVER	SEGMENT 4	CT		55	
	WEEK12/03JUN2013	TL:3/LUNG	LEFT UPPER LOBE OF NODULE	CT		15	
	WEEK12/03JUN2013	TL:4/LUNG	RIGHT LOWER LOBE OF NODULE	CT		21	
	WEEK12/03JUN2013	NTL:1/LUNG	MULTIPLE NODULES IN LEFT UPPER LOBE AND RIGHT LOWER LOBE	CT	Present	.	

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Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
304-0003 /56/F/A2	WEEK12/03JUN2013	NTL:2/LUNG	SMALL GROUND GLASS OPACITIES IN RIGHT UPPER AND LEFT LOWER LUNGS.	CT	Present	.	
	WEEK12/03JUN2013	NTL:3/LIVE	MULTIPLE LIVER HEPATOMA IN BOTH LOBES OF LIVER.	CT	UP	.	
	Summary:					.	SLD = 129, %CN = 22.86, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 05JUN2013
304-0004 /69/M/A2	SCREENING/30MAY2013	TL:1/LIVER	S7	CT		27	
	SCREENING/30MAY2013	TL:2/LIVER	S2	CT		16	SLD = 43
	SCREENING/30MAY2013	NTL:1/NODE	LYMPH NODE IN PORTA HEPATIS	CT		.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
304-0007 /72/M/A2	SCREENING/07NOV2013	TL:1/LIVER	SEGMENT 8	CT		81	
	SCREENING/07NOV2013	TL:2/NODES	IN PORTA HEPATIS REGION LYMPH NODE	CT		16	SLD = 97
	SCREENING/07NOV2013	NTL:1/LIVE	RIGHT PORTAL VEIN AND PORTAL TRUNK THROMBUS	CT		.	
	WEEK12/29JAN2014	TL:1/LIVER	SEGMENT 8	CT		93	
	WEEK12/29JAN2014	TL:2/NODES	IN PORTA HEPATIS REGION LYMPH NODE	CT		25	
	WEEK12/29JAN2014	NTL:1/LIVE	RIGHT PORTAL VEIN AND PORTAL TRUNK THROMBUS	CT	Present	.	

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Tumor Assessment Summary Listing
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Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
304-0007 /72/M/A2	WEEK12/29JAN2014	NTL:2/GI	MESENTERIC REGION	CT	New	.	
	Summary:					.	SLD = 118, %CN = 21.65, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 29JAN2014
305-0001 /79/M/A2	SCREENING/03FEB2012	TL:1/LIVER	SEGMENT 8	CT		14	
	SCREENING/03FEB2012	TL:2/LIVER	SEGMENT 4	CT		10	
	SCREENING/03FEB2012	TL:3/LUNG	RLL	CT		19	
	SCREENING/03FEB2012	TL:4/LUNG	LLL	CT		11	SLD = 54

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
305-0001 /79/M/A2	SCREENING/03FEB2012	NTL:1/LIVE	LEFT LOBE TUMOR	CT		.	
	SCREENING/03FEB2012	NTL:2/LIVE	RIGHT LOBE TUMOR	CT		.	
	SCREENING/03FEB2012	NTL:3/LIVE	LEFT PORTAL VEIN THOMBOSES	CT		.	
	SCREENING/03FEB2012	NTL:4/LIVE	RIGHT PORTAL VEIN THROMBOSES	CT		.	
	SCREENING/03FEB2012	NTL:5/LIVE	PORTAL TRUNK THROMBOSES	CT		.	
	SCREENING/03FEB2012	NTL:6/LIVE	RIGHT HEPATIC VEIN THROMBOSES	CT		.	

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Tumor Assessment Summary Listing
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Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
305-0004 /79/M/A2	SCREENING/03FEB2012	TL:1/LIVER	SEGMENT 8	CT		14	
	SCREENING/03FEB2012	TL:2/LIVER	SEGMENT 4	CT		10	
	SCREENING/03FEB2012	TL:3/LUNG	RIGHT LOWER LOBE	CT		19	
	SCREENING/03FEB2012	TL:4/LUNG	LEFT LOWER LOBE	CT		11	SLD = 54
	SCREENING/03FEB2012	NTL:1/LIVE	LEFT LOBE TUMOR	CT		.	
	SCREENING/03FEB2012	NTL:2/LIVE	RIGHT LOBE TUMOR	CT		.	

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Tumor Assessment Summary Listing
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Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
305-0004 /79/M/A2	SCREENING/03FEB2012	NTL:3/LIVE	LEFT PORTAL VEIN THOMBOSES	CT		.	
	SCREENING/03FEB2012	NTL:4/LIVE	RIGHT PORTAL VEIN THROMBOSES	CT		.	
	SCREENING/03FEB2012	NTL:5/LIVE	PORTAL TRUNK THROMBOSES	CT		.	
	SCREENING/03FEB2012	NTL:6/LIVE	RIGHT HEPATIC VEIN THROMBOSES	CT		.	
	SCREENING/03FEB2012	NTL:7/LIVE	INFERIOR VENA CAVA	CT		.	
	WEEK12/07MAY2012	TL:1/LIVER	SEGMENT 8	CT		14	

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[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
305-0004 /79/M/A2	WEEK12/07MAY2012	TL:2/LIVER	SEGMENT 4	CT		8	
	WEEK12/07MAY2012	TL:3/LUNG	RIGHT LOWER LOBE	CT		21	
	WEEK12/07MAY2012	TL:4/LUNG	LEFT LOWER LOBE	CT		11	
	WEEK12/07MAY2012	NTL:1/LIVE	LEFT LOBE TUMOR	CT	Present	.	
	WEEK12/07MAY2012	NTL:2/LIVE	RIGHT LOBE TUMOR	CT	Present	.	
	WEEK12/07MAY2012	NTL:3/LIVE	LEFT PORTAL VEIN THOMBOSES	CT	Present	.	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
305-0004 /79/M/A2	WEEK12/07MAY2012	NTL:4/LIVE	RIGHT PORTAL VEIN THROMBOSES	CT	Present	.	
	WEEK12/07MAY2012	NTL:5/LIVE	PORTAL TRUNK THROMBOSES	CT	Present	.	
	WEEK12/07MAY2012	NTL:6/LIVE	RIGHT HEPATIC VEIN THROMBOSES	CT	Present	.	
	WEEK12/07MAY2012	NTL:7/LIVE	INFERIOR VENA CAVA	CT	Present	.	
	Summary:					.	SLD = 54, %CN = 0, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
305-0007 /67/M/A2	SCREENING/07MAR2012	TL:1/LIVER	SEGMENT 5	CT		61	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
305-0007 /67/M/A2	SCREENING/07MAR2012	TL:2/LIVER	SEGMENT 8	CT		35	SLD = 96
	WEEK12/01JUN2012	TL:1/LIVER	SEGMENT 5	CT		67	
	WEEK12/01JUN2012	TL:2/LIVER	SEGMENT 8	CT		38	
	Summary:					.	SLD = 105, %CN = 9.38, TL: SD, NTL: NotAssessed, OR: SD, PD confirmed: No
	WEEK24/24AUG2012	TL:1/LIVER	SEGMENT 5	CT		80	
	WEEK24/24AUG2012	TL:2/LIVER	SEGMENT 8	CT		44	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
305-0007 /67/M/A2	Summary:					.	SLD = 124, %CN = 29.17, TL: PD, NTL: NotAssessed, OR: PD, PD confirmed: Yes, 24AUG2012
305-0015 /84/M/A2	SCREENING/04JUL2012	TL:1/LIVER	SEGMENT 7	CT		39	
	SCREENING/04JUL2012	TL:2/LIVER	SEGMENT 7	CT		25	SLD = 64
	SCREENING/04JUL2012	NTL:1/LIVE	LEFT LOBE TUMOR	CT		.	
	SCREENING/04JUL2012	NTL:2/LIVE	RIGHT LOBE TUMOR	CT		.	
	SCREENING/04JUL2012	NTL:3/LUNG	LEFT LOBE TUMOR	CT		.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
305-0015 /84/M/A2	SCREENING/04JUL2012	NTL:4/LUNG	RIGHT LOBE TOMOR	CT		.	
	WEEK12/17SEP2012	TL:1/LIVER	SEGMENT 7	CT		44	
	WEEK12/17SEP2012	TL:2/LIVER	SEGMENT 7	CT		35	
	WEEK12/17SEP2012	NTL:1/LIVE	LEFT LOBE TUMOR	CT	Present	.	
	WEEK12/17SEP2012	NTL:2/LIVE	RIGHT LOBE TUMOR	CT	Present	.	
	WEEK12/17SEP2012	NTL:3/LUNG	LEFT LOBE TUMOR	CT	Present	.	

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Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
305-0015 /84/M/A2	WEEK12/17SEP2012	NTL:4/LUNG	RIGHT LOBE TOMOR	CT	Present	.	
	WEEK12/17SEP2012	NTL:5/LIVE	LEFT PORTAL VEIN THROMBOSES	CT	New	.	
	WEEK12/17SEP2012	NTL:6/LIVE	MIDDLE HEPATIC VEIN THROMBOSES	CT	New	.	
	Summary:					.	SLD = 79, %CN = 23.44, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 20SEP2012
305-0016 /78/M/A2	SCREENING/19JUN2012	TL:1/LIVER	SEGMENT 6/7	CT		69	SLD = 69
	UNSCHEDULED/16AUG2012	TL:1/LIVER	SEGMENT 6/7	CT		48	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
305-0016 /78/M/A2	Summary:					.	SLD = 48, %CN = 0, TL: PR, NTL: NotAssessed, OR: PR, PD confirmed: No
	WEEK12/25SEP2012	TL:1/LIVER	SEGMENT 6/7	CT		74	
	Summary:					.	SLD = 74, %CN = 7.25, TL: PD, NTL: NotAssessed, OR: PD, PD confirmed: Yes, 25SEP2012
305-0021 /83/F/A2	SCREENING/16NOV2012	TL:1/LIVER	SEGMENT 3	CT		19	
	SCREENING/16NOV2012	TL:2/LIVER	SEGMENT 2	CT		17	
	SCREENING/16NOV2012	TL:3/NODES	LEFT AXILLA NODE	CT		36	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
305-0021 /83/F/A2	SCREENING/16NOV2012	TL:4/NODES	PARAAORTIC NODE	CT		19	SLD = 91
	SCREENING/16NOV2012	NTL:1/LIVE	RIGHT LOBE TUMORS	CT		.	
	SCREENING/16NOV2012	NTL:2/LIVE	LEFT LOBE TUMORS	CT		.	
	WEEK12/08FEB2013	TL:1/LIVER	SEGMENT 3	CT		22	
	WEEK12/08FEB2013	TL:2/LIVER	SEGMENT 2	CT		14	
	WEEK12/08FEB2013	TL:3/NODES	LEFT AXILLA NODE	CT		46	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
305-0021 /83/F/A2	WEEK12/08FEB2013	TL:4/NODES	PARAAORTIC NODE	CT		20	
	WEEK12/08FEB2013	NTL:1/LIVE	RIGHT LOBE TUMORS	CT	UP	.	
	WEEK12/08FEB2013	NTL:2/LIVE	LEFT LOBE TUMORS	CT	Present	.	
	WEEK12/08FEB2013	NTL:3/LIVE	RIGHT LOBE TUMORS	CT	New	.	
	WEEK12/08FEB2013	NTL:4/LIVE	LEFT LOBE TUMORS	CT	New	.	
	WEEK12/08FEB2013	NTL:5/NODE	LEFT AXILLA	CT	New	.	

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Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
305-0021 /83/F/A2	WEEK12/08FEB2013	NTL:6/NODE	PARACAVAL	CT	New	.	
	WEEK12/08FEB2013	NTL:7/LUNG	LEFT LOBE TUMORS	CT	New	.	
	WEEK12/08FEB2013	NTL:8/LUNG	RIGHT LOBE TUMORS	CT	New	.	
	Summary:					.	SLD = 102, %CN = 12.09, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 15FEB2013
305-0024 /68/M/A2	SCREENING/14JAN2013	TL:1/LIVER	SEGMENT 2	CT		89	SLD = 89
	SCREENING/14JAN2013	NTL:1/LIVE	LEFT LOBE TUMORS	CT		.	

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Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
305-0024 /68/M/A2	SCREENING/14JAN2013	NTL:2/LIVE	PORTAL VEIN THROMBOSES	CT		.	
	WEEK12/12APR2013	TL:1/LIVER	SEGMENT 2	CT		114	
	WEEK12/12APR2013	NTL:1/LIVE	LEFT LOBE TUMORS	CT	Present	.	
	WEEK12/12APR2013	NTL:2/LIVE	PORTAL VEIN THROMBOSES	CT	Present	.	
	Summary:					.	SLD = 114, %CN = 28.09, TL: PD, NTL: IncompleteResponse/SD, OR: PD, PD confirmed: Yes, 12APR2013
305-0033 /37/F/A2	SCREENING/25JUN2013	TL:1/LIVER	SEGMENT 4	CT		68	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
305-0033 /37/F/A2	SCREENING/25JUN2013	TL:2/LIVER	SEGMENT 2	CT		61	
	SCREENING/25JUN2013	TL:3/LUNG	RUL	CT		13	SLD = 142
	SCREENING/25JUN2013	NTL:1/LUNG	MULTIPLE LUNG	CT		.	
	SCREENING/25JUN2013	NTL:2/LIVE	PORTAL VEIN THROMBOSIS	CT		.	
	WEEK12/24SEP2013	TL:1/LIVER	SEGMENT 4	CT		89	
	WEEK12/24SEP2013	TL:2/LIVER	SEGMENT 2	CT		52	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
305-0033 /37/F/A2	WEEK12/24SEP2013	TL:3/LUNG	RUL	CT		11	
	WEEK12/24SEP2013	NTL:1/LUNG	MULTIPLE LUNG	CT	Present	.	
	WEEK12/24SEP2013	NTL:2/LIVE	PORTAL VEIN THROMBOSIS	CT	Present	.	
	WEEK12/24SEP2013	NTL:3/LUNG	RLL	CT	New	.	
	WEEK12/24SEP2013	NTL:4/LUNG	LUL	CT	New	.	
	Summary:					.	SLD = 152, %CN = 7.04, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 24SEP2013

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
305-0035 /60/M/A2	SCREENING/27AUG2013	TL:1/LIVER	SEGMENT 6	CT		77	
	SCREENING/27AUG2013	TL:2/LIVER	SEGMENT 8	CT		91	SLD = 168
	WEEK12/20NOV2013	TL:1/LIVER	SEGMENT 6	CT		87	
	WEEK12/20NOV2013	TL:2/LIVER	SEGMENT 8	CT		73	
	Summary:					.	SLD = 160, %CN = -4.76, TL: SD, NTL: NotAssessed, OR: SD, PD confirmed: No
	WEEK24/12FEB2014	TL:1/LIVER	SEGMENT 6	CT		107	

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[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
305-0035 /60/M/A2	WEEK24/12FEB2014	TL:2/LIVER	SEGMENT 8	CT		124	
	Summary:					.	SLD = 231, %CN = 44.38, TL: PD, NTL: NotAssessed, OR: PD, PD confirmed: Yes, 12FEB2014
305-0046 /60/M/A2	SCREENING/31OCT2014	TL:1/LIVER	LEFT LOBE	CT		44	SLD = 44
	SCREENING/31OCT2014	NTL:1/LIVE	LEFT LOBE TUMORS	CT		.	
	WEEK12/23JAN2015	TL:1/LIVER	LEFT LOBE	CT		51	
	WEEK12/23JAN2015	NTL:1/LIVE	LEFT LOBE TUMORS	CT	Present	.	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
305-0046 /60/M/A2	Summary:					.	SLD = 51, %CN = 15.91, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK24/14APR2015	TL:1/LIVER	LEFT LOBE	CT		67	
	WEEK24/14APR2015	NTL:1/LIVE	LEFT LOBE TUMORS	CT	Present	.	
	Summary:					.	SLD = 67, %CN = 52.27, TL: PD, NTL: IncompleteResponse/SD, OR: PD, PD confirmed: Yes, 23APR2015
306-0004 /46/M/A2	SCREENING/15FEB2012	TL:1/LIVER	SEGMENT 8	CT		74	
	SCREENING/15FEB2012	TL:2/LIVER	S5	CT		70	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
306-0004 /46/M/A2	SCREENING/15FEB2012	TL:3/GI	GALLBLADER	CT		25	SLD = 169
	UNSCHEDULED/03APR2012	TL:1/LIVER	S8	CT	UP	.	
	UNSCHEDULED/03APR2012	TL:2/LIVER	S5	CT	UP	.	
	UNSCHEDULED/03APR2012	TL:3/GI	GALLBLADER	CT	NE	.	
	UNSCHEDULED/03APR2012	NTL:1/LUNG	BIL. LUNG METASTASIS	CT	New	.	
	Summary:					.	SLD = ., %CN = ., TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 06APR2012

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
306-0010 /69/M/A2	SCREENING/16MAR2012	TL:1/LUNG	RIGHT UPPER LOBE	CT		50	
	SCREENING/16MAR2012	TL:2/NODES	RIGHT HILAR LN	CT		24	
	SCREENING/16MAR2012	TL:3/LIVER	S3	CT		14	
	SCREENING/16MAR2012	TL:4/GU	RIGHT ADRENAL	CT		33	
	SCREENING/16MAR2012	TL:5/GU	LEFT ADRENAL	CT		105	SLD = 226
	SCREENING/16MAR2012	NTL:1/LUNG	LEFT LOWER LOBE	CT		.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
306-0010 /69/M/A2	WEEK12/06JUN2012	TL:1/LUNG	RIGHT UPPER LOBE	CT		59	
	WEEK12/06JUN2012	TL:2/NODES	RIGHT HILAR LN	CT		27	
	WEEK12/06JUN2012	TL:3/LIVER	S3	CT		14	
	WEEK12/06JUN2012	TL:4/GU	RIGHT ADRENAL	CT		37	
	WEEK12/06JUN2012	TL:5/GU	LEFT ADRENAL	CT		114	
	WEEK12/06JUN2012	NTL:1/LUNG	LEFT LOWER LOBE	CT	Present	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
306-0010 /69/M/A2	WEEK12/06JUN2012	NTL:2/BONE	LEFT FEMEROL ADDUCTOR MAGNUS MUSCLE WITH POSTERIOR ASPECT SUBTROCHANTER BONY CORTEX DESTRUCTION	CT	New	.	
	Summary:					.	SLD = 251, %CN = 11.06, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 12JUN2012
306-0013 /42/M/A2	SCREENING/13APR2012	TL:1/LUNG	RIGHT MIDDLE LUNG	CT		42	
	SCREENING/13APR2012	TL:2/LUNG	LEFT LOWER LOBE	CT		31	
	SCREENING/13APR2012	TL:3/LIVER	S2	CT		35	
	SCREENING/13APR2012	TL:4/LIVER	S4	CT		28	SLD = 136

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
306-0013 /42/M/A2	SCREENING/13APR2012	NTL:1/PLEU	PLEURAL EFFUSION	CT		.	
306-0015 /73/M/A2	SCREENING/20APR2012	TL:1/LIVER	S7	CT		26	
	SCREENING/20APR2012	TL:2/LIVER	S6	CT		25	
	SCREENING/20APR2012	TL:3/NODES	PERICAVAL	CT		30	
	SCREENING/20APR2012	TL:4/NODES	AORTOCAVAL	CT		46	SLD = 127
	UNSCHEDULED/28JUN2012	TL:1/LIVER	S7	CT		26	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
306-0015 /73/M/A2	UNSCHEDULED/28JUN2012	TL:2/LIVER	S6	CT		30	
	UNSCHEDULED/28JUN2012	TL:3/NODES	PERICAVAL	CT		37	
	UNSCHEDULED/28JUN2012	TL:4/NODES	AORTOCAVAL	CT		54	
	UNSCHEDULED/28JUN2012	NTL:1/LUNG	RIGHT UPPER LOBE	CT	New	.	
	Summary:					.	SLD = 147, %CN = 15.75, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 02JUL2012
306-0016 /58/M/A2	SCREENING/31MAY2012	TL:1/LIVER	S8	CT		14	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
306-0016 /58/M/A2	SCREENING/31MAY2012	TL:2/LIVER	S8	CT		46	
	SCREENING/31MAY2012	TL:3/NODES	AZYGOESOPHAGEAL LN	CT		18	
	SCREENING/31MAY2012	TL:4/NODES	PORTO-CAVAL LN	CT		21	SLD = 99
	SCREENING/31MAY2012	NTL:1/NODE	RIGHT PARATRACHEAL LN	CT		.	
	WEEK12/11SEP2012	TL:1/LIVER	S8	CT		12	
	WEEK12/11SEP2012	TL:2/LIVER	S8	CT		50	

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[3] UP=Unequivocally Progressed
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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
306-0016 /58/M/A2	WEEK12/11SEP2012	TL:3/NODES	AZYGOESOPHAGEAL LN	CT		33	
	WEEK12/11SEP2012	TL:4/NODES	PORTO-CAVAL LN	CT		47	
	WEEK12/11SEP2012	NTL:1/NODE	RIGHT PARATRACHEAL LN	CT	Present	.	
	Summary:					.	SLD = 142, %CN = 43.43, TL: PD, NTL: IncompleteResponse/SD, OR: PD, PD confirmed: Yes, 17SEP2012
306-0022 /56/M/A2	SCREENING/25OCT2012	TL:1/LIVER	S3	CT		29	
	SCREENING/25OCT2012	TL:2/LIVER	S4	CT		24	SLD = 53

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
306-0022 /56/M/A2	SCREENING/25OCT2012	NTL:1/LIVE	S5	CT		.	
	SCREENING/25OCT2012	NTL:2/LIVE	S5	CT		.	
	WEEK12/24JAN2013	TL:1/LIVER	S3	CT		31	
	WEEK12/24JAN2013	TL:2/LIVER	S4	CT		26	
	WEEK12/24JAN2013	NTL:1/LIVE	S5	CT	Present	.	
	WEEK12/24JAN2013	NTL:2/LIVE	S5	CT	Present	.	

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[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
306-0022 /56/M/A2	Summary:					.	SLD = 57, %CN = 7.55, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK24/25APR2013	TL:1/LIVER	S3	CT		32	
	WEEK24/25APR2013	TL:2/LIVER	S4	CT		29	
	WEEK24/25APR2013	NTL:1/LIVE	S5	CT	Present	.	
	WEEK24/25APR2013	NTL:2/LIVE	S5	CT	Present	.	
	WEEK24/25APR2013	NTL:3/LIVE	S8	CT	New	.	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
306-0022 /56/M/A2	Summary:					.	SLD = 61, %CN = 15.09, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 30APR2013
306-0028 /53/M/A2	SCREENING/21MAR2013	TL:1/NODES	LEFT CLAVICLE	CT		24	
	SCREENING/21MAR2013	TL:2/NODES	LEFT CLAVICLE	CT		21	
	SCREENING/21MAR2013	TL:3/LIVER	S4	CT		24	
	SCREENING/21MAR2013	TL:4/LIVER	S8	CT		25	SLD = 94
	SCREENING/21MAR2013	NTL:1/NODE	LEFT CLAVICLE	CT		.	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
306-0028 /53/M/A2	SCREENING/21MAR2013	NTL:2/LIVE	S6	CT		.	
	SCREENING/21MAR2013	NTL:3/NODE	AORTOCAVAL	CT		.	
	WEEK12/13JUN2013	TL:1/NODES	LEFT CLAVICLE	CT		26	
	WEEK12/13JUN2013	TL:2/NODES	LEFT CLAVICLE	CT		28	
	WEEK12/13JUN2013	TL:3/LIVER	S4	CT		23	
	WEEK12/13JUN2013	TL:4/LIVER	S8	CT		28	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
306-0028 /53/M/A2	WEEK12/13JUN2013	NTL:1/NODE	LEFT CLAVICLE	CT	Present	.	
	WEEK12/13JUN2013	NTL:2/LIVE	S6	CT	Present	.	
	WEEK12/13JUN2013	NTL:3/NODE	AORTOCAVAL	CT	Present	.	
	Summary:					.	SLD = 105, %CN = 11.7, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: Yes, 19JUN2013
306-0045 /60/F/A1	SCREENING/13JUN2014	TL:1/LUNG	RIGHT LOWER LUNG	CT		17	
	SCREENING/13JUN2014	TL:2/NODES	RIGHT HILAR LYMPH NODE	CT		25	SLD = 42

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
306-0045 /60/F/A1	SCREENING/13JUN2014	NTL:1/LIVE	SEGMENT 4	CT		.	
	UNSCHEDULED/15AUG2014	TL:1/LUNG	RIGHT LOWER LUNG	CT		18	
	UNSCHEDULED/15AUG2014	TL:2/NODES	RIGHT HILAR LYMPH NODE	CT		22	
	UNSCHEDULED/15AUG2014	NTL:1/LIVE	S4	CT	Present	.	
	Summary:					.	SLD = 40, %CN = 0, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK12/02SEP2014	TL:1/LUNG	RIGHT LOWER LUNG	CT		19	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
306-0045 /60/F/A1	WEEK12/02SEP2014	TL:2/NODES	RIGHT HILAR LYMPH NODE	CT		24	
	WEEK12/02SEP2014	NTL:1/LIVE	SEGMENT 4	CT	UP	.	
	Summary:					.	SLD = 43, %CN = 2.38, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 09SEP2014
307-0006 /72/M/A2	SCREENING/08NOV2011	TL:1/LIVER	SEGMENT 8	CT		22	
	SCREENING/08NOV2011	TL:2/LIVER	SEGMENT 2	CT		44	
	SCREENING/08NOV2011	TL:3/BONE	RIGHT 8TH RIB	CT		51	SLD = 117

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
307-0006 /72/M/A2	SCREENING/08NOV2011	NTL:1/LIVE	SEGMENT 5-6	CT		.	
	SCREENING/08NOV2011	NTL:2/LIVE	BOTH LOBES	CT		.	
	SCREENING/08NOV2011	NTL:3/LUNG	BOTH LUNGS	CT		.	
307-0009 /53/M/A2	SCREENING/28DEC2011	TL:1/LIVER	HCC, S2	CT		58	
	SCREENING/28DEC2011	TL:2/LIVER	HCC, S6-7	CT		71	
	SCREENING/28DEC2011	TL:3/SPLEE	METASTASIS	CT		87	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
307-0009 /53/M/A2	SCREENING/28DEC2011	TL:4/NODES	LYMPH NODE, SPLENIC HILAR	CT		55	
	SCREENING/28DEC2011	TL:5/NODES	LYMPH NODE, AORTO-CAVAL	CT		29	SLD = 300
	SCREENING/28DEC2011	NTL:1/LIVE	HCC, BOTH LOBES	CT		.	
	SCREENING/28DEC2011	NTL:2/SPLE	SPLENIC VEIN THROMBOSIS	CT		.	
307-0012 /42/M/A2	SCREENING/03FEB2012	TL:1/LIVER	S2 SEGMENT	CT		16	
	SCREENING/03FEB2012	TL:2/LIVER	S7 SEGMENT	CT		23	

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[3] UP=Unequivocally Progressed
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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
307-0012 /42/M/A2	SCREENING/03FEB2012	TL:3/NODES	PERI-PANCREATIC	CT		15	
	SCREENING/03FEB2012	TL:4/NODES	HEPATO-DUODENAL	CT		21	SLD = 75
	SCREENING/03FEB2012	NTL:1/LIVE	POST TREATMENT	CT		.	
307-0015 /75/M/A2	SCREENING/20APR2012	TL:1/LIVER	SEGMENT 8	CT		40	
	SCREENING/20APR2012	TL:2/NODES	PERI-PANCREATIC	CT		15	SLD = 55
	SCREENING/20APR2012	NTL:1/LIVE	RIGHT PORTAL VEIN THROMBOSIS	CT		.	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
307-0015 /75/M/A2	WEEK12/11JUL2012	TL:1/LIVER	SEGMENT 8	CT		48	
	WEEK12/11JUL2012	TL:2/NODES	PERI-PANCREATIC	CT		15	
	WEEK12/11JUL2012	NTL:1/LIVE	RIGHT PORTAL VEIN THROMBOSIS	CT	Present	.	
	Summary:					.	SLD = 63, %CN = 14.55, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK24/04OCT2012	TL:1/LIVER	SEGMENT 8	CT		48	
	WEEK24/04OCT2012	TL:2/NODES	PERI-PANCREATIC	CT		15	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
307-0015 /75/M/A2	WEEK24/04OCT2012	NTL:1/LIVE	RIGHT PORTAL VEIN THROMBOSIS	CT	Present	.	
	WEEK24/04OCT2012	NTL:2/LIVE	SEGMENT 4	CT	New	.	
	Summary:					.	SLD = 63, %CN = 14.55, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 05OCT2012
307-0021 /68/M/A2	SCREENING/01AUG2012	TL:1/LIVER	RIGHT LOBE	CT		121	
	SCREENING/01AUG2012	TL:2/NODES	UPPER PARATRACHEAL	CT		26	SLD = 147
	SCREENING/01AUG2012	NTL:1/LUNG	RIGHT MIDDLE LOBE	CT		.	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
307-0021 /68/M/A2	SCREENING/01AUG2012	NTL:2/LUNG	LEFT LOWER LOBE	CT		.	
	SCREENING/01AUG2012	NTL:3/LIVE	PORTAL VEIN THROMBOSIS	CT		.	
	WEEK12/08NOV2012	TL:1/LIVER	RIGHT LOBE	CT		139	
	WEEK12/08NOV2012	TL:2/NODES	UPPER PARATRACHEAL	CT		29	
	WEEK12/08NOV2012	NTL:1/LUNG	RIGHT MIDDLE LOBE	CT	Present	.	
	WEEK12/08NOV2012	NTL:2/LUNG	LEFT LOWER LOBE	CT	Present	.	

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[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
307-0021 /68/M/A2	WEEK12/08NOV2012	NTL:3/LIVE	PORTAL VEIN THROMBOSIS	CT	Present	.	
	Summary:					.	SLD = 168, %CN = 14.29, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
307-0028 /69/F/A2	SCREENING/09JAN2013	TL:1/LIVER	SEGMENT 8	CT		19	
	SCREENING/09JAN2013	TL:2/GI	METASTASIS, GREATER OMENTUM	CT		33	
	SCREENING/09JAN2013	TL:3/GI	METASTASIS, GREATER OMENTUM	CT		45	SLD = 97
	SCREENING/09JAN2013	NTL:1/ASCI		CT		.	

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[3] UP=Unequivocally Progressed
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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
307-0028 /69/F/A2	WEEK12/01APR2013	TL:1/LIVER	SEGMENT 8	CT		31	
	WEEK12/01APR2013	TL:2/GI	METASTASIS, GREATER OMENTUM	CT		50	
	WEEK12/01APR2013	TL:3/GI	METASTASIS, GREATER OMENTUM	CT		118	
	WEEK12/01APR2013	NTL:1/ASCI		CT	Present	.	
	WEEK12/01APR2013	NTL:2/LIVE	SEGMENT 4	CT	New	.	
	WEEK12/01APR2013	NTL:3/LIVE	SEGMENT 5	CT	New	.	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
307-0028 /69/F/A2	WEEK12/01APR2013	NTL:4/LIVE	SEGMENT 6	CT	New	.	
	WEEK12/01APR2013	NTL:5/LIVE	SEGMENT 4	CT	New	.	
	Summary:					.	SLD = 199, %CN = 105.15, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 08APR2013
307-0034 /48/M/A2	SCREENING/08AUG2013	TL:1/LIVER	SEGMENT 5-8	CT		55	
	SCREENING/08AUG2013	TL:2/LIVER	SEGMENT 5	CT		105	
	SCREENING/08AUG2013	TL:3/LUNG	RIGHT UPPER LUNG	CT		65	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
307-0034 /48/M/A2	SCREENING/08AUG2013	TL:4/LUNG	RIGHT LOWER LUNG	CT		42	SLD = 267
	SCREENING/08AUG2013	NTL:1/LIVE	SEGMENT 4 AND RIGHT LOBE	CT		.	
	SCREENING/08AUG2013	NTL:2/LUNG	LUNG METASTASES, BOTH LUNGS	CT		.	
	SCREENING/08AUG2013	NTL:3/LIVE	PORTAL VEIN THROMBOSIS, RIGHT	CT		.	
	SCREENING/08AUG2013	NTL:4/LIVE	HEPATIC VEIN THROMBOSIS, RIGHT	CT		.	
	SCREENING/08AUG2013	NTL:5/LUNG	PULMONARY ARTERY THROMBOSIS, RIGHT	CT		.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
307-0034 /48/M/A2	WEEK12/29OCT2013	TL:1/LIVER	SEGMENT 5-8	CT		73	
	WEEK12/29OCT2013	TL:2/LIVER	SEGMENT 5			108	
	WEEK12/29OCT2013	TL:3/LUNG	RIGHT UPPER LUNG	CT		66	
	WEEK12/29OCT2013	TL:4/LUNG	RIGHT LOWER LUNG	CT		42	
	WEEK12/29OCT2013	NTL:1/LIVE	SEGMENT 4 AND RIGHT LOBE	CT	Present	.	
	WEEK12/29OCT2013	NTL:10/LIV	HEPATIC VEIN THROMBOSIS, SHORT	CT	New	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
307-0034 /48/M/A2	WEEK12/29OCT2013	NTL:2/LUNG	LUNG METASTASES, BOTH LUNGS	CT	Present	.	
	WEEK12/29OCT2013	NTL:3/LIVE	PORTAL VEIN THROMBOSIS, RIGHT	CT	Present	.	
	WEEK12/29OCT2013	NTL:4/LIVE	HEPATIC VEIN THROMBOSIS, RIGHT	CT	Present	.	
	WEEK12/29OCT2013	NTL:5/LUNG	PULMONARY ARTERY THROMBOSIS, RIGHT	CT	Present	.	
	WEEK12/29OCT2013	NTL:6/NODE	LOWER PARATRACHEAL	CT	New	.	
	WEEK12/29OCT2013	NTL:7/NODE	SUBCARINAL	CT	New	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
307-0034 /48/M/A2	WEEK12/29OCT2013	NTL:8/LIVE	PORTAL VEIN THROMBOSIS, LEFT	CT	New	.	
	WEEK12/29OCT2013	NTL:9/LIVE	HEPATIC VEIN THROMBOSIS, MIDDLE	CT	New	.	
	Summary:					.	SLD = 289, %CN = 8.24, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 31OCT2013
307-0036 /76/M/A2	SCREENING/27SEP2013	TL:1/LUNG	LEFT UPPER LUNG	CT		42	
	SCREENING/27SEP2013	TL:2/LUNG	LEFT UPPER LUNG	CT		22	SLD = 64
	SCREENING/27SEP2013	NTL:1/LUNG	BOTH LUNGS	CT		.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

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307-0036 /76/M/A2	WEEK12/18DEC2013	TL:1/LUNG	LEFT UPPER LUNG	CT		52	
	WEEK12/18DEC2013	TL:2/LUNG	LEFT UPPER LUNG	CT		40	
	WEEK12/18DEC2013	NTL:1/LUNG	BOTH LUNGS	CT	Present	.	
	Summary:					.	SLD = 92, %CN = 43.75, TL: PD, NTL: IncompleteResponse/SD, OR: PD, PD confirmed: Yes, 19DEC2013
307-0042 /55/M/A2	SCREENING/10JUN2014	TL:1/LUNG	LEFT UPPER LUNG	CT		21	
	SCREENING/10JUN2014	TL:2/LUNG	RIGHT MEDIUM LUNG	CT		17	SLD = 38

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Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
307-0042 /55/M/A2	SCREENING/10JUN2014	NTL:1/LUNG	BOTH LUNG	CT		.	
	WEEK12/04SEP2014	TL:1/LUNG	LEFT UPPER LUNG	CT		24	
	WEEK12/04SEP2014	TL:2/LUNG	RIGHT MEDIUM LUNG	CT		14	
	WEEK12/04SEP2014	NTL:1/LUNG	BOTH LUNG	CT	Present	.	
	Summary:					.	SLD = 38, %CN = 0, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK24/27NOV2014	TL:1/LUNG	LEFT UPPER LUNG	CT		27	

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Tumor Assessment Summary Listing
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Treatment Group: Placebo

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307-0042 /55/M/A2	WEEK24/27NOV2014	TL:2/LUNG	RIGHT MEDIUM LUNG	CT		10	
	WEEK24/27NOV2014	NTL:1/LUNG	BOTH LUNG	CT	UP	.	
	Summary:					.	SLD = 37, %CN = 0, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 27NOV2014
308-0002 /36/F/A2	SCREENING/27DEC2012	TL:1/LIVER	S7	CT		46	
	SCREENING/27DEC2012	TL:2/LIVER	S8	CT		48	
	SCREENING/27DEC2012	TL:3/LUNG	RML	CT		42	

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Tumor Assessment Summary Listing
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Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
308-0002 /36/F/A2	SCREENING/27DEC2012	TL:4/LUNG	RLL	CT		25	SLD = 161
	SCREENING/27DEC2012	NTL:1/LIVE	S4	CT		.	
	SCREENING/27DEC2012	NTL:2/LIVE	LIVER RIGHT LOBE	CT		.	
	SCREENING/27DEC2012	NTL:3/LUNG	BILATERAL LUNGS	CT		.	
	WEEK12/21MAR2013	TL:1/LIVER	S7	CT		100	
	WEEK12/21MAR2013	TL:2/LIVER	S8	CT		66	

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Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
308-0002 /36/F/A2	WEEK12/21MAR2013	TL:3/LUNG	RML	CT		60	
	WEEK12/21MAR2013	TL:4/LUNG	RLL	CT		56	
	WEEK12/21MAR2013	NTL:1/LIVE	S4	CT	UP	.	
	WEEK12/21MAR2013	NTL:2/LIVE	LIVER RIGHT LOBE	CT	UP	.	
	WEEK12/21MAR2013	NTL:3/LUNG	BILATERAL LUNGS	CT	Present	.	
	Summary:					.	SLD = 282, %CN = 75.16, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 26MAR2013

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Tumor Assessment Summary Listing
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Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
308-0004 /52/M/A2	SCREENING/31JAN2013	TL:1/LIVER	S4	CT		15	
	SCREENING/31JAN2013	TL:2/LIVER	S8	CT		11	
	SCREENING/31JAN2013	TL:3/LUNG	RIGHT LOWER LUNG	CT		12	
	SCREENING/31JAN2013	TL:4/LUNG	RIGHT LOWER LUNG	CT		12	SLD = 50
	SCREENING/31JAN2013	NTL:1/LUNG	BILATERAL	CT		.	
	SCREENING/31JAN2013	NTL:2/NODE	MEDIASTINUM	CT		.	

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Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
308-0004 /52/M/A2	WEEK12/25APR2013	TL:1/LIVER	S4	CT		32	
	WEEK12/25APR2013	TL:2/LIVER	S8	CT		19	
	WEEK12/25APR2013	TL:3/LUNG	RIGHT LOWER LUNG	CT		15	
	WEEK12/25APR2013	TL:4/LUNG	RIGHT LOWER LUNG	CT		11	
	WEEK12/25APR2013	NTL:1/LUNG	BILATERAL	CT	UP	.	
	WEEK12/25APR2013	NTL:2/NODE	MEDIASTINUM	CT	UP	.	

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[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
308-0004 /52/M/A2	Summary:					.	SLD = 77, %CN = 54, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 25APR2013
308-0006 /64/M/A2	SCREENING/09MAY2013	TL:1/LUNG	RIGHT LOWER LOBE	CT		34	
	SCREENING/09MAY2013	TL:2/LUNG	LEFT LOWER LOBE	CT		33	SLD = 67
	SCREENING/09MAY2013	NTL:1/LIVE	SEGEMENT 6/7	CT		.	
	UNSCHEDULED/27JUN2013	TL:/LUNG	RIGHT LOWER LOBE	CT	UP	.	
	UNSCHEDULED/27JUN2013	TL:/LUNG	LEFT LOWER LOBE	CT	UP	.	

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[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
308-0006 /64/M/A2	Summary:					.	SLD = ., %CN = ., TL: PD, NTL: NotAssessed, OR: PD, PD confirmed: Yes, 27JUN2013
308-0008 /47/M/A2	SCREENING/11JUL2013	TL:1/LUNG	RIGHT MIDDLE LOBE	CT		22	
	SCREENING/11JUL2013	TL:2/LUNG	RIGHT MIDDLE LOBE	CT		22	
	SCREENING/11JUL2013	TL:3/NODES	RIGHT PARACOLIC GUTTER	CT		47	SLD = 91
	SCREENING/11JUL2013	NTL:1/LIVE	BILATERAL HEPATIC LOBES	CT		.	
	SCREENING/11JUL2013	NTL:2/NODE	RIGHT SUBPHRENIC REGION	CT		.	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
308-0008 /47/M/A2	WEEK12/04OCT2013	TL:1/LUNG	RIGHT MIDDLE LOBE	CT		13	
	WEEK12/04OCT2013	TL:2/LUNG	RIGHT MIDDLE LOBE	CT		27	
	WEEK12/04OCT2013	TL:3/NODES	RIGHT PARACOLIC GUTTER	CT		73	
	WEEK12/04OCT2013	NTL:1/LIVE	BILATERAL HEPATIC LOBES	CT	Present	.	
	WEEK12/04OCT2013	NTL:2/NODE	RIGHT SUBPHRENIC REGION	CT	Present	.	
	WEEK12/04OCT2013	NTL:3/NODE	RIGHT PARACOLIC GUTTER	CT	New	.	

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[3] UP=Unequivocally Progressed
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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
308-0008 /47/M/A2	WEEK12/04OCT2013	NTL:4/NODE	PERITONEAL TUMOR	CT	New	.	
	WEEK12/04OCT2013	NTL:5/LIVE	SEGMENT 2	CT	New	.	
	WEEK12/04OCT2013	NTL:6/LIVE	SEGMENT 2	CT	New	.	
	Summary:					.	SLD = 113, %CN = 24.18, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 08OCT2013
308-0009 /61/M/A2	SCREENING/27JUN2013	TL:1/LIVER	SEGMENT8	CT		21	
	SCREENING/27JUN2013	TL:2/LIVER	SEGMENT 6	CT		19	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
308-0009 /61/M/A2	SCREENING/27JUN2013	TL:3/NODES	AORTOCAVAL	CT		27	
	SCREENING/27JUN2013	TL:4/NODES	PARAAORTIC	CT		17	SLD = 84
	SCREENING/27JUN2013	NTL:1/LIVE	RIGHT HEPATIC LOBE	CT		.	
309-0006 /56/M/A2	SCREENING/19NOV2012	TL:1/LIVER	SEGMENT 4	CT		20	
	SCREENING/19NOV2012	TL:2/LIVER	SEGMENT 5	CT		36	SLD = 56
	SCREENING/19NOV2012	NTL:1/LIVE	RIGHT HEPATIC VEIN	CT		.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
309-0006 /56/M/A2	WEEK12/04FEB2013	TL:1/LIVER	SEGMENT 4	CT		20	
	WEEK12/04FEB2013	TL:2/LIVER	SEGMENT 5	CT		36	
	WEEK12/04FEB2013	NTL:1/LIVE	RIGHT HEPATIC VEIN	CT	Present	.	
	Summary:					.	SLD = 56, %CN = 0, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK24/29APR2013	TL:1/LIVER	SEGMENT 4	CT		22	
	WEEK24/29APR2013	TL:2/LIVER	SEGMENT 5	CT		37	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
309-0006 /56/M/A2	WEEK24/29APR2013	NTL:1/LIVE	RIGHT HEPATIC VEIN	CT	Present	.	
	Summary:					.	SLD = 59, %CN = 5.36, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK36/22JUL2013	TL:1/LIVER	SEGMENT 4	CT		32	
	WEEK36/22JUL2013	TL:2/LIVER	SEGMENT 5	CT		40	
	WEEK36/22JUL2013	NTL:1/LIVE	RIGHT HEPATIC VEIN	CT	Present	.	
	WEEK36/22JUL2013	NTL:2/LIVE	SEGMENT 8	CT	New	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
309-0006 /56/M/A2	Summary:					.	SLD = 72, %CN = 28.57, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 29JUL2013
309-0007 /58/M/A2	SCREENING/05DEC2012	TL:1/LIVER	LEFT LOBE	CT		243	
	SCREENING/05DEC2012	TL:2/LIVER	SEGMENT 7	CT		28	
	SCREENING/05DEC2012	TL:3/LUNG	LEFT UPPER LOBE	CT		37	
	SCREENING/05DEC2012	TL:4/LUNG	LEFT LOWER LOBE	CT		31	SLD = 339
	SCREENING/05DEC2012	NTL:1/LIVE	MULTIPLE IN LIVER	CT		.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
309-0007 /58/M/A2	SCREENING/05DEC2012	NTL:2/LUNG	MULTIPLE IN BOTH LUNG	CT		.	
	WEEK12/25FEB2013	TL:1/LIVER	LEFT LOBE	CT		262	
	WEEK12/25FEB2013	TL:2/LIVER	SEGMENT 7	CT		44	
	WEEK12/25FEB2013	TL:3/LUNG	LEFT UPPER LOBE	CT		38	
	WEEK12/25FEB2013	TL:4/LUNG	LEFT LOWER LOBE	CT		34	
	WEEK12/25FEB2013	NTL:1/LIVE	MULTIPLE IN LIVER	CT	UP	.	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
309-0007 /58/M/A2	WEEK12/25FEB2013	NTL:2/LUNG	MULTIPLE IN BOTH LUNG	CT	UP	.	
	WEEK12/25FEB2013	NTL:3/LIVE	MULTIPLE IN LIVER NODULES	CT	New	.	
	WEEK12/25FEB2013	NTL:4/LUNG	MULTIPLE IN BOTH LUNG NODULES	CT	New	.	
	Summary:					.	SLD = 378, %CN = 11.5, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 04MAR2013
309-0013 /45/M/A2	SCREENING/11JUN2013	TL:1/LUNG	RIGHT MIDDLE LOBE	CT		13	
	SCREENING/11JUN2013	TL:2/LUNG	LEFT UPPER LOBE	CT		10	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
309-0013 /45/M/A2	SCREENING/11JUN2013	TL:3/SOFTT	INFERIOR VENA CAVA	CT		21	
	SCREENING/11JUN2013	TL:4/SOFTT	RETROPERITONEUM	CT		18	SLD = 62
	SCREENING/11JUN2013	NTL:1/LUNG	MULTIPLE NODULES IN BOTH LUNG	CT		.	
	WEEK12/29AUG2013	TL:1/LUNG	RIGHT MIDDLE LOBE	CT		15	
	WEEK12/29AUG2013	TL:2/LUNG	LEFT UPPER LOBE	CT		18	
	WEEK12/29AUG2013	TL:3/SOFTT	INFERIOR VENA CAVA	CT		28	

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[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
309-0013 /45/M/A2	WEEK12/29AUG2013	TL:4/SOFTT	RETROPERITONEUM	CT		19	
	WEEK12/29AUG2013	NTL:1/LUNG	MULTIPLE NODULES IN BOTH LUNG	CT	UP	.	
	Summary:					.	SLD = 80, %CN = 29.03, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 05SEP2013
309-0014 /39/M/A2	SCREENING/14JUN2013	TL:1/LIVER	SEGMENT 5	CT		24	
	SCREENING/14JUN2013	TL:2/LUNG	RIGHT LOWER LOBE	CT		79	
	SCREENING/14JUN2013	TL:3/LUNG	LEFT UPPER LOBE	CT		31	

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[3] UP=Unequivocally Progressed
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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
309-0014 /39/M/A2	SCREENING/14JUN2013	TL:4/	LEFT ATRIUM	CT		31	
	SCREENING/14JUN2013	TL:5/GU	LEFT ADRENAL	CT		20	SLD = 185
	SCREENING/14JUN2013	NTL:1/LUNG	LUNG	CT		.	
	SCREENING/14JUN2013	NTL:2/SOFT	CHEST WALL	CT		.	
	SCREENING/14JUN2013	NTL:3/SOFT	ABDOMINAL WALL	CT		.	
	WEEK12/29AUG2013	TL:1/LIVER	SEGMENT 5	CT		27	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
309-0014 /39/M/A2	WEEK12/29AUG2013	TL:2/LUNG	RIGHT LOWER LOBE	CT		62	
	WEEK12/29AUG2013	TL:3/LUNG	LEFT UPPER LOBE	CT		33	
	WEEK12/29AUG2013	TL:4/	LEFT ATRIUM	CT		22	
	WEEK12/29AUG2013	TL:5/GU	LEFT ADRENAL	CT		35	
	WEEK12/29AUG2013	NTL:1/LUNG	LUNG	CT	UP	.	
	WEEK12/29AUG2013	NTL:2/SOFT	CHEST WALL	CT	UP	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
309-0014 /39/M/A2	WEEK12/29AUG2013	NTL:3/SOFT	ABDOMINAL WALL	CT	UP	.	
	WEEK12/29AUG2013	NTL:4/SPLE	SPLEEN	CT	New	.	
	WEEK12/29AUG2013	NTL:5/LUNG	BOTH LUNG	CT	New	.	
	Summary:					.	SLD = 179, %CN = -3.24, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 05SEP2013
309-0019 /68/M/A2	SCREENING/17JUN2014	TL:1/LUNG	RIGHT LUNG	CT		14	
	SCREENING/17JUN2014	TL:2/BONE	RIGHT RIB	CT		47	SLD = 61

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
309-0019 /68/M/A2	UNSCHEDULED/19AUG2014	TL:1/LUNG	RIGHT LUNG	CT		20	
	UNSCHEDULED/19AUG2014	TL:2/BONE	RIGHT RIB	CT		47	
	Summary:					.	SLD = 67, %CN = 9.84, TL: SD, NTL: NotAssessed, OR: SD, PD confirmed: No
	WEEK24/25NOV2014	TL:1/LUNG	RIGHT LUNG	CT		25	
	WEEK24/25NOV2014	TL:2/BONE	RIGHT RIB	CT		45	
	Summary:					.	SLD = 70, %CN = 14.75, TL: SD, NTL: NotAssessed, OR: SD, PD confirmed: No

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
309-0019 /68/M/A2	WEEK36/17FEB2015	TL:1/LUNG	RIGHT LUNG	CT		26	
	WEEK36/17FEB2015	TL:2/BONE	RIGHT RIB	CT		42	
	Summary:					.	SLD = 68, %CN = 11.48, TL: SD, NTL: NotAssessed, OR: SD, PD confirmed: No
	WEEK48/12MAY2015	TL:1/LUNG	RIGHT LUNG	CT		28	
	WEEK48/12MAY2015	TL:2/BONE	RIGHT RIB	CT		40	
	Summary:					.	SLD = 68, %CN = 11.48, TL: SD, NTL: NotAssessed, OR: SD, PD confirmed: No

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
309-0027 /49/M/A2	SCREENING/22OCT2014	TL:1/LIVER	SEGMENT 4-5	CT		59	
	SCREENING/22OCT2014	TL:2/LIVER	SEGMENT 8	CT		33	SLD = 92
	SCREENING/22OCT2014	NTL:1/LIVE	LIVER	CT		.	
	SCREENING/22OCT2014	NTL:2/NODE	LYMPH NODES	CT		.	
	WEEK12/12JAN2015	TL:1/LIVER	SEGMENT 4-5	CT		66	
	WEEK12/12JAN2015	TL:2/LIVER	SEGMENT 8	CT		41	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
309-0027 /49/M/A2	WEEK12/12JAN2015	NTL:1/LIVE	LIVER	CT	UP	.	
	WEEK12/12JAN2015	NTL:2/NODE	LYMPH NODES	CT	Present	.	
	Summary:					.	SLD = 107, %CN = 16.3, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 19JAN2015
309-0029 /50/M/A2	SCREENING/18NOV2014	TL:1/LIVER	SEGMENT 8	CT		32	
	SCREENING/18NOV2014	TL:2/LIVER	LIVER DOME	CT		18	
	SCREENING/18NOV2014	TL:3/NODES	BETWEEN INFERIOR VENA CAVA AND AORTA	CT		22	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
309-0029 /50/M/A2	SCREENING/18NOV2014	TL:4/NODES	PREAORTIC REGION	CT		16	SLD = 88
	SCREENING/18NOV2014	NTL:1/LIVE	SEGMENT 7,SEGMENT 8	CT		.	
	SCREENING/18NOV2014	NTL:2/LUNG	BOTH LUNGS	CT		.	
	SCREENING/18NOV2014	NTL:3/NODE	OVER EPI CARDIAC FAT PAD	CT		.	
	WEEK12/09FEB2015	TL:1/LIVER	SEGMENT 8	CT		78	
	WEEK12/09FEB2015	TL:2/LIVER	LIVER DOME	CT		17	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
309-0029 /50/M/A2	WEEK12/09FEB2015	TL:3/NODES	BETWEEN INFERIOR VENA CAVA AND AORTA	CT		24	
	WEEK12/09FEB2015	TL:4/NODES	PREAORTIC REGION	CT		66	
	WEEK12/09FEB2015	NTL:1/LIVE	SEGMENT 7,SEGMENT 8	CT	UP	.	
	WEEK12/09FEB2015	NTL:2/LUNG	BOTH LUNGS	CT	UP	.	
	WEEK12/09FEB2015	NTL:3/NODE	OVER EPI CARDIAC FAT PAD	CT	UP	.	
	WEEK12/09FEB2015	NTL:4/LIVE	LEFT LOBE	CT	New	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
309-0029 /50/M/A2	WEEK12/09FEB2015	NTL:5/NODE	PARAAORTIC LYMPH NODE	CT	New	.	
	WEEK12/09FEB2015	NTL:6/LUNG	BOTH LUNGS	CT	New	.	
	Summary:					.	SLD = 185, %CN = 110.23, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 10FEB2015
310-0004 /50/F/A2	SCREENING/24JAN2013	TL:1/LUNG	RIGHT LOW LUNG	CT		34	
	SCREENING/24JAN2013	TL:2/LUNG	LEFT LOW LUNG	CT		43	
	SCREENING/24JAN2013	TL:3/LIVER	SEGMENT 2-3-4	CT		140	SLD = 217

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
310-0004 /50/F/A2	SCREENING/24JAN2013	NTL:1/LUNG	BOTH LUNG NODULES	CT		.	
	WEEK12/17APR2013	TL:1/LUNG	RIGHT LOW LUNG	CT		40	
	WEEK12/17APR2013	TL:2/LUNG	LEFT LOW LUNG	CT		47	
	WEEK12/17APR2013	TL:3/LIVER	SEGMENT 2-3-4	CT		142	
	WEEK12/17APR2013	NTL:1/LUNG	BOTH LUNG NODULES	CT	UP	.	
	WEEK12/17APR2013	NTL:2/LUNG	BOTH LUNG	CT	New	.	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
310-0004 /50/F/A2	WEEK12/17APR2013	NTL:3/LIVE	SEGMENT 8, SEGMENT 5-6	CT	New	.	
	Summary:					.	SLD = 229, %CN = 5.53, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 24APR2013
310-0005 /58/M/A2	SCREENING/14MAR2013	TL:1/NODES	PREAORTIC	CT		92	
	SCREENING/14MAR2013	TL:2/NODES	SUBCARINAL	CT		68	
	SCREENING/14MAR2013	TL:3/LIVER	SEGMENT 2-3	CT		11	SLD = 171
	SCREENING/14MAR2013	NTL:1/NODE	LEFT UPPER LUNG ACINAR NODULE	CT		.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
310-0005 /58/M/A2	WEEK12/05JUN2013	TL:1/NODES	PREAORTIC	CT		93	
	WEEK12/05JUN2013	TL:2/NODES	SUBCARINAL	CT		68	
	WEEK12/05JUN2013	TL:3/LIVER	SEGMENT 2-3	CT		12	
	WEEK12/05JUN2013	NTL:1/NODE	LEFT UPPER LUNG ACINAR NODULE	CT	Present	.	
	WEEK12/05JUN2013	NTL:2/NODE	LEFT AXILLARY LYMPHADENOPATHY	CT	New	.	
	Summary:					.	SLD = 173, %CN = 1.17, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 10JUN2013

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[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
310-0006 /50/F/A2	SCREENING/25APR2013	TL:1/LUNG	LEFT UPPER LUNG	CT		15	
	SCREENING/25APR2013	TL:2/LUNG	RIGHT UPPER LUNG	CT		11	SLD = 26
	SCREENING/25APR2013	NTL:1/LUNG	BOTH LUNG NODULES	CT		.	
	SCREENING/25APR2013	NTL:2/LIVE	SEGMENT 6	CT		.	
	WEEK12/10JUL2013	TL:1/LUNG	LEFT UPPER LUNG	CT		18	
	WEEK12/10JUL2013	TL:2/LUNG	RIGHT UPPER LUNG	CT		8	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
310-0006 /50/F/A2	WEEK12/10JUL2013	NTL:1/LUNG	BOTH LUNG NODULES	CT	Present	.	
	WEEK12/10JUL2013	NTL:2/LIVE	SEGMENT 6	CT	Present	.	
	Summary:					.	SLD = 26, %CN = 0, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK24/09OCT2013	TL:1/LUNG	LEFT UPPER LUNG	CT		20	
	WEEK24/09OCT2013	TL:2/LUNG	RIGHT UPPER LUNG	CT		10	
	WEEK24/09OCT2013	NTL:1/LUNG	BOTH LUNG NODULES	CT	Present	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
310-0006 /50/F/A2	WEEK24/09OCT2013	NTL:2/LIVE	SEGMENT 6	CT	Present	.	
	Summary:					.	SLD = 30, %CN = 15.38, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK36/23DEC2013	TL:1/LUNG	LEFT UPPER LUNG	CT		20	
	WEEK36/23DEC2013	TL:2/LUNG	RIGHT UPPER LUNG	CT		12	
	WEEK36/23DEC2013	NTL:1/LUNG	BOTH LUNG NODULES	CT	Present	.	
	WEEK36/23DEC2013	NTL:2/LIVE	SEGMENT 6	CT	Present	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
310-0006 /50/F/A2	WEEK36/23DEC2013	NTL:3/BONE	LEFT FEMORAL NECK OSTEOLYTIC LESION	CT	New	.	
	Summary:					.	SLD = 32, %CN = 23.08, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 27DEC2013
310-0007 /74/M/A2	SCREENING/03JUN2013	TL:1/LIVER	SEGMENT 4	CT		101	SLD = 101
	SCREENING/03JUN2013	NTL:1/LIVE	SEGMENT 2 HEPATIC NODULE	CT		.	
	WEEK12/22AUG2013	TL:1/LIVER	SEGMENT 4	CT		107	
	WEEK12/22AUG2013	NTL:1/LIVE	SEGMENT 2 HEPATIC NODULE	CT	Present	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
310-0007 /74/M/A2	Summary:					.	SLD = 107, %CN = 5.94, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK24/14NOV2013	TL:1/LIVER	SEGMENT 4	CT		108	
	WEEK24/14NOV2013	NTL:1/LIVE	SEGMENT 2 HEPATIC NODULE	CT	Present	.	
	Summary:					.	SLD = 108, %CN = 6.93, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK36/06FEB2014	TL:1/LIVER	SEGMENT 4	CT		110	
	WEEK36/06FEB2014	NTL:1/LIVE	SEGMENT 2 HEPATIC NODULE	CT	Present	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
310-0007 /74/M/A2	Summary:					.	SLD = 110, %CN = 8.91, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK48/01MAY2014	TL:1/LIVER	SEGMENT 4	CT		118	
	WEEK48/01MAY2014	NTL:1/LIVE	SEGMENT 2 HEPATIC NODULE	CT	UP	.	
	WEEK48/01MAY2014	NTL:2/LIVE	SEGMENT 3 NODULE	CT	New	.	
	WEEK48/01MAY2014	NTL:3/LIVE	SEGMENT 5 NODULE	CT	New	.	
	WEEK48/01MAY2014	NTL:4/LIVE	SEGMENT 7 NODULE	CT	New	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
310-0007 /74/M/A2	Summary:					.	SLD = 118, %CN = 16.83, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 06MAY2014
310-0009 /46/M/A2	SCREENING/31JUL2013	TL:1/SOFTT	OMENTUM	CT		26	
	SCREENING/31JUL2013	TL:2/GI	PERITONEUM	CT		22	SLD = 48
	SCREENING/31JUL2013	NTL:1/GI	MODERATE ASCITES AND SEEDING	CT		.	
	SCREENING/31JUL2013	NTL:2/LUNG	TINY NODULE OVER RIGHT LOW LUNG	CT		.	
	UNSCHEDULED/27SEP2013	TL:1/SOFTT	OMENTUM	CT		48	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
310-0009 /46/M/A2	UNSCHEDULED/27SEP2013	TL:2/GI	PERITONEUM	CT		90	
	UNSCHEDULED/27SEP2013	NTL:1/GI	MODERATE ASCITES AND SEEDING	CT	UP	.	
	UNSCHEDULED/27SEP2013	NTL:2/LUNG	TINY NODULE OVER RIGHT LOW LUNG	CT	Present	.	
	Summary:					.	SLD = 138, %CN = 187.5, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 27SEP2013
310-0010 /34/F/A2	SCREENING/15AUG2013	TL:1/LIVER	SEGMENT 2	CT		51	
	SCREENING/15AUG2013	TL:2/LIVER	SEGMENT 3	CT		37	

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Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
310-0010 /34/F/A2	SCREENING/15AUG2013	TL:3/BONE	LEFT 8TH RIB	CT		61	
	SCREENING/15AUG2013	TL:4/BONE	LEFT SACRUM	CT		43	SLD = 192
	UNSCHEDULED/25SEP2013	TL:1/LIVER	SEGMENT 2	CT		80	
	UNSCHEDULED/25SEP2013	TL:2/LIVER	SEGMENT 3	CT		49	
	UNSCHEDULED/25SEP2013	TL:3/BONE	LEFT 8TH RIB	CT		67	
	UNSCHEDULED/25SEP2013	TL:4/BONE	LEFT SACRUM	CT		43	

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Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
310-0010 /34/F/A2	UNSCHEDULED/25SEP2013	NTL:1/LIVE	MULTIPLE NODULES OVER LIVER	CT	New	.	
	Summary:					.	SLD = 239, %CN = 24.48, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 26SEP2013
310-0011 /52/M/A2	SCREENING/07OCT2013	TL:1/LUNG	RIGHT PARATRACHEAL	CT		29	
	SCREENING/07OCT2013	TL:2/LUNG	RIGHT HILUM	CT		19	SLD = 48
	SCREENING/07OCT2013	NTL:1/LUNG	RIGHT UPPER LOBE	CT		.	
	SCREENING/07OCT2013	NTL:2/LUNG	RIGHT LOWER LOBE	CT		.	

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Tumor Assessment Summary Listing
(Intent-to-Treat Population)

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Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
310-0011 /52/M/A2	WEEK12/02JAN2014	TL:1/LUNG	RIGHT PARATRACHEAL	CT		38	
	WEEK12/02JAN2014	TL:2/LUNG	RIGHT HILUM	CT		19	
	WEEK12/02JAN2014	NTL:1/LUNG	RIGHT UPPER LOBE	CT	UP	.	
	WEEK12/02JAN2014	NTL:2/LUNG	RIGHT LOWER LOBE	CT	UP	.	
	WEEK12/02JAN2014	NTL:3/NODE	PRECARINA ENLARGED LYMPH NODE	CT	New	.	
	Summary:					.	SLD = 57, %CN = 18.75, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 08JAN2014

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Tumor Assessment Summary Listing
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Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
310-0014 /64/M/A2	SCREENING/17SEP2014	TL:1/LIVER	SEGMENT 7	CT		22	
	SCREENING/17SEP2014	TL:2/LIVER	SEGMENT 6	CT		22	
	SCREENING/17SEP2014	TL:3/LUNG	RIGHR LOWER LOBE	CT		33	
	SCREENING/17SEP2014	TL:4/LUNG	LEFT LOWER LOBE	CT		16	
	SCREENING/17SEP2014	TL:5/BONE	RIGHT ILIAC	CT		17	SLD = 110
	SCREENING/17SEP2014	NTL:1/LUNG	BOTH LUNG NODULES	CT		.	

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Tumor Assessment Summary Listing
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Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
310-0014 /64/M/A2	SCREENING/17SEP2014	NTL:2/LIVE	HEPATIC NODULES	CT		.	
	WEEK12/03DEC2014	TL:1/LIVER	SEGMENT 7	CT		24	
	WEEK12/03DEC2014	TL:2/LIVER	SEGMENT 6	CT		23	
	WEEK12/03DEC2014	TL:3/LUNG	RIGHR LOWER LOBE	CT		46	
	WEEK12/03DEC2014	TL:4/LUNG	LEFT LOWER LOBE	CT		23	
	WEEK12/03DEC2014	TL:5/BONE	RIGHT ILIAC	CT		17	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
310-0014 /64/M/A2	WEEK12/03DEC2014	NTL:1/LUNG	BOTH LUNG NODULES	CT	UP	.	
	WEEK12/03DEC2014	NTL:2/LIVE	HEPATIC NODULES	CT	UP	.	
	WEEK12/03DEC2014	NTL:3/GU	RIGHT ADRENAL MASS	CT	New	.	
	Summary:					.	SLD = 133, %CN = 20.91, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 03DEC2014
311-0003 /44/M/A2	SCREENING/11SEP2013	TL:1/NODES	MEDIASTINUM LYMPHO NODE	CT		29	
	SCREENING/11SEP2013	TL:2/NODES	RIGHT HILAR	CT		23	SLD = 52

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
311-0003 /44/M/A2	SCREENING/11SEP2013	NTL:1/LUNG	BOTH LUNG ZONES	CT		.	
	WEEK12/10DEC2013	TL:1/NODES	MEDIASTINUM LYMPHO NODE	CT		29	
	WEEK12/10DEC2013	TL:2/NODES	RIGHT HILAR	CT		23	
	WEEK12/10DEC2013	NTL:1/LUNG	BOTH LUNG ZONES	CT	UP	.	
	Summary:					.	SLD = 52, %CN = 0, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 11DEC2013
311-0004 /68/M/A2	SCREENING/26SEP2013	TL:1/PLEUR	RIGHT SUBPHRENIC REGION	CT		95	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
311-0004 /68/M/A2	SCREENING/26SEP2013	TL:2/PERIC	CARDIOPHRENIC REGION	CT		25	
	SCREENING/26SEP2013	TL:3/LUNG	LUNG ZONE	CT		31	
	SCREENING/26SEP2013	TL:4/LUNG	LUNG ZONE	CT		22	SLD = 173
	SCREENING/26SEP2013	NTL:1/LUNG	BOTH LUNG ZONE	CT		.	
311-0005 /58/M/A2	SCREENING/18OCT2013	TL:1/NODES	BETWEEN AORTA AND INFERIOR VENA CAVA	CT		20	
	SCREENING/18OCT2013	TL:2/LUNG	RIGHT UPPER LUNG ZONE	CT		33	SLD = 53

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
311-0005 /58/M/A2	SCREENING/18OCT2013	NTL:1/NODE	CELIAC REGION	CT		.	
	WEEK12/30DEC2013	TL:1/NODES	BETWEEN AORTA AND INFERIOR VENA CAVA	CT		25	
	WEEK12/30DEC2013	TL:2/LUNG	RIGHT UPPER LUNG ZONE	CT		47	
	WEEK12/30DEC2013	NTL:1/NODE	CELIAC REGION	CT	UP	.	
	Summary:					.	SLD = 72, %CN = 35.85, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 30DEC2013
311-0006 /73/F/A2	SCREENING/15OCT2013	TL:1/LIVER	SEGMENT 3	CT		20	

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[3] UP=Unequivocally Progressed
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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
311-0006 /73/F/A2	SCREENING/15OCT2013	TL:2/LIVER	SEGMENT 4	CT		45	SLD = 65
	SCREENING/15OCT2013	NTL:1/LUNG	BOTH LUNG ZONE	CT		.	
	WEEK12/16JAN2014	TL:1/LIVER	SEGMENT 3	CT	NE	.	
	WEEK12/16JAN2014	TL:2/LIVER	SEGMENT 4	CT	NE	.	
	WEEK12/16JAN2014	NTL:1/LUNG	BOTH LUNG ZONE	CT	UP	.	
	Summary:					.	SLD = ., %CN = ., TL: NotAssessed, NTL: PD, OR: PD, PD confirmed: Yes, 16JAN2014

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
311-0009 /51/F/A2	SCREENING/04JUL2014	TL:1/LUNG	RIGHT LOWER LOBE	CT		33	
	SCREENING/04JUL2014	TL:2/LUNG	LEFT LOWER LOBE	CT		54	SLD = 87
	SCREENING/04JUL2014	NTL:1/LUNG	BOTH LUNG	CT		.	
	SCREENING/04JUL2014	NTL:2/NODE	HILAR LYMPH NODE	CT		.	
	WEEK12/30SEP2014	TL:1/LUNG	RIGHT LOWER LOBE	CT		45	
	WEEK12/30SEP2014	TL:2/LUNG	LEFT LOWER LOBE	CT		60	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
311-0009 /51/F/A2	WEEK12/30SEP2014	NTL:1/LUNG	BOTH LUNG	CT	UP	.	
	WEEK12/30SEP2014	NTL:2/NODE	HILAR LYMPH NODE	CT	Present	.	
	Summary:					.	SLD = 105, %CN = 20.69, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 30SEP2014
311-0010 /47/M/A2	SCREENING/26AUG2014	TL:1/LUNG	LEFT LOWER LOBE	CT		12	SLD = 12
	SCREENING/26AUG2014	NTL:1/LUNG	BOTH LUNGS	CT		.	
	WEEK12/18NOV2014	TL:1/LUNG	LEFT LOWER LOBE	CT		5	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
311-0010 /47/M/A2	WEEK12/18NOV2014	NTL:1/LUNG	BOTH LUNGS	CT	Present	.	
	Summary:					.	SLD = 5, %CN = -58.33, TL: PR, NTL: IncompleteResponse/SD, OR: PR, PD confirmed: No
	WEEK24/12FEB2015	TL:1/LUNG	LEFT LOWER LOBE	CT		5	
	WEEK24/12FEB2015	NTL:1/LUNG	BOTH LUNGS	CT	Present	.	
	Summary:					.	SLD = 5, %CN = 0, TL: PR, NTL: IncompleteResponse/SD, OR: PR, PD confirmed: No
	WEEK36/07MAY2015	TL:1/LUNG	LEFT LOWER LOBE	CT		5	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
311-0010 /47/M/A2	WEEK36/07MAY2015	NTL:1/LUNG	BOTH LUNGS	CT	Present	.	
	Summary:					.	SLD = 5, %CN = 0, TL: PR, NTL: IncompleteResponse/SD, OR: PR, PD confirmed: No
311-0011 /46/M/A2	SCREENING/28OCT2014	TL:1/LIVER	SEGMENT 6	CT		26	
	SCREENING/28OCT2014	TL:2/LIVER	SEGMENT 2	CT		28	
	SCREENING/28OCT2014	TL:3/LIVER	SEGMENT 2	CT		19	SLD = 73
	UNSCHEDULED/30DEC2014	TL:1/LIVER	SEGMENT 6	CT		31	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
311-0011 /46/M/A2	UNSCHEDULED/30DEC2014	TL:2/LIVER	SEGMENT 2	CT		35	
	UNSCHEDULED/30DEC2014	TL:3/LIVER	SEGMENT 2	CT		21	
	UNSCHEDULED/30DEC2014	NTL:1/LIVE	PORTAL VEIN THROMBI	CT	New	.	
	UNSCHEDULED/30DEC2014	NTL:2/LUNG	RIGHT MIDDLE LOBE	CT	New	.	
	Summary:					.	SLD = 87, %CN = 19.18, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 31DEC2014
311-0012 /55/M/A2	SCREENING/20JAN2015	TL:1/SOFTT	MIDDLE UPPER ABDOMEN	CT		55	SLD = 55

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
311-0012 /55/M/A2	SCREENING/20JAN2015	NTL:1/LUNG	BOTH LUNG ZONE	CT		.	
	WEEK12/16APR2015	TL:1/SOFTT	MIDDLE UPPER ABDOMEN	CT		55	
	WEEK12/16APR2015	NTL:1/LUNG	BOTH LUNG ZONE	CT	Present	.	
	Summary:					.	SLD = 55, %CN = 0, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
401-0001 /70/M/A7	SCREENING/03JUN2013	TL:1/LIVER	RIGHT PERIHEPATIC SPACE	CT		21	SLD = 21
	SCREENING/03JUN2013	NTL:1/LIVE	RIGHT S3	CT		.	

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Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
401-0001 /70/M/A7	SCREENING/03JUN2013	NTL:2/LIVE	LEFT S3	CT		.	
401-0002 /55/M/A7	SCREENING/12JUN2013	TL:1/LIVER		CT		64	
	SCREENING/12JUN2013	TL:2/LIVER		CT		47	
	SCREENING/12JUN2013	TL:3/LIVER		CT		20	
	SCREENING/12JUN2013	TL:4/	T-SPINE	CT		12	SLD = 143
	SCREENING/12JUN2013	NTL:1/LUNG		CT		.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
401-0002 /55/M/A7	SCREENING/12JUN2013	NTL:2/LUNG		CT		.	
	SCREENING/12JUN2013	NTL:3/LUNG		CT		.	
	SCREENING/12JUN2013	NTL:4/LUNG		CT		.	
402-0001 /35/M/A7	SCREENING/29MAR2013	TL:1/LIVER	S6	CT		31	
	SCREENING/29MAR2013	TL:2/LIVER	S7	CT		46	SLD = 77
	UNSCHEDULED/10JUN2013	TL:1/LIVER	S6	CT		35	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
402-0001 /35/M/A7	UNSCHEDULED/10JUN2013	TL:2/LIVER	S7	CT		70	
	Summary:					.	SLD = 105, %CN = 36.36, TL: PD, NTL: NotAssessed, OR: PD, PD confirmed: Yes, 24JUN2013
402-0002 /58/M/A7	SCREENING/10APR2013	TL:1/SPLEE	SPLEEN	CT		20	
	SCREENING/10APR2013	TL:2/BONE	RIGHT RIB MASS	CT		36	SLD = 56
	SCREENING/10APR2013	NTL:1/LUNG	MULTIPLE METASTATIC NODULE	CT		.	
	SCREENING/10APR2013	NTL:2/LIVE	NODULES	CT		.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
402-0002 /58/M/A7	WEEK12/09JUL2013	TL:1/SPLEE	SPLEEN	CT		25	
	WEEK12/09JUL2013	TL:2/BONE	RIGHT RIB MASS	CT		44	
	WEEK12/09JUL2013	NTL:1/LUNG	MULTIPLE METASTATIC NODULE	CT	Present	.	
	WEEK12/09JUL2013	NTL:2/LIVE	NODULES	CT	Present	.	
	Summary:					.	SLD = 69, %CN = 23.21, TL: PD, NTL: IncompleteResponse/SD, OR: PD, PD confirmed: Yes, 09JUL2013
402-0005 /70/M/A7	SCREENING/30APR2013	TL:1/NODES	RIGHT SUPRACLAVICULAR LYMPHNODE	CT		18	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
402-0005 /70/M/A7	SCREENING/30APR2013	TL:2/LIVER	S4	CT		43	SLD = 61
	SCREENING/30APR2013	NTL:1/LUNG	MULTIPLE METASTATIC NODULE	CT		.	
	SCREENING/30APR2013	NTL:2/LIVE	NODULES	CT		.	
	WEEK12/23JUL2013	TL:1/NODES	RIGHT SUPRACLAVICULAR LYMPHNODE	CT		20	
	WEEK12/23JUL2013	TL:2/LIVER		CT		55	
	WEEK12/23JUL2013	NTL:1/LUNG	MULTIPLE METASTATIC NODULE	CT	UP	.	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
402-0005 /70/M/A7	WEEK12/23JUL2013	NTL:2/LIVE	NODULES	CT	UP	.	
	Summary:					.	SLD = 75, %CN = 22.95, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 01AUG2013
402-0010 /50/M/A7	SCREENING/10MAY2013	TL:1/LIVER	S7	CT		40	
	SCREENING/10MAY2013	TL:2/LUNG	LEFT LOWER LOBE	CT		33	
	SCREENING/10MAY2013	TL:3/BONE	LEFT PELVIC BONE	CT		140	SLD = 213
	SCREENING/10MAY2013	NTL:1/PLEU	PLEURAL METASTASIS	CT		.	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
402-0010 /50/M/A7	UNSCHEDULED/02JUL2013	TL:1/LIVER	S7	CT		35	
	UNSCHEDULED/02JUL2013	TL:2/LUNG	LEFT LOWER LOBE	CT		30	
	UNSCHEDULED/02JUL2013	TL:3/BONE	LEFT PELVIC BONE	CT		90	
	UNSCHEDULED/02JUL2013	NTL:1/PLEU	PLEURAL METASTASIS	CT	UP	.	
	Summary:					.	SLD = 155, %CN = 0, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 08JUL2013
402-0022 /60/F/A7	SCREENING/09AUG2013	TL:1/LIVER	S8	CT		14	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
402-0022 /60/F/A7	SCREENING/09AUG2013	TL:2/LUNG	LEFT LOWER LOBE NODULES	CT		11	SLD = 25
	SCREENING/09AUG2013	NTL:1/GI	PERITONEAL SEEDING	CT		.	
	SCREENING/09AUG2013	NTL:2/NODE	METASTATIC LUNG NODULES	CT		.	
	WEEK12/11NOV2013	TL:1/LIVER	S8	CT		15	
	WEEK12/11NOV2013	TL:2/LUNG	LEFT LOWER LOBE NODULES	CT		30	
	WEEK12/11NOV2013	NTL:1/GI	PERITONEAL SEEDING	CT	UP	.	

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Tumor Assessment Summary Listing
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Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
402-0022 /60/F/A7	WEEK12/11NOV2013	NTL:2/NODE	METASTATIC LUNG NODULES	CT	UP	.	
	Summary:					.	SLD = 45, %CN = 80, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 18NOV2013
402-0023 /57/M/A7	SCREENING/06AUG2013	NTL:1/NODE	PARATRACHEAL LYMPH NODES	CT		.	
	SCREENING/22AUG2013	TL:1/LIVER	S2	CT		14	SLD = 14
	WEEK12/19NOV2013	TL:1/LIVER	S2	CT		65	
	WEEK12/19NOV2013	NTL:1/NODE	PARATRACHEAL LYMPH NODES	CT	Present	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
402-0023 /57/M/A7	WEEK12/19NOV2013	NTL:2/LIVE	S5	CT	New	.	
	Summary:					.	SLD = 65, %CN = 364.29, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 26NOV2013
402-0029 /49/M/A7	SCREENING/29OCT2013	TL:1/LUNG	LEFT LOWER LOBE NODULE	CT		26	
	SCREENING/29OCT2013	TL:2/NODES	LEFT SENTINEL LYMPH NODE	CT		15	
	SCREENING/29OCT2013	NTL:2/LUNG	MULTIPLE PULLMONARY METASTASIS	CT		.	
	SCREENING/06NOV2013	TL:3/LIVER	S7, 8	CT		87	SLD = 128

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
402-0029 /49/M/A7	SCREENING/06NOV2013	NTL:1/LIVE	MULTIPLE LIVER METASTASIS	CT		.	
	UNSCHEDULED/30DEC2013	TL:1/LUNG	LEFT LOWER LOBE NODULE	CT		44	
	UNSCHEDULED/30DEC2013	TL:2/NODES	LEFT SENTINEL LYMPH NODE	CT		15	
	UNSCHEDULED/30DEC2013	TL:3/LIVER	S7, 8	CT		80	
	UNSCHEDULED/30DEC2013	NTL:1/LIVE		CT	Present	.	
	UNSCHEDULED/30DEC2013	NTL:2/LUNG		CT	UP	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
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Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
402-0029 /49/M/A7	Summary:					.	SLD = 139, %CN = 8.59, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 06JAN2014
402-0032 /49/F/A7	SCREENING/28NOV2013	TL:1/LIVER	S5	CT		25	
	SCREENING/28NOV2013	TL:2/BONE	RIGHT THIRD RIB MASS	CT		36	SLD = 61
	SCREENING/28NOV2013	NTL:1/LIVE	MULTIPLE LIVER METASTASIS	CT		.	
	SCREENING/28NOV2013	NTL:2/LUNG	MULTIPLE LUNG METASTASIS	CT		.	
	WEEK12/20FEB2014	TL:1/LIVER	S5	CT		40	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
402-0032 /49/F/A7	WEEK12/20FEB2014	TL:2/BONE	RIGHT THIRD RIB MASS	CT		66	
	WEEK12/20FEB2014	NTL:1/LIVE	MULTIPLE LIVER METASTASIS	CT	Present	.	
	WEEK12/20FEB2014	NTL:2/LUNG	MULTIPLE LUNG METASTASIS	CT	Present	.	
	Summary:					.	SLD = 106, %CN = 73.77, TL: PD, NTL: IncompleteResponse/SD, OR: PD, PD confirmed: Yes, 27FEB2014
402-0034 /43/F/A7	SCREENING/11DEC2013	TL:1/LIVER	S4	CT		24	
	SCREENING/11DEC2013	TL:2/LIVER	S6	CT		16	SLD = 40

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[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
402-0034 /43/F/A7	SCREENING/11DEC2013	NTL:1/LIVE	MULTIPLE LIVER NODULE	CT		.	
	SCREENING/11DEC2013	NTL:2/LUNG	RIGHT LUNG METASTASIS	CT		.	
	WEEK12/06MAR2014	TL:1/LIVER	S4	CT		25	
	WEEK12/06MAR2014	TL:2/LIVER	S6	CT		15	
	WEEK12/06MAR2014	NTL:1/LIVE	MULTIPLE LIVER NODULE	CT	Present	.	
	WEEK12/06MAR2014	NTL:2/LUNG	RIGHT LUNG METASTASIS	CT	Present	.	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
402-0034 /43/F/A7	Summary:					.	SLD = 40, %CN = 0, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK24/29MAY2014	TL:1/LIVER	S4	CT		39	
	WEEK24/29MAY2014	TL:2/LIVER	S6	CT		26	
	WEEK24/29MAY2014	NTL:1/LIVE	MULTIPLE LIVER NODULE	CT	Present	.	
	WEEK24/29MAY2014	NTL:2/LUNG	RIGHT LUNG METASTASIS		Present	.	
	Summary:					.	SLD = 65, %CN = 62.5, TL: PD, NTL: IncompleteResponse/SD, OR: PD, PD confirmed: Yes, 05JUN2014

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[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
403-0004 /37/M/A7	SCREENING/03JUL2013	TL:1/LUNG	METASTASIS IN LUL	CT		25	
	SCREENING/03JUL2013	TL:2/LUNG	METASTASIS IN RUL	CT		22	
	SCREENING/03JUL2013	TL:3/LIVER	INFILTRATIVE HCC IN RT LOBE OF LIVER	CT		68	SLD = 115
	SCREENING/03JUL2013	NTL:1/LUNG	MULTIPLE LUNG METASTASIS IN BOTH LUNGS.	CT		.	
	SCREENING/03JUL2013	NTL:2/PLEU	RT MALIGNANT PLEURAL EFFUSION	CT		.	
	SCREENING/03JUL2013	NTL:3/LIVE	RT PORTAL VEIN THROMBOSIS	CT		.	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
403-0004 /37/M/A7	WEEK12/25SEP2013	TL:1/LUNG	METASTASIS IN LUL	CT		29	
	WEEK12/25SEP2013	TL:2/LUNG	METASTASIS IN RUL	CT		19	
	WEEK12/25SEP2013	TL:3/LIVER	INFILTRATIVE HCC IN RT LOBE OF LIVER	CT		70	
	WEEK12/25SEP2013	NTL:1/LUNG	MULTIPLE LUNG METASTASIS IN BOTH LUNGS.	CT	UP	.	
	WEEK12/25SEP2013	NTL:2/PLEU	RT MALIGNANT PLEURAL EFFUSION	CT	Present	.	
	WEEK12/25SEP2013	NTL:3/LIVE	RT PORTAL VEIN THROMBOSIS	CT	Present	.	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
403-0004 /37/M/A7	Summary:					.	SLD = 118, %CN = 2.61, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 01OCT2013
404-0003 /53/M/A7	SCREENING/21AUG2013	TL:1/LIVER	S4	CT		50	
	SCREENING/21AUG2013	TL:2/NODES	LYMPH NODES(GASTROCOLIC)	CT		20	SLD = 70
	SCREENING/21AUG2013	NTL:1/LUNG	RLL #48	CT		.	
	SCREENING/21AUG2013	NTL:2/LUNG	LLL #52	CT		.	
	SCREENING/21AUG2013	NTL:3/PLEU	EFFUSION	CT		.	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
404-0003 /53/M/A7	UNSCHEDULED/30SEP2013	TL:1/LIVER	S4	CT		70	
	UNSCHEDULED/30SEP2013	TL:2/NODES	LYMPH NODES(GASTROCOLIC)	CT		27	
	UNSCHEDULED/30SEP2013	NTL:1/LUNG	RIGHT LOWER LOBE	CT	NE	.	
	UNSCHEDULED/30SEP2013	NTL:2/LUNG	LEFT LOWER LOBE	CT	NE	.	
	UNSCHEDULED/30SEP2013	NTL:3/PLEU	PLEURAL EFFUSION	CT	NE	.	
	Summary:					.	SLD = 97, %CN = 38.57, TL: PD, NTL: NotEvaluable, OR: PD, PD confirmed: Yes, 30SEP2013

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
404-0004 /61/F/A7	SCREENING/08OCT2013	TL:1/LIVER	S5	CT		16	
	SCREENING/08OCT2013	TL:2/BONE	LEFT ILIAC	CT		36	SLD = 52
	UNSCHEDULED/02DEC2013	TL:1/LIVER	S5	CT		13	
	UNSCHEDULED/02DEC2013	TL:2/BONE	LEFT ILIAC	CT		29	
	UNSCHEDULED/02DEC2013	NTL:1/LIVE	LATERAL SEGMENT	CT	New	.	
	Summary:					.	SLD = 42, %CN = 0, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 02DEC2013

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
405-0001 /55/M/A7	SCREENING/22APR2013	TL:1/GU	LEFT ADRENAL	CT		43	SLD = 43
	SCREENING/22APR2013	NTL:1/NODE	INTRAABDOMINAL	CT		.	
	WEEK12/10JUL2013	TL:1/GU	LEFT ADRENAL	CT		68	
	UNSCHEDULED/10JUL2013	NTL:/GU	LEFT KIDNEY	CT	New	.	
	WEEK12/10JUL2013	NTL:1/NODE	INTRAABDOMINAL	CT	Present	.	
	WEEK12/10JUL2013	NTL:2/GU	LEFT KIDENY	CT	New	.	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
405-0001 /55/M/A7	Summary:					.	SLD = 68, %CN = 58.14, TL: PD, NTL: IncompleteResponse/SD, OR: PD, PD confirmed: Yes, 10JUL2013
405-0005 /35/M/A6	SCREENING/19APR2013	TL:1/LUNG	RIGHT LOWER LOBE	CT		11	
	SCREENING/19APR2013	TL:2/LUNG	RIGHT LOWER LOBE	CT		12	
	SCREENING/19APR2013	TL:3/GI	PERITONEUM	CT		24	
	SCREENING/19APR2013	TL:4/GI	PERITONEUM	CT		19	SLD = 66
	SCREENING/19APR2013	NTL:1/LIVE	LIPIODOLIZED	CT		.	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
405-0005 /35/M/A6	SCREENING/19APR2013	NTL:2/GI	PERITONEUM	CT		.	
	SCREENING/19APR2013	NTL:3/LUNG	MULTIPLE	CT		.	
	WEEK12/10JUL2013	TL:1/LUNG	RIGHT LOWER LOBE	CT		4	
	WEEK12/10JUL2013	TL:2/LUNG	RIGHT LOWER LOBE	CT		8	
	WEEK12/10JUL2013	TL:3/GI	PERITONEUM	CT		29	
	WEEK12/10JUL2013	TL:4/GI	PERITONEUM	CT		21	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
405-0005 /35/M/A6	WEEK12/10JUL2013	NTL:1/LIVE	LIPIODOLIZED	CT	Present	.	
	WEEK12/10JUL2013	NTL:2/GI	PERITONEUM	CT	Present	.	
	WEEK12/10JUL2013	NTL:3/LUNG	MULTIPLE	CT	Present	.	
	Summary:					.	SLD = 62, %CN = -6.06, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK24/02OCT2013	TL:1/LUNG	RIGHT LOWER LOBE	CT		4	
	WEEK24/02OCT2013	TL:2/LUNG	RIGHT LOWER LOBE	CT		7	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
405-0005 /35/M/A6	WEEK24/02OCT2013	TL:3/GI	PERITONEUM	CT		32	
	WEEK24/02OCT2013	TL:4/GI	PERITONEUM	CT		28	
	WEEK24/02OCT2013	NTL:1/LIVE	LIPIODOLIZED	CT	Present	.	
	WEEK24/02OCT2013	NTL:2/GI	PERITONEUM	CT	Present	.	
	WEEK24/02OCT2013	NTL:3/LUNG	MULTIPLE	CT	Present	.	
	Summary:					.	SLD = 71, %CN = 14.52, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
405-0005 /35/M/A6	WEEK36/23DEC2013	TL:1/LUNG	RIGHT LOWER LOBE	CT		4	
	WEEK36/23DEC2013	TL:2/LUNG	RIGHT LOWER LOBE	CT		8	
	WEEK36/23DEC2013	TL:3/GI	PERITONEUM	CT		37	
	WEEK36/23DEC2013	TL:4/GI	PERITONEUM	CT		37	
	WEEK36/23DEC2013	NTL:1/LIVE	LIPIODOLIZED	CT	Present	.	
	WEEK36/23DEC2013	NTL:2/GI	PERITONEUM	CT	Present	.	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
405-0005 /35/M/A6	WEEK36/23DEC2013	NTL:3/LUNG	MULTIPLE	CT	Present	.	
	Summary:					.	SLD = 86, %CN = 38.71, TL: PD, NTL: IncompleteResponse/SD, OR: PD, PD confirmed: Yes, 23DEC2013
405-0012 /72/M/A7	SCREENING/03MAY2013	TL:1/LIVER	SEGMENTATION 2	CT		17	
	SCREENING/03MAY2013	TL:2/LUNG	RIGHT LOWER LOBE	CT		77	
	SCREENING/03MAY2013	TL:3/LUNG	RIGHT LOWER LOBE	CT		41	
	SCREENING/03MAY2013	TL:4/NODES	PREVASCULAR	CT		16	SLD = 151

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
405-0012 /72/M/A7	SCREENING/03MAY2013	NTL:1/LIVE	MULTIPLE	CT		.	
	SCREENING/03MAY2013	NTL:2/LUNG	MULTIPLE	CT		.	
	SCREENING/03MAY2013	NTL:3/NODE	MULTIPLE	CT		.	
	WEEK12/29JUL2013	TL:1/LIVER	SEGMENTATION 2	CT		14	
	WEEK12/29JUL2013	TL:2/LUNG	RIGHT LOWER LOBE	CT		86	
	WEEK12/29JUL2013	TL:3/LUNG	RIGHT LOWER LOBE	CT		42	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
405-0012 /72/M/A7	WEEK12/29JUL2013	TL:4/NODES	PREVASCULAR	CT		18	
	WEEK12/29JUL2013	NTL:1/LIVE	MULTIPLE	CT	Present	.	
	WEEK12/29JUL2013	NTL:2/LUNG	MULTIPLE	CT	Present	.	
	WEEK12/29JUL2013	NTL:3/NODE	MULTIPLE	CT	Present	.	
	Summary:					.	SLD = 160, %CN = 5.96, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK24/21OCT2013	TL:1/LIVER	SEGMENTATION 2	CT		20	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
405-0012 /72/M/A7	WEEK24/21OCT2013	TL:2/LUNG	RIGHT LOWER LOBE	CT		90	
	WEEK24/21OCT2013	TL:3/LUNG	RIGHT LOWER LOBE	CT		44	
	WEEK24/21OCT2013	TL:4/NODES	PREVASCULAR	CT		23	
	WEEK24/21OCT2013	NTL:1/LIVE	MULTIPLE	CT	Present	.	
	WEEK24/21OCT2013	NTL:2/LUNG	MULTIPLE	CT	UP	.	
	WEEK24/21OCT2013	NTL:3/NODE	MULTIPLE	CT	Present	.	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
405-0012 /72/M/A7	Summary:					.	SLD = 177, %CN = 17.22, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 21OCT2013
405-0019 /61/M/A7	SCREENING/18JUN2013	TL:1/LIVER	SEGMENT 7	MRI		60	
	SCREENING/18JUN2013	TL:2/LIVER	SEGMENT8	MRI		35	SLD = 95
	SCREENING/18JUN2013	NTL:1/LIVE	MULTIPLE	MRI		.	
	SCREENING/18JUN2013	NTL:2/SOFT	PERITONEUM	MRI		.	
405-0024 /69/M/A7	SCREENING/21JUN2013	TL:1/LIVER	SEGMENT 7	CT		100	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
405-0024 /69/M/A7	SCREENING/21JUN2013	TL:2/LIVER	SEGMENT 4	CT		52	
	SCREENING/21JUN2013	TL:3/LUNG	LEFT LOWER LOBE	CT		33	
	SCREENING/21JUN2013	TL:4/LUNG	LEFT UPPER LOBE	CT		16	SLD = 201
	SCREENING/21JUN2013	NTL:1/LIVE	MULTIPLE	CT		.	
	SCREENING/21JUN2013	NTL:2/LUNG	MULTIPLE	CT		.	
405-0026 /67/M/A7	SCREENING/26JUN2013	TL:1/LIVER	SEGMENT 4	CT		46	SLD = 46

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
405-0026 /67/M/A7	WEEK12/25SEP2013	TL:1/LIVER	SEGMENT 4	CT		69	
	Summary:					.	SLD = 69, %CN = 50, TL: PD, NTL: NotAssessed, OR: PD, PD confirmed: Yes, 25SEP2013
405-0036 /70/M/A7	SCREENING/16AUG2013	TL:1/LIVER	SEGMENT 7	CT		83	
	SCREENING/16AUG2013	TL:2/NODES	LEFT ADRENAL	CT		32	
	SCREENING/16AUG2013	TL:3/LUNG	RIGHT MIDDLE LOBE	CT		11	SLD = 126
	SCREENING/16AUG2013	NTL:1/LIVE	MULTIPLE	CT		.	

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[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
405-0036 /70/M/A7	SCREENING/16AUG2013	NTL:2/LUNG	MULTIPLE	CT		.	
	UNSCHEDULED/16OCT2013	TL:1/LIVER	SEGMENT 7	CT		85	
	UNSCHEDULED/16OCT2013	TL:2/NODES	LEFT ADRENAL	CT		49	
	UNSCHEDULED/16OCT2013	TL:3/LUNG	RIGHT MIDDLE LOBE	CT		12	
	UNSCHEDULED/16OCT2013	NTL:1/LIVE	MULTIPLE	CT	Present	.	
	UNSCHEDULED/16OCT2013	NTL:2/LUNG	MULTIPLE	CT	Present	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
405-0036 /70/M/A7	Summary:					.	SLD = 146, %CN = 15.87, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK12/12NOV2013	TL:1/LIVER	SEGMENT 7	CT		90	
	WEEK12/12NOV2013	TL:2/NODES	LEFT ADRENAL	CT		52	
	WEEK12/12NOV2013	TL:3/LUNG	RIGHT MIDDLE LOBE	CT		13	
	WEEK12/12NOV2013	NTL:1/LIVE	MULTIPLE	CT	UP	.	
	WEEK12/12NOV2013	NTL:2/LUNG	MULTIPLE	CT	UP	.	

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[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
405-0036 /70/M/A7	Summary:					.	SLD = 155, %CN = 23.02, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 12NOV2013
405-0041 /57/M/A7	SCREENING/07SEP2013	TL:1/LIVER	SEGMENT7	CT		79	
	SCREENING/07SEP2013	TL:2/LIVER	SEGMENT5	CT		30	SLD = 109
	SCREENING/07SEP2013	NTL:1/LIVE	MULTIPLE	CT		.	
	SCREENING/07SEP2013	NTL:2/LUNG	RUL	CT		.	
	WEEK12/25NOV2013	TL:1/LIVER	SEGMENT7	CT		87	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
405-0041 /57/M/A7	WEEK12/25NOV2013	TL:2/LIVER	SEGMENT5	CT		34	
	WEEK12/25NOV2013	NTL:1/LIVE	MULTIPLE	CT	Present	.	
	WEEK12/25NOV2013	NTL:2/LUNG	RUL	CT	Present	.	
	Summary:					.	SLD = 121, %CN = 11.01, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK24/17FEB2014	TL:1/LIVER	SEGMENT7	CT		85	
	WEEK24/17FEB2014	TL:2/LIVER	SEGMENT5	CT		35	

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[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
405-0041 /57/M/A7	WEEK24/17FEB2014	NTL:1/LIVE	MULTIPLE	CT	Present	.	
	WEEK24/17FEB2014	NTL:2/LUNG	RUL	CT	Present	.	
	Summary:					.	SLD = 120, %CN = 10.09, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK36/02MAY2014	TL:1/LIVER	SEGMENT7	CT		100	
	WEEK36/02MAY2014	TL:2/LIVER	SEGMENT5	CT		43	
	WEEK36/02MAY2014	NTL:1/LIVE	MULTIPLE	CT	UP	.	

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[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
405-0041 /57/M/A7	WEEK36/02MAY2014	NTL:2/LUNG	RUL	CT	Present	.	
	Summary:					.	SLD = 143, %CN = 31.19, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 02MAY2014
501-0003 /22/M/A1	SCREENING/03DEC2013	TL:1/LUNG	LEFT LUNG METASTASES LESION	CT		25	
	SCREENING/03DEC2013	TL:2/LUNG	RIGHT LUNG METASTASES	CT		31	
	SCREENING/03DEC2013	TL:3/SOFTT	THE LEFT CHEST WALL	CT		28	SLD = 84
	SCREENING/03DEC2013	NTL:1/LUNG	RIGHT LUNG	CT		.	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
501-0003 /22/M/A1	SCREENING/03DEC2013	NTL:2/NODE	HILUS PULMONIS,MEDIAS TINUM	CT		.	
	SCREENING/03DEC2013	NTL:3/PLEU	PLEURAL EFFUSION	CT		.	
	WEEK12/25FEB2014	TL:1/LUNG	LEFT LUNG METASTASES LESION	CT		31	
	WEEK12/25FEB2014	TL:2/LUNG	RIGHT LUNG METASTASES	CT		38	
	WEEK12/25FEB2014	TL:3/SOFTT	THE LEFT CHEST WALL	CT		32	
	WEEK12/25FEB2014	NTL:1/LUNG	RIGHT LUNG	CT	Present	.	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
501-0003 /22/M/A1	WEEK12/25FEB2014	NTL:2/NODE	HILUS PULMONIS,MEDIAS TINUM	CT	Present	.	
	WEEK12/25FEB2014	NTL:3/PLEU	PLEURAL EFFUSION	CT	Present	.	
	WEEK12/25FEB2014	NTL:4/LUNG	BILATERAL PULMONARY	CT	New	.	
	WEEK12/25FEB2014	NTL:5/SOFT	CHEST WALL	CT	New	.	
	WEEK12/25FEB2014	NTL:6/BONE	THE 11TH RIB	CT	New	.	
	Summary:					.	SLD = 101, %CN = 20.24, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 25FEB2014

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
501-0004 /26/M/A1	SCREENING/14DEC2013	TL:1/LIVER	RIGHT LIVER	CT		70	
	SCREENING/14DEC2013	TL:2/LUNG	LEFT LUNG	CT		15	SLD = 85
	SCREENING/14DEC2013	NTL:1/LUNG	DOUBLE LUNG	CT		.	
	SCREENING/14DEC2013	NTL:2/BONE	RIGHT NUMBER 9 COSTAL BONE	CT		.	
	SCREENING/14DEC2013	NTL:3/LIVE	LEFT LIVER	CT		.	
	SCREENING/14DEC2013	NTL:4/NODE	LYMPHADENECTASIS OF SUPERIOR MEDIASTINUM AND RETROPERITONEAL POSITION	CT		.	

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Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

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501-0004 /26/M/A1	SCREENING/14DEC2013	NTL:5/ASCI	ASCITES	CT		.	
	WEEK12/05MAR2014	TL:1/LIVER	RIGHT LIVER	CT		110	
	WEEK12/05MAR2014	TL:2/LUNG	LEFT LUNG	CT		35	
	WEEK12/05MAR2014	NTL:1/LUNG	DOUBLE LUNG	CT	Present	.	
	WEEK12/05MAR2014	NTL:2/BONE	RIGHT NUMBER 9 COSTAL BONE	CT	Present	.	
	WEEK12/05MAR2014	NTL:3/LIVE	LEFT LIVER	CT	Present	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
501-0004 /26/M/A1	WEEK12/05MAR2014	NTL:4/NODE	LYMPHADENECTASIS OF SUPERIOR MEDIASTINUM AND RETROPERITONEAL POSITION	CT	Present	.	
	WEEK12/05MAR2014	NTL:5/ASCI	ASCITES	CT	Absent	.	
	Summary:					.	SLD = 145, %CN = 70.59, TL: PD, NTL: IncompleteResponse/SD, OR: PD, PD confirmed: Yes, 05MAR2014
501-0011 /61/M/A1	SCREENING/19SEP2014	TL:1/LIVER	THE RIGHT LIVER	CT		35	
	SCREENING/19SEP2014	TL:2/LIVER	THE RIGHT HEPATIC LOBE	CT		30	SLD = 65
	SCREENING/19SEP2014	NTL:1/LIVE	MULTIPLE LIVER METASTASIS	CT		.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
501-0011 /61/M/A1	SCREENING/19SEP2014	NTL:2/BONE	SEVERAL BONE METASTASES	CT		.	
	SCREENING/19SEP2014	NTL:3/ASCI		CT		.	
	WEEK12/10DEC2014	TL:1/LIVER	THE RIGHT LIVER	CT		65	
	WEEK12/10DEC2014	TL:2/LIVER	THE RIGHT HEPATIC LOBE	CT		40	
	WEEK12/10DEC2014	NTL:1/LIVE	MULTIPLE LIVER METASTASIS	CT	Present	.	
	WEEK12/10DEC2014	NTL:2/BONE	SEVERAL BONE METASTASES	CT	Present	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
501-0011 /61/M/A1	WEEK12/10DEC2014	NTL:3/ASCI		CT	Present	.	
	WEEK12/10DEC2014	NTL:4/	RIGHT ADRENAL	CT	New	.	
	Summary:					.	SLD = 105, %CN = 61.54, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 12DEC2014
502-0001 /70/M/A1	SCREENING/13DEC2013	TL:1/LIVER	LIVER, LOW-DENSITY LESIONS, PRIMARY	CT		92	
	SCREENING/13DEC2013	TL:2/LIVER	LIVER, LOW-DENSITY LESIONS, PRIMARY	CT		30	SLD = 122
502-0003 /48/M/A1	SCREENING/13JAN2014	TL:1/LIVER	LOW-DENSITY LESION	CT		32	

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Tumor Assessment Summary Listing
(Intent-to-Treat Population)

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Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
502-0003 /48/M/A1	SCREENING/13JAN2014	TL:2/LIVER	LOW-DENSITY LESION	CT		18	
	SCREENING/13JAN2014	TL:3/SOFTT	LEFT ADRENAL METASTASIS	CT		10	SLD = 60
	SCREENING/13JAN2014	NTL:1/LIVE	LIVER NODULES	CT		.	
	WEEK12/04APR2014	TL:1/LIVER	LOW-DENSITY LESION	CT		35	
	WEEK12/04APR2014	TL:2/LIVER	LOW-DENSITY LESION	CT		20	
	WEEK12/04APR2014	TL:3/SOFTT	LEFT ADRENAL METASTASIS	CT		10	

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Tumor Assessment Summary Listing
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Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
502-0003 /48/M/A1	WEEK12/04APR2014	NTL:1/LIVE	LIVER NODULES	CT	Present	.	
	WEEK12/04APR2014	NTL:2/LIVE	LIVER NODULES	CT	New	.	
	Summary:					.	SLD = 65, %CN = 8.33, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 10APR2014
503-0002 /71/F/A1	SCREENING/10FEB2014	TL:1/LIVER	RIGHT LOBE OF LIVER	CT		70	SLD = 70
	SCREENING/10FEB2014	NTL:1/LUNG	MIDDLE LOBE OF RIGHT LUNG	CT		.	
	WEEK12/13MAY2014	TL:1/LIVER	RIGHT LOBE OF LIVER	CT		73	

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Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
503-0002 /71/F/A1	WEEK12/13MAY2014	NTL:1/LUNG	MIDDLE LOBE OF RIGHT LUNG	CT	Present	.	
	Summary:					.	SLD = 73, %CN = 4.29, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK24/04AUG2014	TL:1/LIVER	RIGHT LOBE OF LIVER	CT		80	
	WEEK24/04AUG2014	NTL:1/LUNG	MIDDLE LOBE OF RIGHT LUNG	CT	Present	.	
	Summary:					.	SLD = 80, %CN = 14.29, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK36/28OCT2014	TL:1/LIVER	RIGHT LOBE OF LIVER	CT		96	

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Tumor Assessment Summary Listing
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Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
503-0002 /71/F/A1	WEEK36/28OCT2014	NTL:1/LUNG	MIDDLE LOBE OF RIGHT LUNG	CT	Present	.	
	Summary:					.	SLD = 96, %CN = 37.14, TL: PD, NTL: IncompleteResponse/SD, OR: PD, PD confirmed: Yes, 22OCT2014
503-0003 /47/F/A1	SCREENING/07MAR2014	TL:1/LIVER	RIGHT	CT		170	SLD = 170
503-0005 /72/M/A1	SCREENING/25MAR2014	TL:1/LIVER	RIGHT LOBE OF LIVER	CT		60	SLD = 60
	SCREENING/25MAR2014	NTL:1/LIVE	MULTIPLE SMALL LESIONS	CT		.	
	WEEK12/17JUN2014	TL:1/LIVER	RIGHT LOBE OF LIVER	CT		50	

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Tumor Assessment Summary Listing
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Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
503-0005 /72/M/A1	WEEK12/17JUN2014	NTL:1/LIVE	MULTIPLE SMALL LESIONS	CT	Present	.	
	Summary:					.	SLD = 50, %CN = -16.67, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK24/11SEP2014	TL:1/LIVER	RIGHT LOBE OF LIVER	CT		56	
	WEEK24/11SEP2014	NTL:1/LIVE	MULTIPLE SMALL LESIONS	CT	Present	.	
	Summary:					.	SLD = 56, %CN = 12, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK36/25NOV2014	TL:1/LIVER	RIGHT LOBE OF LIVER	CT		56	

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Tumor Assessment Summary Listing
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Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
503-0005 /72/M/A1	WEEK36/25NOV2014	NTL:1/LIVE	MULTIPLE SMALL LESIONS	CT	Present	.	
	Summary:					.	SLD = 56, %CN = 12, TL: SD, NTL: IncompleteResponse/SD, OR: SD, PD confirmed: No
	WEEK48/02MAR2015	TL:1/LIVER	RIGHT LOBE OF LIVER	CT		57	
	WEEK48/02MAR2015	NTL:1/LIVE	MULTIPLE SMALL LESIONS	CT	New	.	
	Summary:					.	SLD = 57, %CN = 14, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 02MAR2015
504-0003 /53/M/A1	SCREENING/13MAR2014	TL:1/NODES	RETROPERITONEAL LYMPH NODE	CT		80	SLD = 80

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
504-0003 /53/M/A1	Summary:					.	SLD = 81, %CN = 1.25, TL: SD, NTL: PD, OR: PD, PD confirmed: Yes, 14APR2014
	UNSCHEDULED/14APR2014	TL:1/NODES	RETROPERITONEAL LYMPH NODE	CT		81	
	UNSCHEDULED/14APR2014	NTL:1/BONE	L2 CENTRUM TRANSITIVITY	CT	New	.	
504-0005 /41/F/A1	SCREENING/02SEP2014	TL:1/PLEUR		CT		25	SLD = 25
	SCREENING/02SEP2014	NTL:1/BREA	CHEST WALL LUMPS	CT		.	
	SCREENING/02SEP2014	NTL:2/LIVE	LESION IN LIVER	CT		.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
504-0006 /51/M/A1	SCREENING/04SEP2014	TL:1/LIVER		CT		70	
	SCREENING/04SEP2014	TL:2/LIVER		CT		23	SLD = 93
	SCREENING/04SEP2014	NTL:1/LIVE	2.EXIST	CT		.	
506-0001 /43/M/A1	SCREENING/01APR2014	TL:1/LIVER	LEFT LOBE OF LIVER	MRI		62	
	SCREENING/01APR2014	TL:2/LIVER	RIGHT LOBE OF LIVER	MRI		46	
	SCREENING/01APR2014	TL:3/GI	ABDOMINAL CAVITY	MRI		53	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
506-0001 /43/M/A1	SCREENING/01APR2014	TL:4/GI	ABDOMINAL CAVITY	MRI		76	SLD = 237
	SCREENING/01APR2014	NTL:1/GI	MULTIPLE PERITONEAL	MRI		.	
	SCREENING/01APR2014	NTL:2/LUNG	LUNG	CT		.	
506-0005 /24/M/A1	SCREENING/16DEC2014	TL:1/LUNG	MIDDLE LOBE OF RIGHT LUNG	CT		33	
	SCREENING/16DEC2014	TL:2/LUNG	SUPERIOR LOBE OF LEFT LUNG	CT		15	SLD = 48
	SCREENING/16DEC2014	NTL:1/BREA	ON THE RIGHT SIDE PLEURAL EFFUSION	CT		.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
506-0005 /24/M/A1	SCREENING/16DEC2014	NTL:6/LUNG	MULTIPLE METASTASES	CT		.	
	SCREENING/17DEC2014	NTL:7/ASCI	PELVIC CAVITY	CT		.	
	SCREENING/18DEC2014	NTL:2/ASCI	ASCITES	MRI		.	
	SCREENING/18DEC2014	NTL:3/LIVE	RIGHT BRANCH OF PORTAL VEIN	MRI		.	
	SCREENING/18DEC2014	NTL:4/LIVE	LIVER MULTIPLE METASTASES	MRI		.	
	SCREENING/18DEC2014	NTL:5/NODE	THE PERITONEAL CAVITY AND RETROPERITONEAL	MRI		.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
507-0001 /51/M/A1	SCREENING/11JUL2014	TL:1/LIVER	LEFT LOBE OF LIVER METASTASIS	MRI		30	
	SCREENING/11JUL2014	TL:2/LIVER	LEFT LOBE OF LIVER METASTASIS	MRI		36	SLD = 66
	WEEK12/13OCT2014	TL:1/LIVER	LEFT LOBE OF LIVER METASTASIS	MRI		53	
	WEEK12/13OCT2014	TL:2/LIVER	LEFT LOBE OF LIVER METASTASIS	MRI		60	
	WEEK12/13OCT2014	NTL:1/LIVE	MULTIPLE LIVER	MRI	New	.	
	Summary:					.	SLD = 113, %CN = 71.21, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 14OCT2014

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
507-0002 /44/M/A1	SCREENING/29JUL2014	TL:1/LIVER	RIGHT LOBE OF LIVER METASTASIS	CT		37	
	SCREENING/29JUL2014	TL:2/LIVER	RIGHT LOBE OF LIVER METASTASIS	CT		47	SLD = 84
	SCREENING/29JUL2014	NTL:1/LUNG	LUNG METASTASIS	CT		.	
	UNSCHEDULED/17SEP2014	TL:1/LIVER	RIGHT LOBE OF LIVER METASTASIS	CT		50	
	UNSCHEDULED/17SEP2014	TL:2/LIVER	RIGHT LOBE OF LIVER METASTASIS	CT		56	
	UNSCHEDULED/17SEP2014	NTL:1/LUNG	LUNG METASTASIS	CT	Present	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
507-0002 /44/M/A1	UNSCHEDULED/17SEP2014	NTL:2/LIVE	HEPATIC METASTASIS	CT	New	.	
	Summary:					.	SLD = 106, %CN = 26.19, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 17SEP2014
508-0002 /64/M/A1	SCREENING/14FEB2014	TL:1/LUNG	LEFT UPPER LUNG	CT		19	
	SCREENING/14FEB2014	TL:2/LUNG	RIGHT LOWER LUNG	CT		23	SLD = 42
	SCREENING/14FEB2014	NTL:1/LUNG	MULTIPLE LUNG METASTASES	CT		.	
	SCREENING/14FEB2014	NTL:2/LIVE	MULTIPLE LIVER LESIONS	CT		.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
508-0002 /64/M/A1	SCREENING/14FEB2014	NTL:3/LIVE	HEPATIC VEIN TUMOR THROMBUS	CT		.	
	SCREENING/14FEB2014	NTL:4/LIVE	PORTAL VEIN TUMOR THROMBUS	CT		.	
	SCREENING/14FEB2014	NTL:5/NODE	RETROPERITONEAL	CT		.	
508-0004 /58/M/A1	SCREENING/26AUG2014	TL:1/RETRO	LYMPH NODE	CT		63	
	SCREENING/26AUG2014	TL:2/RETRO	LYMPH NODE	CT		43	SLD = 106
	SCREENING/26AUG2014	NTL:1/LIVE	NODULE	CT		.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
508-0004 /58/M/A1	SCREENING/26AUG2014	NTL:2/NODE	LYMPH NODE	CT		.	
509-0003 /39/M/A1	SCREENING/17JUL2014	TL:1/LIVER	THE RIGHT HEPATIC LOBE LESIONS (PRIMARY)	CT		110	SLD = 110
	SCREENING/17JUL2014	NTL:1/NODE	PARAAORTIC LYMPH NODE	CT		.	
	SCREENING/17JUL2014	NTL:2/BONE	LUMBAR VERTEBRAL METASTASES	CT		.	
	WEEK12/14OCT2014	TL:1/LIVER	THE RIGHT HEPATIC LOBE LESIONS (PRIMARY)	CT		140	
	WEEK12/14OCT2014	NTL:1/NODE	PARAAORTIC LYMPH NODE	CT	UP	.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
509-0003 /39/M/A1	WEEK12/14OCT2014	NTL:2/BONE	LUMBAR VERTEBRAL METASTASES	CT	Present	.	
	WEEK12/14OCT2014	NTL:3/LIVE	LIVER V, IV CECTION NEW LESIONS/METASTATIC	CT	New	.	
	WEEK12/14OCT2014	NTL:4/ASCI	PERITONEUM/METASTATIC	CT	New	.	
	Summary:					.	SLD = 140, %CN = 27.27, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 09OCT2014
510-0001 /67/M/A1	SCREENING/21FEB2014	TL:1/LIVER	TRANSFER	CT		20	SLD = 20
	SCREENING/21FEB2014	NTL:1/LIVE	TRANSFER	CT		.	

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Listing 16.2.6.2
Tumor Assessment Summary Listing
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Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
510-0001 /67/M/A1	WEEK12/15MAY2014	TL:1/LIVER	TRANSFER	CT		5	
	WEEK12/15MAY2014	NTL:1/LIVE	TRANSFER	CT	Present	.	
	Summary:					.	SLD = 5, %CN = -75, TL: PR, NTL: IncompleteResponse/SD, OR: PR, PD confirmed: No
	WEEK24/06AUG2014	TL:1/LIVER	TRANSFER	CT		5	
	WEEK24/06AUG2014	NTL:1/LIVE	TRANSFER	CT	Present	.	
	Summary:					.	SLD = 5, %CN = 0, TL: PR, NTL: IncompleteResponse/SD, OR: PR, PD confirmed: No

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Tumor Assessment Summary Listing
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Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
510-0001 /67/M/A1	WEEK36/30OCT2014	TL:1/LIVER	TRANSFER	CT		5	
	WEEK36/30OCT2014	NTL:1/LIVE	TRANSFER	CT	Present	.	
	Summary:					.	SLD = 5, %CN = 0, TL: PR, NTL: IncompleteResponse/SD, OR: PR, PD confirmed: No
	UNSCHEDULED/08DEC2014	TL:1/LIVER	TRANSFER	CT		5	
	UNSCHEDULED/08DEC2014	NTL:1/LIVE	TRANSFER	CT	Present	.	
	UNSCHEDULED/08DEC2014	NTL:2/LIVE	TANSFER	CT	New	.	

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Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
510-0001 /67/M/A1	Summary:					.	SLD = 5, %CN = 0, TL: PR, NTL: PD, OR: PD, PD confirmed: Yes, 08DEC2014
510-0003 /43/M/A1	SCREENING/04JUN2014	TL:1/LIVER	THE LEFT HEPATIC LOBE	CT		61	
	SCREENING/04JUN2014	TL:2/NODES	RETROPERITONEAL LYMPH NODE METASTASES	CT		50	SLD = 111
	SCREENING/04JUN2014	NTL:1/LIVE	INTRAHEPATIC METASTASES	CT		.	
	SCREENING/04JUN2014	NTL:2/LUNG	METASTASES TO THE LUNGS	CT		.	
	SCREENING/04JUN2014	NTL:3/NODE	RETROPERITONEAL LYMPH NODE METASTASES	CT		.	

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[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
510-0003 /43/M/A1	UNSCHEDULED/14AUG2014	TL:1/LIVER	LEFT LOBE OF LIVER	CT		60	
	UNSCHEDULED/14AUG2014	TL:2/NODES	RETROPERITONEAL LYMPH NODE METASTASES	CT		81	
	UNSCHEDULED/14AUG2014	NTL:1/LIVE	INTRAHEPATIC METASTASES	CT	Present	.	
	UNSCHEDULED/14AUG2014	NTL:2/LUNG	METASTASES TO THE LUNGS	CT	Present	.	
	UNSCHEDULED/14AUG2014	NTL:3/NODE	RETROPERITONEAL LYMPH NODE METASTASES	CT	Present	.	
	UNSCHEDULED/14AUG2014	NTL:4/SPLE	THE SPLEEN METASTASES	CT	New	.	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
510-0003 /43/M/A1	Summary:					.	SLD = 141, %CN = 27.03, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 14AUG2014
513-0003 /46/M/A1	SCREENING/24APR2014	TL:1/LIVER	POSTERIOR SEGMENT OF RIGHT LIVER LOBE ,THE PRIMARY	CT		99	
	SCREENING/24APR2014	NTL:2/ADRE	THE LEFT ADRENAL GLAND,METASTASIS.	CT		.	
	SCREENING/25APR2014	TL:2/LUNG	ANTERIOR SEGMENT OF UPPER LOBE OF RIGHT LUNG,METASTASIS.	CT		33	
	SCREENING/25APR2014	TL:3/LUNG	UPPER LOBE OF RIGHT LUNG, ADJACENT TO HILUS PULMONIS,METASTASIS.	CT		31	SLD = 163
	SCREENING/25APR2014	NTL:1/LUNG	DOUBLE LUNG,METASTASIS.	CT		.	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
515-0005 /45/M/A1	SCREENING/16JUN2014	TL:1/LIVER	SECTION II OF LIVER	CT		18	
	SCREENING/16JUN2014	TL:2/LIVER	SECTION VII OF LIVER	CT		17	SLD = 35
	SCREENING/16JUN2014	NTL:1/LIVE	LIVER DIFFUSE MULTIPLE LESIONS	CT		.	
	WEEK12/09SEP2014	TL:1/LIVER	SECTION II OF LIVER	CT		26	
	WEEK12/09SEP2014	TL:2/LIVER	SECTION VII OF LIVER	CT		32	
	WEEK12/09SEP2014	NTL:1/LIVE	LIVER DIFFUSE MULTIPLE LESIONS	CT	UP	.	

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
515-0005 /45/M/A1	WEEK12/09SEP2014	NTL:2/PLEU	BILATERAL PLEURAL EFFUSION	CT	New	.	
	WEEK12/09SEP2014	NTL:3/ASCI	ASCITES	CT	New	.	
	WEEK12/09SEP2014	NTL:4/LUNG	UNDER THE LEFT LUNG,SMALL NODULAR METASTASIS LESION	CT	New	.	
	Summary:					.	SLD = 58, %CN = 65.71, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 09SEP2014
517-0003 /45/M/A1	SCREENING/14MAY2014	TL:1/LIVER	THE FIFTH LOBE OF LIVER	CT		32	
	SCREENING/14MAY2014	TL:2/LIVER	THE SEVENTH LOBE OF LIVER	CT		29	SLD = 61

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
517-0003 /45/M/A1	WEEK12/01AUG2014	TL:1/LIVER	THE FIFTH LOBE OF LIVER	CT		57	
	WEEK12/01AUG2014	TL:2/LIVER	THE SEVENTH LOBE OF LIVER	CT		58	
	WEEK12/01AUG2014	NTL:1/LIVE		CT	New	.	
	Summary:					.	SLD = 115, %CN = 88.52, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 01AUG2014
517-0010 /67/M/A1	SCREENING/05NOV2014	TL:1/LIVER	THE EIGHTH LEAF OF THE LIVER	CT		18	
	SCREENING/05NOV2014	TL:2/LIVER	THE FOURTH A LEAF OF THE LIVER	CT		14	SLD = 32

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.2
Tumor Assessment Summary Listing
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit or Summary/Date of Assessment	Lesion Type:Lesion No./Side Code	Description	Method	Lesion Status[3]	Diameter (mm)	Summary[4]
517-0010 /67/M/A1	SCREENING/05NOV2014	NTL:1/LIVE		CT		.	
	WEEK12/02FEB2015	TL:1/LIVER	THE EIGHTH LEAF OF THE LIVER	CT		25	
	WEEK12/02FEB2015	TL:2/LIVER	THE FOURTH A LEAF OF THE LIVER	CT		20	
	WEEK12/02FEB2015	NTL:1/LIVE		CT	UP	.	
	Summary:					.	SLD = 45, %CN = 40.63, TL: PD, NTL: PD, OR: PD, PD confirmed: Yes, 02FEB2015

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[3] UP=Unequivocally Progressed
[4] SLD = Sum of Longest Diameters, % CN = % Change Nadir, TL:Target Lesion, NTL: Non-Targte Lesion, OR: Overall Response

Listing 16.2.6.3
Progression-Free Survival
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
101-0001/59/M/A2	26JUL2011	.	03JAN2012	03JAN2012	5.4+	Lost to follow-up
101-0005/77/M/W2	08AUG2011	17APR2013	25OCT2011	.	2.6	
101-0006/62/M/W2	12AUG2011	17APR2012	12OCT2011	.	2.1	
101-0007/77/M/A1	16AUG2011	11MAY2013	08NOV2011	.	2.8	
101-0008/83/M/BL	22AUG2011	11AUG2012	15NOV2011	.	2.8	
101-0009/82/M/A1	14SEP2011	05SEP2012	20DEC2011	.	3.3	
101-0011/75/F/W2	14NOV2011	16DEC2011	29NOV2011	.	0.5	
101-0012/68/M/W2	29NOV2011	02AUG2012	18JAN2012	.	1.7	
101-0013/66/F/A5	10JAN2012	14JUL2014	23MAR2012	.	2.5	
101-0016/61/M/A4	10JAN2012	.	11SEP2012	.	14	
101-0018/51/M/A1	21FEB2012	31MAR2012	.	16FEB2012	0+	No post-treatment radiological assessment

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[3] Duration of Progression-Free Survival is calculated as (date of death or disease progression — date of randomization + 1) / 30. Censored records are indicated with '+'. For censoring rules, refer to Table 2 in the Statistical Analysis Plan.

Listing 16.2.6.3
Progression-Free Survival
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
101-0019/68/M/W2	28FEB2012	20MAR2014	15MAY2012	.	2.6	
101-0021/74/M/W2	20MAR2012	10JUN2013	29MAY2012	.	2.4	
101-0022/55/M/BL	20MAR2012	31MAY2012	13APR2012	.	0.8	
101-0023/70/M/W2	30MAR2012	18DEC2012	.	14JUN2012	2.6+	No progression
101-0024/35/F/A4	01MAY2012	05NOV2013	10JUL2012	.	2.4	
101-0025/57/F/W2	20APR2012	03AUG2012	15JUN2012	.	1.9	
101-0026/82/M/W2	15MAY2012	16MAY2013	11JAN2013	.	8.1	
101-0028/60/M/W2	15JUN2012	02APR2013	.	07SEP2012	2.8+	No progression
101-0029/70/M/A1	18JUN2012	02AUG2013	28AUG2012	.	2.4	
101-0030/51/M/W2	05JUL2012	20DEC2012	05SEP2012	.	2.1	
101-0032/84/M/W2	01AUG2012	06JUL2013	.	09OCT2012	2.3+	No progression
101-0033/66/F/W2	03AUG2012	.	04JAN2013	.	5.2	

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[3] Duration of Progression-Free Survival is calculated as (date of death or disease progression — date of randomization + 1) / 30. Censored records are indicated with '+'. For censoring rules, refer to Table 2 in the Statistical Analysis Plan.

Listing 16.2.6.3
Progression-Free Survival
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
101-0036/67/M/A4	23OCT2012	05FEB2013	12DEC2012	.	1.7	
101-0037/57/M/A1	07DEC2012	.	.	.	0+	Lost to follow-up and no post-treatment radio
101-0038/56/M/W2	05FEB2013	01FEB2014	.	30JAN2013	0+	No post-treatment radiological assessment
101-0039/77/F/W2	05APR2013	.	27NOV2013	.	7.9	
101-0040/60/M/W2	27JUN2013	03NOV2013	06AUG2013	.	1.4	
101-0041/54/M/W2	30JUL2013	24NOV2014	.	12JUL2013	0+	No post-treatment radiological assessment
101-0042/64/M/W2	05AUG2013	12OCT2014	.	15JUL2013	0+	No post-treatment radiological assessment

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[3] Duration of Progression-Free Survival is calculated as (date of death or disease progression — date of randomization + 1) / 30. Censored records are indicated with '+'. For censoring rules, refer to Table 2 in the Statistical Analysis Plan.

Listing 16.2.6.3
Progression-Free Survival
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
101-0044/78/M/W2	17OCT2013	24OCT2014	27DEC2013	.	2.4	
101-0045/74/F/W2	21OCT2013	26APR2014	16JAN2014	.	2.9	
101-0046/70/M/OTH	22OCT2013	28MAR2014	02JAN2014	.	2.4	
101-0047/52/M/W2	22OCT2013	26FEB2015	16DEC2013	.	1.9	
101-0048/66/F/W2	22OCT2013	.	30DEC2013	.	2.3	
101-0049/71/M/A8	28OCT2013	.	08JAN2014	.	2.4	
101-0050/59/M/W2	29OCT2013	15JAN2014	05DEC2013	.	1.3	
102-0001/53/M/BL	25APR2012	09NOV2012	07JUN2012	.	1.5	
102-0003/63/M/BL	12SEP2012	25JAN2013	23NOV2012	.	2.4	
102-0008/64/M/BL	08JAN2014	10FEB2014	.	02JAN2014	0+	No post-treatment radiological assessment
102-0009/58/M/W2	29OCT2014	04FEB2015	09DEC2014	.	1.4	

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[3] Duration of Progression-Free Survival is calculated as (date of death or disease progression — date of randomization + 1) / 30. Censored records are indicated with '+'. For censoring rules, refer to Table 2 in the Statistical Analysis Plan.

Listing 16.2.6.3
Progression-Free Survival
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
103-0001/56/M/W2	11MAY2012	23OCT2012	26JUL2012	.	2.6	
103-0003/66/M/W2	15FEB2013	26OCT2013	23JUL2013	.	5.3	
103-0004/40/F/A1	17APR2014	01SEP2014	03JUN2014	.	1.6	
104-0003/56/F/W2	19JUL2012	19OCT2012	.	16JUL2012	0+	No post-treatment radiological assessment
104-0004/74/M/W2	23OCT2012	24MAY2013	.	01OCT2012	0+	No post-treatment radiological assessment
104-0008/55/M/PI	03SEP2013	11SEP2014	.	29NOV2013	2.9+	No progression
104-0010/71/F/A8	08JAN2014	.	17SEP2014	.	8.4	
104-0012/78/F/A2	02OCT2014	25MAR2015	29NOV2014	.	2	
106-0001/42/F/W2	28FEB2012	05OCT2012	29JUN2012	.	4.1	
107-0002/71/M/W2	23AUG2012	23DEC2013	07NOV2012	.	2.6	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Duration of Progression-Free Survival is calculated as (date of death or disease progression — date of randomization + 1) / 30. Censored records are indicated with '+'. For censoring rules, refer to Table 2 in the Statistical Analysis Plan.

Listing 16.2.6.3
Progression-Free Survival
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
107-0003/73/M/BL	22FEB2013	07MAY2013	.	07FEB2013	0+	No post-treatment radiological assessment
107-0004/63/M/W2	01MAR2013	.	.	21MAY2013	2.7+	No progression
107-0006/60/M/W2	14MAY2013	04APR2014	29JUL2013	.	2.6	
108-0001/60/F/W2	20MAR2012	19JUN2012	18JUN2012	.	1.5	
108-0002/78/M/BL	31MAY2012	03APR2013	10JUL2012	.	1.2	
108-0004/61/M/W2	18APR2013	22JUL2014	.	.	1	
108-0005/68/M/W2	08MAY2013	19OCT2013	29JUL2013	.	2.8	
108-0008/77/M/W2	09OCT2014	.	17MAR2015	.	5.3	
109-0003/68/M/W2	03MAY2013	09AUG2013	01JUL2013	.	2	
109-0004/57/M/W2	19JUL2013	22FEB2014	07OCT2013	.	2.7	
109-0006/62/M/PI	22AUG2013	25AUG2014	06NOV2013	.	2.6	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Duration of Progression-Free Survival is calculated as (date of death or disease progression — date of randomization + 1) / 30. Censored records are indicated with '+'. For censoring rules, refer to Table 2 in the Statistical Analysis Plan.

Listing 16.2.6.3
Progression-Free Survival
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
109-0007/55/M/W2	05DEC2013	10AUG2014	23APR2014	.	4.7	
109-0008/70/F/W2	22MAY2014	.	18NOV2014	.	5.9	
109-0009/57/M/W2	09JUL2014	25MAY2015	22SEP2014	.	2.5	
109-0010/65/M/W2	09JUL2014	.	24SEP2014	.	2.6	
109-0011/64/M/A4	24SEP2014	.	09DEC2014	.	2.6	
109-0013/64/F/W2	05NOV2014	10MAY2015	13APR2015	.	5.3	
110-0003/63/M/OTH	09JUL2012	01DEC2013	.	17DEC2012	5.4+	No progression
110-0004/53/M/A4	25OCT2012	23NOV2013	.	08JAN2013	2.5+	No progression
110-0005/77/M/W2	15MAR2013	.	.	24MAY2013	2.4+	No progression
110-0007/62/M/A4	17MAY2013	26FEB2014	13JAN2014	.	8.1	
110-0008/63/F/BL	09JUL2013	10FEB2014	.	11JUN2013	0+	No post-treatment radiological assessment

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Duration of Progression-Free Survival is calculated as (date of death or disease progression — date of randomization + 1) / 30. Censored records are indicated with '+'. For censoring rules, refer to Table 2 in the Statistical Analysis Plan.

Listing 16.2.6.3
Progression-Free Survival
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
110-0011/77/M/A1	22JAN2015	.	07APR2015	.	2.5	
111-0001/37/M/A4	12JUL2012	06JUL2014	27JUL2012	.	0.5	
111-0004/64/M/W2	23MAY2013	29AUG2013	.	31JUL2013	2.3+	No progression
111-0006/59/M/W2	03OCT2013	12MAY2014	.	.	7.4	
111-0007/55/M/W2	06FEB2014	.	14APR2014	.	2.3	
112-0006/58/M/W2	26MAR2013	29AUG2013	03JUN2013	.	2.3	
112-0009/50/M/A8	19JUN2013	12DEC2013	04SEP2013	.	2.6	
112-0011/56/M/A4	10JAN2014	28JUN2014	28FEB2014	.	1.7	
112-0012/71/M/W2	23MAY2014	07FEB2015	08AUG2014	.	2.6	
112-0013/28/F/W2	23MAY2014	29OCT2014	.	12JUL2014	1.7+	No progression
112-0014/79/M/A8	06JUN2014	24OCT2014	22AUG2014	.	2.6	
112-0015/66/M/A8	24OCT2014	02JAN2015	12DEC2014	.	1.7	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Duration of Progression-Free Survival is calculated as (date of death or disease progression — date of randomization + 1) / 30. Censored records are indicated with '+'. For censoring rules, refer to Table 2 in the Statistical Analysis Plan.

Listing 16.2.6.3
Progression-Free Survival
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
113-0001/60/M/W2	24AUG2012	20JAN2014	06FEB2013	.	5.6	
113-0002/64/F/W2	12OCT2012	11APR2014	10JUN2013	.	8.3	
113-0005/58/M/W2	22JAN2014	05APR2014	.	09JAN2014	0+	No post-treatment radiological assessment
113-0008/78/M/A8	13FEB2014	.	.	31JAN2014	0+	No post-treatment radiological assessment
113-0010/59/M/W2	28APR2014	22JUN2014	.	18APR2014	0+	No post-treatment radiological assessment
113-0013/56/M/W2	04NOV2014	.	13JAN2015	.	2.4	
113-0016/72/M/A8	03FEB2015	.	21APR2015	.	2.6	
114-0003/59/M/W2	29NOV2012	07OCT2013	.	10APR2013	4.4+	No progression
114-0005/73/M/W2	05DEC2013	.	.	06FEB2014	2.1+	Lost to follow-up

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Duration of Progression-Free Survival is calculated as (date of death or disease progression — date of randomization + 1) / 30. Censored records are indicated with '+'. For censoring rules, refer to Table 2 in the Statistical Analysis Plan.

Listing 16.2.6.3
Progression-Free Survival
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
114-0007/60/F/W2	18NOV2014	.	.	01MAY2015	5.5+	No progression
115-0001/59/F/A4	27NOV2012	.	11FEB2013	.	2.6	
115-0002/45/F/W2	27NOV2012	18FEB2013	10JAN2013	.	1.5	
115-0003/63/M/W2	17JAN2013	17AUG2013	.	24JUN2013	5.3+	No progression
115-0008/51/M/A8	19JUN2013	17JUL2013	.	.	1	
115-0009/85/M/W2	12DEC2013	01SEP2014	21MAY2014	.	5.4	
115-0011/56/M/W2	05JUN2014	27NOV2014	29AUG2014	.	2.9	
115-0014/72/M/W2	10FEB2015	10MAY2015	.	21JAN2015	0+	No post-treatment radiological assessment
116-0002/67/F/W2	18MAR2013	14DEC2013	18NOV2013	.	8.1	
116-0003/66/M/BL	28MAR2013	29MAY2013	21MAY2013	.	1.8	
117-0001/69/M/W2	02APR2013	08NOV2014	12JUN2013	.	2.4	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Duration of Progression-Free Survival is calculated as (date of death or disease progression — date of randomization + 1) / 30. Censored records are indicated with '+'. For censoring rules, refer to Table 2 in the Statistical Analysis Plan.

Listing 16.2.6.3
Progression-Free Survival
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
118-0001/67/F/A8	09AUG2013	29NOV2014	29OCT2013	.	2.7	
119-0001/80/M/A8	21JAN2014	01AUG2014	.	14JAN2014	0+	No post-treatment radiological assessment
121-0001/62/M/W2	14FEB2014	.	.	06MAY2014	2.7+	Lost to follow-up
121-0004/64/F/W2	02JAN2015	06MAR2015	.	30DEC2014	0+	No post-treatment radiological assessment
201-0001/68/F/W2	25JAN2012	24SEP2012	24APR2012	.	3	
201-0005/73/M/W2	19JUL2012	14JAN2013	10OCT2012	.	2.8	
201-0008/79/M/W2	16MAY2013	15OCT2013	.	29JUL2013	2.5+	No progression
201-0011/73/M/W2	04JUL2013	.	20SEP2013	.	2.6	
201-0012/79/M/W2	24JUL2013	.	18SEP2014	.	14	
201-0013/67/F/W2	24JUL2013	19MAY2014	11OCT2013	.	2.7	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Duration of Progression-Free Survival is calculated as (date of death or disease progression — date of randomization + 1) / 30. Censored records are indicated with '+'. For censoring rules, refer to Table 2 in the Statistical Analysis Plan.

Listing 16.2.6.3
Progression-Free Survival
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
201-0016/72/M/W2	14NOV2013	30APR2015	18APR2014	.	5.2	
201-0017/82/M/W2	28NOV2013	05MAR2015	.	25NOV2013	0+	No post-treatment radiological assessment
201-0018/78/F/W2	06DEC2013	21JAN2014	.	14NOV2013	0+	No post-treatment radiological assessment
201-0019/68/M/W2	19DEC2013	.	12MAR2014	.	2.6	
201-0020/67/M/W2	23JAN2014	.	.	09JAN2014	0+	No post-treatment radiological assessment
201-0021/54/M/W2	13FEB2014	10JUN2014	05MAY2014	.	2.6	
201-0024/74/M/W2	29JAN2015	11APR2015	13MAR2015	.	1.5	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Duration of Progression-Free Survival is calculated as (date of death or disease progression — date of randomization + 1) / 30. Censored records are indicated with '+'. For censoring rules, refer to Table 2 in the Statistical Analysis Plan.

Listing 16.2.6.3
Progression-Free Survival
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
201-0025/75/M/W2	29JAN2015	.	.	12JAN2015	0+	No post-treatment radiological assessment
203-0001/61/F/W2	06MAR2012	06JUN2012	.	23FEB2012	0+	No post-treatment radiological assessment
203-0002/72/M/W2	06MAR2012	19APR2012	.	.	1.5	
203-0005/53/M/W2	05APR2012	26JUN2013	09JUL2012	.	3.2	
203-0013/68/M/W2	30DEC2013	17MAR2014	.	03DEC2013	0+	No post-treatment radiological assessment
203-0015/85/M/W2	30JAN2014	01JUN2014	10APR2014	.	2.4	
203-0017/58/M/W2	03MAR2014	29AUG2014	.	25FEB2014	0+	No post-treatment radiological assessment

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Duration of Progression-Free Survival is calculated as (date of death or disease progression — date of randomization + 1) / 30. Censored records are indicated with '+'. For censoring rules, refer to Table 2 in the Statistical Analysis Plan.

Listing 16.2.6.3
Progression-Free Survival
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
203-0018/58/F/W2	04APR2014	24JUL2014	.	26MAR2014	0+	No post-treatment radiological assessment
205-0001/77/M/W2	24FEB2012	06NOV2014	01OCT2013	.	19.5	
205-0004/77/F/W2	20MAR2012	24JUN2012	05JUN2012	.	2.6	
205-0008/76/M/W2	27APR2012	30JUL2012	.	03APR2012	0+	No post-treatment radiological assessment
205-0012/73/F/W2	06DEC2012	08JAN2013	.	27NOV2012	0+	No post-treatment radiological assessment
205-0015/71/M/W2	19JUN2013	22JUN2014	.	11JUN2013	0+	No post-treatment radiological assessment
205-0016/70/M/W2	25JUN2013	.	.	21APR2015	22.2+	No progression

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Duration of Progression-Free Survival is calculated as (date of death or disease progression — date of randomization + 1) / 30. Censored records are indicated with '+'. For censoring rules, refer to Table 2 in the Statistical Analysis Plan.

Listing 16.2.6.3
Progression-Free Survival
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
205-0017/71/M/W2	08AUG2013	18AUG2014	14JAN2014	.	5.3	
205-0020/82/M/W2	11OCT2013	18MAY2014	27DEC2013	.	2.6	
205-0022/67/M/W2	05NOV2013	22NOV2013	.	08OCT2013	0+	No post-treatment radiological assessment
205-0024/80/M/W2	03DEC2013	16AUG2014	25FEB2014	.	2.8	
205-0025/63/F/W2	29NOV2013	21MAR2014	27FEB2014	.	2.5	
207-0001/81/F/W2	19MAR2012	23OCT2012	.	06FEB2012	0+	No post-treatment radiological assessment
207-0005/74/M/W2	12JUN2012	.	.	.	0+	Lost to follow-up and no post-treatment radio
207-0006/73/M/W2	18JUN2012	03OCT2012	19SEP2012	.	3	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Duration of Progression-Free Survival is calculated as (date of death or disease progression — date of randomization + 1) / 30. Censored records are indicated with '+'. For censoring rules, refer to Table 2 in the Statistical Analysis Plan.

Listing 16.2.6.3
Progression-Free Survival
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
207-0008/66/M/W2	09JUL2012	28AUG2012	.	11JUN2012	0+	No post-treatment radiological assessment
207-0011/78/M/W2	21JAN2013	06MAR2013	.	11JAN2013	0+	No post-treatment radiological assessment
207-0015/77/M/W2	13AUG2013	02OCT2014	23OCT2013	.	2.4	
207-0020/77/M/W2	18JUN2014	17SEP2014	05SEP2014	.	2.6	
207-0021/74/M/W2	19JUN2014	30MAR2015	20FEB2015	.	8	
207-0022/74/M/W2	10JUL2014	.	.	23SEP2014	2.5+	No progression
208-0001/59/M/W2	20SEP2012	.	.	17JUN2015	33.4+	No progression
208-0002/82/F/W2	20SEP2012	08MAR2013	12DEC2012	.	2.8	
208-0006/69/F/W2	28AUG2013	20JUL2014	13NOV2013	.	2.6	
208-0007/53/M/W2	07JUL2014	.	08OCT2014	.	2.7	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Duration of Progression-Free Survival is calculated as (date of death or disease progression — date of randomization + 1) / 30. Censored records are indicated with '+'. For censoring rules, refer to Table 2 in the Statistical Analysis Plan.

Listing 16.2.6.3
Progression-Free Survival
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
209-0001/66/M/W2	15NOV2012	04MAY2013	31JAN2013	.	2.6	
209-0004/74/M/W2	09APR2013	26OCT2013	24JUN2013	.	2.6	
209-0008/66/M/W2	11JUL2013	01NOV2013	30SEP2013	.	2.7	
209-0012/63/M/W2	03DEC2013	04AUG2014	22MAY2014	.	5.7	
209-0013/52/M/W2	23DEC2013	.	.	.	2.6	
210-0001/67/M/W2	30AUG2013	30APR2014	06MAR2014	.	6	
210-0002/80/M/W2	09OCT2013	20MAY2015	04SEP2014	.	11	
210-0007/72/M/W2	07JUL2014	.	.	04JUN2015	11.1+	No progression
210-0009/49/F/W2	10NOV2014	.	29JAN2015	.	2.6	
210-0011/73/M/W2	17NOV2014	04MAR2015	05FEB2015	.	2.6	
210-0012/47/F/W2	16DEC2014	.	26MAR2015	.	3.1	
210-0014/71/F/W2	26JAN2015	.	07MAY2015	.	3.1	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Duration of Progression-Free Survival is calculated as (date of death or disease progression — date of randomization + 1) / 30. Censored records are indicated with '+'. For censoring rules, refer to Table 2 in the Statistical Analysis Plan.

Listing 16.2.6.3
Progression-Free Survival
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
251-0001/55/F/W2	24JUL2012	26DEC2012	.	16OCT2012	2.8+	No progression
252-0002/76/M/W2	28AUG2012	26MAY2013	.	31JUL2012	0+	No post-treatment radiological assessment
252-0003/68/M/W2	28DEC2012	24AUG2013	19MAR2013	.	2.7	
252-0007/77/M/W2	25FEB2014	03MAY2014	.	25MAR2014	0+	No post-treatment radiological assessment
252-0011/81/M/BL	24NOV2014	.	.	07MAY2015	5.5+	No progression
253-0002/63/M/W2	09MAR2012	09AUG2012	25MAY2012	.	2.6	
253-0010/76/M/W2	07JUN2013	30MAY2014	13NOV2013	.	5.3	
254-0001/69/M/W2	17MAY2012	04DEC2012	08AUG2012	.	2.8	
257-0001/47/M/A4	04APR2012	10SEP2012	.	19MAR2012	0+	No post-treatment radiological assessment

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Duration of Progression-Free Survival is calculated as (date of death or disease progression — date of randomization + 1) / 30. Censored records are indicated with '+'. For censoring rules, refer to Table 2 in the Statistical Analysis Plan.

Listing 16.2.6.3
Progression-Free Survival
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
257-0002/56/M/W2	18APR2012	22DEC2012	.	30MAR2012	0+	No post-treatment radiological assessment
257-0007/80/M/W2	21FEB2013	20JAN2014	09MAY2013	.	2.6	
257-0008/80/F/W2	26MAR2013	06JUN2014	13JUN2013	.	2.7	
257-0010/42/M/BL	23MAY2013	.	05AUG2013	.	2.5	
257-0012/75/M/W2	13MAY2013	25JUN2013	.	.	1.5	
257-0015/69/F/BL	14APR2014	25MAY2014	.	07APR2014	0+	No post-treatment radiological assessment
257-0017/74/M/A8	02MAY2014	10JUL2015	21JUL2014	.	2.7	
257-0018/53/M/A6	28APR2014	31MAY2014	.	11APR2014	0+	No post-treatment radiological assessment
257-0022/60/M/W2	01DEC2014	29MAY2015	02FEB2015	.	2.1	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Duration of Progression-Free Survival is calculated as (date of death or disease progression — date of randomization + 1) / 30. Censored records are indicated with '+'. For censoring rules, refer to Table 2 in the Statistical Analysis Plan.

Listing 16.2.6.3
Progression-Free Survival
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
257-0024/75/M/W2	22DEC2014	31MAR2015	.	15DEC2014	0+	No post-treatment radiological assessment
257-0025/69/M/BL	22DEC2014	30APR2015	09MAR2015	.	2.6	
257-0026/65/M/W2	19JAN2015	.	.	05JAN2015	0+	No post-treatment radiological assessment
257-0027/52/M/A6	19JAN2015	02MAR2015	.	29DEC2014	0+	No post-treatment radiological assessment
258-0005/64/M/OTH	09AUG2013	16MAY2014	.	09OCT2013	2.1+	No progression
258-0007/74/M/W2	09OCT2013	23NOV2013	.	02OCT2013	0+	No post-treatment radiological assessment

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Duration of Progression-Free Survival is calculated as (date of death or disease progression — date of randomization + 1) / 30. Censored records are indicated with '+'. For censoring rules, refer to Table 2 in the Statistical Analysis Plan.

Listing 16.2.6.3
Progression-Free Survival
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
258-0008/70/M/W2	18NOV2013	26MAR2014	.	06NOV2013	0+	No post-treatment radiological assessment
258-0009/64/M/W2	19MAY2014	30APR2015	29OCT2014	.	5.5	
258-0010/53/M/W2	02JUN2014	.	12NOV2014	.	5.5	
258-0012/66/F/W2	15JUL2014	09APR2015	09OCT2014	.	2.6	
258-0015/65/M/W2	02DEC2014	.	.	02DEC2014	0+	No post-treatment radiological assessment
259-0001/68/F/W2	03JUN2013	.	.	30APR2014	11.1+	No progression
259-0002/54/F/W2	09SEP2013	06JUL2014	27NOV2013	.	2.7	
260-0003/81/M/A7	05NOV2014	.	.	03JUL2015	8+	No progression
301-0005/61/M/A2	24MAY2012	24NOV2012	12AUG2012	.	2.6	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Duration of Progression-Free Survival is calculated as (date of death or disease progression — date of randomization + 1) / 30. Censored records are indicated with '+'. For censoring rules, refer to Table 2 in the Statistical Analysis Plan.

Listing 16.2.6.3
Progression-Free Survival
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
301-0007/55/F/A2	04JAN2013	26MAR2013	.	02JAN2013	0+	No post-treatment radiological assessment
301-0009/55/M/A2	11JAN2013	01MAY2013	28MAR2013	.	2.6	
302-0002/32/F/A2	07NOV2011	15DEC2011	.	03NOV2011	0+	No post-treatment radiological assessment
302-0004/57/M/A2	10JAN2012	21MAR2012	.	05JAN2012	0+	No post-treatment radiological assessment
302-0007/76/M/A2	14FEB2012	23MAR2013	03MAY2012	.	2.7	
302-0008/37/M/A2	28FEB2012	07SEP2012	14MAY2012	.	2.6	
302-0010/45/M/A2	17APR2012	08DEC2012	05JUL2012	.	2.7	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
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Listing 16.2.6.3
Progression-Free Survival
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
302-0011/52/M/A2	24APR2012	06JUN2012	.	02APR2012	0+	No post-treatment radiological assessment
302-0015/60/M/A2	16APR2013	10MAR2014	08JUL2013	.	2.8	
302-0016/60/M/A2	16APR2013	28JAN2014	09JUL2013	.	2.6	
302-0019/52/M/A2	14MAY2013	20MAY2014	05AUG2013	.	2.6	
302-0022/65/M/A2	09JUL2013	05OCT2013	23SEP2013	.	2.4	
302-0023/68/M/A2	10SEP2013	07SEP2014	.	09SEP2013	0+	No post-treatment radiological assessment
302-0024/66/F/A2	24SEP2013	09APR2015	10DEC2013	.	2.6	
302-0025/40/M/A2	22OCT2013	06JUL2014	.	17OCT2013	0+	No post-treatment radiological assessment
302-0026/49/M/A2	12NOV2013	.	15JUL2014	.	8.2	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Duration of Progression-Free Survival is calculated as (date of death or disease progression — date of randomization + 1) / 30. Censored records are indicated with '+'. For censoring rules, refer to Table 2 in the Statistical Analysis Plan.

Listing 16.2.6.3
Progression-Free Survival
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
303-0001/50/M/A2	03FEB2012	18FEB2013	25APR2012	.	2.5	
303-0003/47/M/A2	28NOV2012	20APR2013	20FEB2013	.	2.7	
303-0004/18/M/A2	10DEC2012	10MAY2013	27FEB2013	.	2.5	
303-0006/64/M/A2	10APR2013	25JUL2013	29MAY2013	.	1.4	
303-0007/50/M/A2	24JUL2013	25OCT2013	.	12JUL2013	0+	No post-treatment radiological assessment
304-0001/54/M/A2	05NOV2012	08FEB2013	14DEC2012	.	1.3	
304-0005/58/M/A2	05JUN2013	05JUL2013	29JUN2013	.	0.8	
305-0002/57/M/A2	14FEB2012	23DEC2013	24FEB2012	.	0.4	
305-0003/50/M/A2	15FEB2012	07AUG2013	03AUG2012	.	5.7	
305-0005/48/M/A2	21FEB2012	09MAY2012	.	16FEB2012	0+	No post-treatment radiological assessment

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Duration of Progression-Free Survival is calculated as (date of death or disease progression — date of randomization + 1) / 30. Censored records are indicated with '+'. For censoring rules, refer to Table 2 in the Statistical Analysis Plan.

Listing 16.2.6.3
Progression-Free Survival
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
305-0006/65/M/A2	08MAR2012	22OCT2012	22AUG2012	.	5.6	
305-0009/45/F/A2	11APR2012	15JUL2014	26SEP2012	.	5.6	
305-0010/64/F/A2	18APR2012	30AUG2013	10JUL2012	.	2.8	
305-0011/68/M/A2	27APR2012	26NOV2012	10AUG2012	.	3.5	
305-0012/62/F/A2	04MAY2012	.	11JAN2013	.	8.4	
305-0014/61/F/A2	10JUL2012	09MAR2013	23SEP2012	.	2.5	
305-0019/35/M/A2	11SEP2012	13NOV2012	.	07SEP2012	0+	No post-treatment radiological assessment
305-0023/54/M/A2	02JAN2013	03SEP2013	.	.	2.8	
305-0025/77/F/A2	22JAN2013	02AUG2013	16APR2013	.	2.8	
305-0026/45/M/A2	26FEB2013	20DEC2013	.	13AUG2013	5.6+	No progression
305-0028/73/F/A2	15MAR2013	16JUN2013	05JUN2013	.	2.8	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
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Listing 16.2.6.3
Progression-Free Survival
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
305-0030/61/M/A2	02APR2013	26JUN2014	.	28MAR2013	0+	No post-treatment radiological assessment
305-0031/29/M/A2	02APR2013	13MAY2013	.	29MAR2013	0+	No post-treatment radiological assessment
305-0034/53/M/A2	03JUL2013	24AUG2013	05AUG2013	.	1.1	
305-0036/38/M/A2	05SEP2013	.	28NOV2013	22NOV2013	2.6+	Lost to follow-up
305-0037/50/M/A2	24OCT2013	24JUN2014	.	09JAN2014	2.6+	No progression
305-0039/35/M/A2	28NOV2013	26DEC2013	.	.	1	
305-0040/61/M/A2	15NOV2013	26JUN2014	.	11NOV2013	0+	No post-treatment radiological assessment
305-0043/70/M/A2	01JUL2014	.	26SEP2014	.	2.6	
305-0044/67/M/A2	08JUL2014	.	07OCT2014	.	2.8	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Duration of Progression-Free Survival is calculated as (date of death or disease progression — date of randomization + 1) / 30. Censored records are indicated with '+'. For censoring rules, refer to Table 2 in the Statistical Analysis Plan.

Listing 16.2.6.3
Progression-Free Survival
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
305-0045/65/M/A2	17OCT2014	05DEC2014	.	06OCT2014	0+	No post-treatment radiological assessment
305-0047/58/M/A2	25DEC2014	28JAN2015	.	24DEC2014	0+	No post-treatment radiological assessment
305-0048/55/M/A2	24FEB2015	.	13MAY2015	.	2.6	
306-0001/56/M/A2	17FEB2012	04NOV2013	08MAY2012	.	2.6	
306-0002/73/M/A2	14FEB2012	21AUG2012	08MAY2012	.	2.6	
306-0005/69/F/A2	24FEB2012	29JUL2012	26APR2012	.	2.1	
306-0006/43/M/A2	20MAR2012	14MAY2012	12APR2012	.	0.8	
306-0007/56/M/A2	05MAR2012	28NOV2012	24APR2012	.	1.7	
306-0008/40/M/A2	12MAR2012	12JUN2012	.	07MAR2012	0+	No post-treatment radiological assessment

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Duration of Progression-Free Survival is calculated as (date of death or disease progression — date of randomization + 1) / 30. Censored records are indicated with '+'. For censoring rules, refer to Table 2 in the Statistical Analysis Plan.

Listing 16.2.6.3
Progression-Free Survival
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
306-0011/47/M/A2	15MAR2012	02JUN2012	04JUN2012	.	2.6	
306-0012/61/M/A2	02APR2012	22NOV2012	.	11SEP2012	5.4+	No progression
306-0014/47/M/A2	19APR2012	20JUN2012	.	06APR2012	0+	No post-treatment radiological assessment
306-0017/49/M/A2	12JUL2012	16NOV2012	31AUG2012	.	1.4	
306-0019/78/M/A2	22AUG2012	04DEC2012	05NOV2012	.	2.5	
306-0020/63/M/A2	04OCT2012	07JUN2013	24DEC2012	.	2.6	
306-0023/68/M/A2	27NOV2012	28JUN2013	08JAN2013	.	1.3	
306-0026/58/M/A2	04FEB2013	.	17OCT2013	.	8.3	
306-0027/67/M/A2	19FEB2013	.	09JUL2014	.	16.6	
306-0030/63/M/A2	23APR2013	18JUL2013	.	18APR2013	0+	No post-treatment radiological assessment

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Duration of Progression-Free Survival is calculated as (date of death or disease progression — date of randomization + 1) / 30. Censored records are indicated with '+'. For censoring rules, refer to Table 2 in the Statistical Analysis Plan.

Listing 16.2.6.3
Progression-Free Survival
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
306-0031/40/M/A2	15MAY2013	17MAY2014	24JUL2013	.	2.2	
306-0034/65/M/A2	01JUL2013	09AUG2013	01AUG2013	.	0.8	
306-0035/48/M/A2	08JUL2013	01DEC2013	26AUG2013	.	1.5	
306-0036/73/M/A2	09JUL2013	25NOV2013	24SEP2014	.	2.1	
306-0038/66/M/A2	21AUG2013	04MAY2014	06NOV2013	.	2.4	
306-0039/62/M/A2	20AUG2013	15DEC2013	05NOV2013	.	2.4	
306-0040/44/F/A2	24SEP2013	09JUL2014	11MAR2014	.	5.5	
306-0041/62/M/A2	29OCT2013	12MAR2014	24FEB2014	.	3.9	
306-0043/56/M/A2	19MAY2014	07OCT2014	11AUG2014	.	2.6	
307-0002/61/M/A2	03NOV2011	16APR2012	20JAN2012	.	2.6	
307-0003/68/M/A2	10NOV2011	09FEB2013	.	10JUL2012	8.1+	No progression
307-0004/60/M/A2	10NOV2011	18MAR2012	27JAN2012	.	2.4	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Duration of Progression-Free Survival is calculated as (date of death or disease progression — date of randomization + 1) / 30. Censored records are indicated with '+'. For censoring rules, refer to Table 2 in the Statistical Analysis Plan.

Listing 16.2.6.3
Progression-Free Survival
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
307-0008/58/M/A2	20DEC2011	01OCT2012	12MAR2012	.	2.7	
307-0011/75/M/A2	07FEB2012	02APR2012	.	03FEB2012	0+	No post-treatment radiological assessment
307-0014/61/M/A2	16FEB2012	21MAY2013	28JUL2012	.	5.4	
307-0018/70/M/A2	14JUN2012	14JAN2015	16MAY2013	.	11	
307-0020/68/F/A2	16AUG2012	23MAR2013	31OCT2012	.	2.5	
307-0022/59/M/A2	27NOV2012	18APR2013	18FEB2013	.	2.7	
307-0025/68/M/A2	18DEC2012	25SEP2013	03JUN2013	.	5.5	
307-0026/65/M/A2	27DEC2012	09DEC2013	05JUN2013	.	5.3	
307-0030/53/M/A2	06MAR2013	31MAY2013	14MAY2013	.	2.3	
307-0031/60/M/A2	15MAR2013	19DEC2013	18NOV2013	.	8.2	
307-0032/74/F/A2	11APR2013	11MAY2013	.	.	1	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Duration of Progression-Free Survival is calculated as (date of death or disease progression — date of randomization + 1) / 30. Censored records are indicated with '+'. For censoring rules, refer to Table 2 in the Statistical Analysis Plan.

Listing 16.2.6.3
Progression-Free Survival
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
307-0037/61/M/A2	03OCT2013	19APR2014	.	30SEP2013	0+	No post-treatment radiological assessment
307-0039/51/M/A2	05NOV2013	16OCT2014	24JAN2014	.	2.6	
307-0040/65/M/A2	27MAY2014	04AUG2014	.	22MAY2014	0+	No post-treatment radiological assessment
307-0043/54/M/A2	25JUN2014	01NOV2014	.	09SEP2014	2.6+	No progression
307-0044/53/M/A2	27JUN2014	11SEP2014	.	23JUN2014	0+	No post-treatment radiological assessment
307-0045/48/M/A2	07JUL2014	.	22SEP2014	.	2.6	
307-0046/46/M/A2	17JUL2014	13MAR2015	.	30JUN2014	0+	No post-treatment radiological assessment

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Duration of Progression-Free Survival is calculated as (date of death or disease progression — date of randomization + 1) / 30. Censored records are indicated with '+'. For censoring rules, refer to Table 2 in the Statistical Analysis Plan.

Listing 16.2.6.3
Progression-Free Survival
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
308-0003/54/M/A2	29JAN2013	10DEC2013	15OCT2013	.	8.3	
308-0005/68/F/A2	30APR2013	10SEP2013	18JUL2013	.	2.7	
309-0001/46/M/A2	12JUN2012	04APR2013	27AUG2012	.	2.4	
309-0002/56/M/A2	13JUN2012	27OCT2012	27JUN2012	.	0.3	
309-0003/52/F/A2	20JUN2012	29JAN2013	05SEP2012	.	2.4	
309-0004/55/M/A2	25JUN2012	19JUL2012	.	19JUN2012	0+	No post-treatment radiological assessment
309-0008/38/M/A2	21FEB2013	31DEC2013	09MAY2013	.	2.4	
309-0010/47/M/A2	25MAR2013	.	27OCT2014	.	19.2	
309-0011/59/M/A2	08APR2013	02JUL2013	24JUN2013	.	2.4	
309-0012/82/M/A2	23MAY2013	31DEC2013	08AUG2013	.	2.4	
309-0015/62/M/A2	24JUN2013	20MAY2014	09SEP2013	.	2.4	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Duration of Progression-Free Survival is calculated as (date of death or disease progression — date of randomization + 1) / 30. Censored records are indicated with '+'. For censoring rules, refer to Table 2 in the Statistical Analysis Plan.

Listing 16.2.6.3
Progression-Free Survival
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
309-0016/72/F/A2	05SEP2013	14JAN2014	21NOV2013	.	2.4	
309-0017/73/F/A2	02DEC2013	26JUN2014	17FEB2014	.	2.4	
309-0018/82/M/A2	03JUN2014	28OCT2014	01SEP2014	.	2.8	
309-0021/54/F/A2	17JUL2014	28NOV2014	22SEP2014	.	2.1	
309-0025/49/M/A2	25AUG2014	04SEP2014	.	.	0.4	
309-0026/41/M/A2	22SEP2014	15FEB2015	29JAN2015	.	4.3	
309-0028/62/M/A2	03NOV2014	.	13APR2015	.	5.2	
309-0030/33/M/A2	15DEC2014	20FEB2015	09FEB2015	.	1.9	
309-0031/34/M/A2	25DEC2014	03APR2015	13MAR2015	.	2.6	
309-0032/63/M/A2	08JAN2015	30MAR2015	26MAR2015	.	2.4	
309-0033/78/F/A2	29JAN2015	.	08JUL2015	.	5.2	
310-0001/61/M/A2	19JUN2012	01JUN2013	22AUG2012	.	2.1	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Duration of Progression-Free Survival is calculated as (date of death or disease progression — date of randomization + 1) / 30. Censored records are indicated with '+'. For censoring rules, refer to Table 2 in the Statistical Analysis Plan.

Listing 16.2.6.3
Progression-Free Survival
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
310-0002/55/M/A2	12JUL2012	13OCT2012	.	28JUN2012	0+	No post-treatment radiological assessment
310-0003/61/M/A2	06FEB2013	29APR2014	24APR2013	.	2.6	
310-0008/49/M/A2	19JUN2013	13AUG2013	.	30MAY2013	0+	No post-treatment radiological assessment
310-0012/73/M/A2	07NOV2013	.	14APR2014	.	5.2	
310-0013/54/M/A2	03SEP2014	29APR2015	17NOV2014	.	2.4	
311-0002/60/M/A2	14AUG2013	20NOV2013	16OCT2013	.	1.9	
311-0007/55/M/A2	18NOV2013	13NOV2014	27JAN2013	.	2.4	
311-0008/71/M/A2	21MAY2014	01DEC2014	09JUL2014	.	1.7	
401-0003/36/M/A7	24JUN2013	24NOV2013	03SEP2013	.	2.4	
401-0005/58/M/A7	16OCT2013	17MAY2014	18DEC2013	.	2.1	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Duration of Progression-Free Survival is calculated as (date of death or disease progression — date of randomization + 1) / 30. Censored records are indicated with '+'. For censoring rules, refer to Table 2 in the Statistical Analysis Plan.

Listing 16.2.6.3
Progression-Free Survival
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
402-0003/75/M/A7	30APR2013	08NOV2013	08OCT2013	.	5.4	
402-0006/71/M/A7	02MAY2013	20NOV2013	30JUL2013	.	2.7	
402-0008/43/M/A7	21MAY2013	22JUL2013	14JUN2013	.	0.5	
402-0009/70/M/A7	16MAY2013	11AUG2013	11JUL2013	.	1.7	
402-0011/64/M/A7	23MAY2013	04OCT2013	11JUL2013	.	1.4	
402-0017/50/M/A7	11JUN2013	09AUG2013	.	27MAY2013	0+	No post-treatment radiological assessment
402-0018/48/M/A7	24JUN2013	08DEC2013	16SEP2013	.	2.6	
402-0019/54/M/A7	01JUL2013	06NOV2013	16SEP2013	.	2.6	
402-0021/64/M/A7	13AUG2013	.	07OCT2014	.	13.8	
402-0024/57/M/A7	27AUG2013	24DEC2013	05NOV2013	.	2.4	
402-0025/58/M/A7	25SEP2013	08JAN2015	19DEC2013	.	2.6	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Duration of Progression-Free Survival is calculated as (date of death or disease progression — date of randomization + 1) / 30. Censored records are indicated with '+'. For censoring rules, refer to Table 2 in the Statistical Analysis Plan.

Listing 16.2.6.3
Progression-Free Survival
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
402-0027/52/M/A7	04OCT2013	28NOV2013	21NOV2013	.	1.6	
402-0028/60/M/A7	04OCT2013	29JAN2014	.	26SEP2013	0+	No post-treatment radiological assessment
402-0031/65/M/A7	12NOV2013	.	29JAN2014	.	2.6	
402-0033/63/F/A7	06DEC2013	07APR2014	07FEB2014	.	1.8	
402-0035/44/M/A7	24DEC2013	02MAY2014	.	18DEC2013	0+	No post-treatment radiological assessment
403-0001/55/M/A7	22MAY2013	11SEP2013	03JUL2013	.	1.4	
403-0002/52/M/A7	11JUN2013	11OCT2013	22AUG2013	.	2.4	
403-0005/50/F/A7	16JUL2013	28OCT2013	02AUG2013	.	0.6	
403-0006/66/M/A7	29JUL2013	24MAR2014	23OCT2013	.	2.7	
403-0007/64/M/MIX	21AUG2013	05JAN2014	14NOV2013	.	2.6	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
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Progression-Free Survival
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
404-0001/71/M/A7	22JUL2013	11SEP2013	12AUG2013	.	0.7	
404-0002/56/F/A7	22AUG2013	01JUN2014	12SEP2013	.	0.7	
405-0002/46/M/A7	16APR2013	12MAY2013	.	03APR2013	0+	No post-treatment radiological assessment
405-0004/38/M/A7	24APR2013	21MAY2014	10JUL2013	.	2.6	
405-0006/62/M/A7	29APR2013	10JUN2013	.	23APR2013	0+	No post-treatment radiological assessment
405-0007/53/M/A7	07MAY2013	02AUG2014	.	23JUL2013	2.6+	No progression
405-0009/50/M/A7	14MAY2013	19AUG2013	.	10JUN2013	0.9+	No progression
405-0010/39/M/A7	23MAY2013	.	07AUG2013	06AUG2013	2.5+	Lost to follow-up
405-0011/63/M/A7	13MAY2013	05JUN2014	21OCT2013	.	5.4	
405-0013/45/M/A7	20MAY2013	.	.	05AUG2013	2.6+	Lost to follow-up

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Duration of Progression-Free Survival is calculated as (date of death or disease progression — date of randomization + 1) / 30. Censored records are indicated with '+'. For censoring rules, refer to Table 2 in the Statistical Analysis Plan.

Listing 16.2.6.3
Progression-Free Survival
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
405-0014/35/M/A7	31MAY2013	19JUL2013	03JUL2013	.	1	
405-0016/41/M/A7	27MAY2013	14JUL2013	25JUN2013	.	1	
405-0018/70/F/A7	12JUN2013	13JUL2013	03JUL2013	.	0.7	
405-0020/69/M/A7	19JUN2013	14OCT2014	14MAY2014	.	11	
405-0021/47/M/A7	19JUN2013	05OCT2014	07AUG2014	.	13.8	
405-0022/65/M/A7	04JUL2013	17MAR2014	18DEC2013	.	5.4	
405-0023/46/M/A7	17JUN2013	10DEC2013	09SEP2013	.	2.7	
405-0025/47/M/A7	26JUN2013	10DEC2013	24JUL2013	.	0.7	
405-0028/67/M/A7	24JUL2013	07DEC2013	07OCT2013	.	2.5	
405-0030/35/M/A7	31JUL2013	06NOV2013	25SEP2013	.	1.9	
405-0032/69/M/A7	23JUL2013	13FEB2015	15SEP2014	.	13.7	
405-0033/43/M/A7	08AUG2013	28APR2014	23OCT2013	.	2.6	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Duration of Progression-Free Survival is calculated as (date of death or disease progression — date of randomization + 1) / 30. Censored records are indicated with '+'. For censoring rules, refer to Table 2 in the Statistical Analysis Plan.

Listing 16.2.6.3
Progression-Free Survival
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
405-0034/61/M/A7	08AUG2013	07OCT2014	23OCT2013	.	2.6	
405-0035/66/M/A7	19AUG2013	.	16OCT2013	.	14	
405-0039/73/M/A7	13SEP2013	02JUN2014	03DEC2013	.	2.7	
405-0040/65/M/A7	23SEP2013	.	09DEC2013	.	2.6	
405-0042/53/M/A7	04OCT2013	26DEC2013	06DEC2013	.	1.8	
405-0043/49/M/A7	26SEP2013	20DEC2013	05DEC2013	.	2.4	
405-0044/56/M/A7	25SEP2013	05DEC2014	13NOV2013	.	1.7	
501-0001/59/M/A1	13NOV2013	26MAY2014	23JAN2014	.	2.4	
501-0002/36/F/A1	02DEC2013	16JAN2015	19FEB2014	.	2.7	
501-0005/80/M/A1	23JAN2014	.	03JUN2015	.	16.6	
501-0006/60/M/A1	13FEB2014	18NOV2014	28APR2014	.	2.5	
501-0007/43/M/A1	03MAR2014	27JUN2014	19MAY2014	.	2.6	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Duration of Progression-Free Survival is calculated as (date of death or disease progression — date of randomization + 1) / 30. Censored records are indicated with '+'. For censoring rules, refer to Table 2 in the Statistical Analysis Plan.

Listing 16.2.6.3
Progression-Free Survival
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
501-0008/76/F/A1	15APR2014	23MAY2015	02JUL2014	.	2.6	
501-0009/62/M/A1	18JUL2014	.	29SEP2014	.	2.5	
501-0010/65/M/A1	10SEP2014	26MAR2015	26NOV2014	.	2.6	
502-0002/65/M/A1	08JAN2014	19JAN2014	.	08JAN2014	0+	No post-treatment radiological assessment
503-0001/32/M/A1	09DEC2013	14FEB2014	03JAN2014	.	1	
503-0004/49/M/A1	11MAR2014	05APR2014	.	.	0.9	
503-0006/54/M/A1	06AUG2014	.	.	14JAN2015	5.4+	No progression
503-0007/57/M/A1	28OCT2014	.	12JAN2015	.	2.6	
503-0008/50/M/A1	30OCT2014	30APR2015	.	29OCT2014	0+	No post-treatment radiological assessment

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Duration of Progression-Free Survival is calculated as (date of death or disease progression — date of randomization + 1) / 30. Censored records are indicated with '+'. For censoring rules, refer to Table 2 in the Statistical Analysis Plan.

Listing 16.2.6.3
Progression-Free Survival
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
503-0009/57/M/A1	19NOV2014	29NOV2014	.	18NOV2014	0+	No post-treatment radiological assessment
504-0001/47/M/A1	17FEB2014	27JUL2014	.	06MAY2014	2.6+	No progression
504-0007/32/M/A1	11OCT2014	31OCT2014	.	.	0.7	
505-0001/70/M/A1	12AUG2014	24JAN2015	28SEP2014	.	1.6	
506-0002/54/M/A1	12MAY2014	.	10APR2015	.	11.1	
506-0003/66/M/A1	10SEP2014	04APR2015	29OCT2014	.	1.6	
506-0004/49/M/A1	27OCT2014	15FEB2015	25DEC2014	.	2	
508-0001/36/M/A1	08JAN2014	.	11FEB2014	08FEB2014	1.1+	Lost to follow-up
508-0003/49/F/A1	17MAR2014	15APR2014	.	13MAR2014	0+	No post-treatment radiological assessment
509-0001/45/M/A1	30APR2014	06AUG2014	18JUL2014	.	2.7	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Duration of Progression-Free Survival is calculated as (date of death or disease progression — date of randomization + 1) / 30. Censored records are indicated with '+'. For censoring rules, refer to Table 2 in the Statistical Analysis Plan.

Listing 16.2.6.3
Progression-Free Survival
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
509-0002/51/M/A1	26MAY2014	.	.	.	0+	Lost to follow-up and no post-treatment radio
510-0002/50/M/A1	23MAY2014	13AUG2014	.	21MAY2014	0+	No post-treatment radiological assessment
510-0004/72/M/A1	01AUG2014	.	15OCT2014	.	2.5	
511-0001/35/M/A1	21JAN2014	25AUG2014	26FEB2014	.	1.2	
511-0002/49/M/A1	11MAR2014	.	20AUG2014	.	5.4	
512-0001/59/M/A1	04MAR2014	04SEP2014	.	24MAY2014	2.7+	No progression
513-0001/28/M/A1	09APR2014	21JUN2014	22MAY2014	26MAY2014	1.6+	New anticancer treatment started
513-0004/46/M/A1	18JUN2014	26JUL2014	16JUL2014	.	1	
513-0005/61/M/A1	31OCT2014	01MAR2015	20JAN2015	.	2.7	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Duration of Progression-Free Survival is calculated as (date of death or disease progression — date of randomization + 1) / 30. Censored records are indicated with '+'. For censoring rules, refer to Table 2 in the Statistical Analysis Plan.

Listing 16.2.6.3
Progression-Free Survival
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
515-0001/64/M/A1	20FEB2014	17JUL2014	07MAY2014	.	2.6	
515-0003/69/M/A1	13MAY2014	05APR2015	29JUL2014	.	2.6	
515-0004/52/M/A1	27MAY2014	19SEP2014	.	.	3.9	
515-0006/47/M/A1	05AUG2014	.	20OCT2014	.	2.6	
515-0007/39/M/A1	17SEP2014	22NOV2014	.	12SEP2014	0+	No post-treatment radiological assessment
515-0008/60/M/A1	27NOV2014	12MAY2015	11FEB2015	.	2.6	
516-0001/45/M/A1	07AUG2014	.	16JAN2015	.	5.4	
517-0001/42/M/A1	23DEC2013	02MAR2014	20JAN2014	.	1.2	
517-0002/43/M/A1	26MAR2014	.	04SEP2014	.	5.4	
517-0005/46/M/MIX	04JUN2014	28JUL2014	.	23MAY2014	0+	No post-treatment radiological assessment

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Duration of Progression-Free Survival is calculated as (date of death or disease progression — date of randomization + 1) / 30. Censored records are indicated with '+'. For censoring rules, refer to Table 2 in the Statistical Analysis Plan.

Listing 16.2.6.3
Progression-Free Survival
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
517-0006/67/F/A1	20AUG2014	.	23APR2015	.	8.2	
517-0007/66/M/A1	20AUG2014	15NOV2014	.	07AUG2014	0+	No post-treatment radiological assessment
517-0008/59/M/A1	22AUG2014	18JAN2015	.	18AUG2014	0+	No post-treatment radiological assessment
517-0009/23/M/A1	17SEP2014	31MAY2015	10DEC2014	.	2.8	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Duration of Progression-Free Survival is calculated as (date of death or disease progression — date of randomization + 1) / 30. Censored records are indicated with '+'. For censoring rules, refer to Table 2 in the Statistical Analysis Plan.

Listing 16.2.6.3
Progression-Free Survival
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
101-0002/70/M/OTH	29JUL2011	04JUN2012	18OCT2011	.	2.6	
101-0004/78/F/A2	05AUG2011	.	13JAN2012	.	13.8	
101-0010/43/M/BL	14SEP2011	27OCT2011	.	26AUG2011	0+	No post-treatment radiological assessment
101-0014/61/M/W2	06JAN2012	26OCT2012	.	16MAR2012	2.4+	No progression
101-0015/65/M/A4	06JAN2012	03JAN2013	22MAR2012	.	2.6	
101-0017/60/M/W2	21FEB2012	19JAN2013	01MAY2012	.	2.4	
101-0020/86/M/W2	12MAR2012	30DEC2012	21AUG2012	.	5.4	
101-0027/72/M/W2	22MAY2012	11AUG2012	.	30APR2012	0+	No post-treatment radiological assessment
101-0031/69/F/W2	17JUL2012	15NOV2012	29SEP2012	.	2.5	
101-0034/44/M/OTH	11SEP2012	04DEC2013	.	02NOV2012	1.8+	No progression

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Duration of Progression-Free Survival is calculated as (date of death or disease progression — date of randomization + 1) / 30. Censored records are indicated with '+'. For censoring rules, refer to Table 2 in the Statistical Analysis Plan.

Listing 16.2.6.3
Progression-Free Survival
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
101-0035/37/M/A6	14SEP2012	25JAN2013	.	20AUG2012	0+	No post-treatment radiological assessment
101-0043/69/M/W1	22OCT2013	26MAY2014	.	02JAN2014	2.4+	No progression
101-0051/70/F/W2	27JAN2014	23MAY2014	.	13JAN2014	0+	No post-treatment radiological assessment
102-0006/66/M/BL	11DEC2013	11OCT2014	23FEB2014	.	2.5	
102-0007/61/M/W2	02JAN2014	19MAY2014	.	19MAR2014	2.6+	No progression
103-0002/74/M/W2	12DEC2012	09FEB2015	20MAY2013	.	5.3	
103-0006/57/M/W2	19NOV2014	.	04FEB2015	.	2.6	
104-0002/80/M/W2	07MAY2012	27JUL2013	.	12JAN2013	8.4+	No progression
104-0007/89/M/A1	07AUG2013	.	.	05JUN2015	22.3+	No progression
105-0003/57/M/W2	05NOV2013	.	.	03OCT2014	11.1+	No progression

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
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[3] Duration of Progression-Free Survival is calculated as (date of death or disease progression — date of randomization + 1) / 30. Censored records are indicated with '+'. For censoring rules, refer to Table 2 in the Statistical Analysis Plan.

Listing 16.2.6.3
Progression-Free Survival
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
105-0006/60/F/BL	29DEC2014	.	18JUN2015	.	5.5	
108-0003/85/M/W2	19NOV2012	30NOV2013	31DEC2012	.	1.4	
109-0002/63/M/W2	22MAR2013	.	30AUG2013	.	5.4	
109-0005/64/F/W2	30JUL2013	08OCT2013	.	24JUL2013	0+	No post-treatment radiological assessment
109-0012/21/F/W2	25SEP2014	.	.	18NOV2014	1.8+	No progression
109-0014/50/F/W2	26JAN2015	11APR2015	13MAR2015	.	1.6	
111-0003/37/M/A1	08JAN2013	19MAR2013	13MAR2013	.	2.2	
112-0010/56/F/W2	06DEC2013	26APR2014	21FEB2014	.	2.6	
113-0007/74/M/W2	30JAN2014	27JUL2014	.	02JUL2014	5.1+	No progression
113-0015/58/F/BL	26NOV2014	.	.	24OCT2014	0+	No post-treatment radiological assessment

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Duration of Progression-Free Survival is calculated as (date of death or disease progression — date of randomization + 1) / 30. Censored records are indicated with '+'. For censoring rules, refer to Table 2 in the Statistical Analysis Plan.

Listing 16.2.6.3
Progression-Free Survival
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
114-0001/25/F/OTH	02AUG2012	05DEC2012	27SEP2014	.	1.9	
114-0004/54/F/A1	06FEB2013	09JUN2014	.	27MAR2013	1.7+	No progression
115-0005/60/M/W2	15MAR2013	16MAY2013	.	.	2.1	
115-0006/62/M/W2	11APR2013	31JUL2013	.	25JUN2013	2.5+	No progression
115-0007/57/M/W2	19APR2013	23JUN2013	16MAY2013	.	0.9	
115-0010/54/M/A4	14APR2014	21OCT2014	20JUN2014	.	2.3	
121-0003/65/M/BL	01JUL2014	12JAN2015	.	27AUG2014	1.9+	No progression
201-0002/76/M/W2	15MAR2012	02OCT2013	11FEB2013	.	11.1	
201-0006/71/M/W2	12JUL2012	10NOV2013	21DEC2012	.	5.4	
201-0007/71/M/W2	26JUL2012	14JUL2014	02APR2013	.	8.2	
201-0009/64/M/W2	20JUN2013	.	.	20APR2015	22.3+	No progression
201-0010/81/F/W2	27JUN2013	26JAN2014	13SEP2013	.	2.6	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Duration of Progression-Free Survival is calculated as (date of death or disease progression — date of randomization + 1) / 30. Censored records are indicated with '+'. For censoring rules, refer to Table 2 in the Statistical Analysis Plan.

Listing 16.2.6.3
Progression-Free Survival
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
201-0014/73/M/W2	17JUL2013	18MAR2014	04OCT2013	.	2.7	
201-0015/49/M/W2	08AUG2013	28OCT2014	17MAR2014	.	7.3	
201-0022/80/F/W2	09MAY2014	.	28OCT2014	.	5.7	
203-0004/81/M/W2	30MAR2012	09MAY2013	13DEC2012	.	8.6	
203-0006/76/M/W2	11APR2012	07JUL2012	.	.	2.9	
203-0007/59/M/W2	04JUN2012	02OCT2012	.	08MAY2012	0+	No post-treatment radiological assessment
203-0009/73/M/W2	13SEP2012	07JAN2015	31OCT2013	.	13.8	
203-0010/74/M/W2	26SEP2012	.	.	02OCT2014	24.6+	No progression
203-0014/73/M/W2	23JAN2014	13OCT2014	.	10JAN2014	0+	No post-treatment radiological assessment
203-0016/57/M/W2	04FEB2014	22SEP2014	31JUL2014	.	5.9	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Duration of Progression-Free Survival is calculated as (date of death or disease progression — date of randomization + 1) / 30. Censored records are indicated with '+'. For censoring rules, refer to Table 2 in the Statistical Analysis Plan.

Listing 16.2.6.3
Progression-Free Survival
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
203-0019/68/M/W2	22MAY2014	18AUG2014	04JUL2014	.	1.5	
204-0003/64/M/W2	08JUL2013	08JAN2014	26SEP2013	.	2.8	
204-0004/76/F/W2	15SEP2013	25JUN2014	17DEC2013	.	3.1	
205-0002/71/M/W2	24FEB2012	14JUN2012	08MAY2012	.	2.5	
205-0003/79/M/W2	27MAR2012	18DEC2013	04DEC2012	.	8.4	
205-0005/71/M/W2	20MAR2012	09NOV2012	11JUN2012	.	2.6	
205-0014/70/M/W2	18JUN2013	02NOV2013	.	11JUN2013	0+	No post-treatment radiological assessment
205-0023/72/M/W2	08NOV2013	10JUN2014	30JAN2014	.	2.5	
205-0026/61/F/W2	09FEB2015	.	05MAY2015	.	2.6	
205-0028/73/F/W2	27JAN2015	15FEB2015	.	20JAN2015	0+	No post-treatment radiological assessment

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Duration of Progression-Free Survival is calculated as (date of death or disease progression — date of randomization + 1) / 30. Censored records are indicated with '+'. For censoring rules, refer to Table 2 in the Statistical Analysis Plan.

Listing 16.2.6.3
Progression-Free Survival
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
207-0002/71/M/W2	21MAR2012	02OCT2012	20JUN2012	.	2.6	
207-0007/71/M/W2	02JUL2012	04JAN2013	18SEP2012	.	2.6	
207-0012/66/M/W2	21MAR2013	12APR2014	19FEB2014	.	11.2	
207-0016/82/F/W2	10OCT2013	04OCT2014	.	03JAN2014	2.9+	No progression
207-0017/81/F/W2	22NOV2013	07MAR2014	19FEB2014	.	3	
207-0019/55/M/W2	03JUN2014	25JUL2014	.	09MAY2014	0+	No post-treatment radiological assessment
209-0006/68/M/W2	02MAY2013	16JUL2014	08JAN2014	.	8.4	
209-0011/69/M/W2	03DEC2013	.	17FEB2014	.	2.6	
209-0014/79/M/W2	17MAR2014	.	01SEP2014	.	5.4	
210-0003/74/M/W2	04NOV2013	18JUL2014	.	21OCT2013	0+	No post-treatment radiological assessment

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Duration of Progression-Free Survival is calculated as (date of death or disease progression — date of randomization + 1) / 30. Censored records are indicated with '+'. For censoring rules, refer to Table 2 in the Statistical Analysis Plan.

Listing 16.2.6.3
Progression-Free Survival
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
210-0004/71/M/W2	08JAN2014	22AUG2014	28MAR2014	.	2.6	
210-0005/53/M/W2	20FEB2014	23DEC2014	07MAY2014	.	2.6	
210-0006/45/M/W2	23JUN2014	26NOV2014	29SEP2014	.	2.9	
251-0002/69/M/W2	07AUG2013	20NOV2013	16OCT2013	.	2.4	
251-0003/68/M/W2	05NOV2013	26NOV2014	15APR2014	.	5.4	
252-0001/65/M/A3	08MAY2012	23DEC2012	.	01MAY2012	0+	No post-treatment radiological assessment
252-0004/50/M/A1	28MAY2013	06SEP2013	25JUL2013	.	2	
252-0006/64/M/W2	01OCT2013	23APR2015	.	11MAR2014	5.4+	No progression
252-0008/76/M/W2	27MAY2014	07MAR2015	12AUG2014	.	2.6	
252-0010/56/F/W2	04NOV2014	31MAR2015	20JAN2015	.	2.6	
253-0003/75/M/W2	15JUN2012	30SEP2013	13FEB2013	.	8.1	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Duration of Progression-Free Survival is calculated as (date of death or disease progression — date of randomization + 1) / 30. Censored records are indicated with '+'. For censoring rules, refer to Table 2 in the Statistical Analysis Plan.

Listing 16.2.6.3
Progression-Free Survival
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
253-0004/79/M/W2	07SEP2012	16MAR2013	19NOV2012	.	2.5	
253-0005/74/F/W2	02NOV2012	08MAR2013	.	15OCT2012	0+	No post-treatment radiological assessment
253-0006/63/M/A3	28DEC2012	09SEP2014	17MAY2013	.	4.7	
253-0011/67/M/W2	06OCT2014	.	.	08JUN2015	8.2+	No progression
253-0012/67/M/W2	08DEC2014	20JAN2015	.	12NOV2014	0+	No post-treatment radiological assessment
257-0005/66/M/W2	03JAN2013	19MAY2013	21MAR2013	.	2.5	
257-0013/63/M/W2	30MAY2013	07AUG2013	.	02MAY2013	0+	No post-treatment radiological assessment
257-0020/72/M/A1	27OCT2014	21JAN2015	22NOV2014	.	0.8	
258-0002/69/F/W2	11APR2013	21JUL2014	11DEC2013	.	8.2	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Duration of Progression-Free Survival is calculated as (date of death or disease progression — date of randomization + 1) / 30. Censored records are indicated with '+'. For censoring rules, refer to Table 2 in the Statistical Analysis Plan.

Listing 16.2.6.3
Progression-Free Survival
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
258-0003/67/F/W2	15MAY2013	.	28OCT2013	.	5.4	
258-0004/65/M/W2	21MAY2013	23JUN2013	.	09MAY2013	0+	No post-treatment radiological assessment
258-0006/69/M/W2	15OCT2013	07DEC2013	.	02OCT2013	0+	No post-treatment radiological assessment
258-0013/59/M/W2	11NOV2014	21MAR2015	28JAN2015	.	2.6	
259-0003/73/M/W2	11JUN2014	10JUL2015	.	29APR2015	10.8+	No progression
259-0004/52/M/W2	21JUL2014	31DEC2014	.	16JUL2014	0+	No post-treatment radiological assessment
260-0002/66/M/W2	02OCT2013	24JUL2014	20NOV2013	.	1.5	
301-0001/47/F/A2	01NOV2011	18APR2013	19JAN2012	.	2.6	
301-0003/61/F/A2	01MAR2012	28AUG2012	24MAY2012	.	2.6	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Duration of Progression-Free Survival is calculated as (date of death or disease progression — date of randomization + 1) / 30. Censored records are indicated with '+'. For censoring rules, refer to Table 2 in the Statistical Analysis Plan.

Listing 16.2.6.3
Progression-Free Survival
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
301-0008/53/M/A2	04JAN2013	22MAY2013	23MAR2013	.	2.6	
302-0006/49/M/A2	10JAN2012	24MAR2012	.	04JAN2012	0+	No post-treatment radiological assessment
302-0009/73/M/A2	17APR2012	04JUL2012	.	03APR2012	0+	No post-treatment radiological assessment
302-0012/62/M/A2	24APR2012	11OCT2012	19JUL2012	.	2.7	
302-0013/62/M/A2	26MAR2013	14DEC2013	.	21MAR2013	0+	No post-treatment radiological assessment
302-0020/52/M/A2	21MAY2013	26NOV2013	.	16MAY2013	0+	No post-treatment radiological assessment
302-0021/75/F/A2	11JUN2013	14FEB2014	25NOV2013	.	5.4	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Duration of Progression-Free Survival is calculated as (date of death or disease progression — date of randomization + 1) / 30. Censored records are indicated with '+'. For censoring rules, refer to Table 2 in the Statistical Analysis Plan.

Listing 16.2.6.3
Progression-Free Survival
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
304-0003/56/F/A2	14MAR2013	.	05JUN2013	.	2.7	
304-0004/69/M/A2	03JUN2013	25SEP2013	.	30MAY2013	0+	No post-treatment radiological assessment
304-0007/72/M/A2	13NOV2013	28SEP2014	29JAN2014	.	2.6	
305-0004/79/M/A2	24FEB2012	03JUL2012	.	07MAY2012	2.5+	No progression
305-0007/67/M/A2	09MAR2012	08NOV2013	24AUG2012	.	5.6	
305-0015/84/M/A2	06JUL2012	28NOV2012	20SEP2012	.	2.5	
305-0016/78/M/A2	10JUL2012	12NOV2012	25SEP2012	.	2.6	
305-0021/83/F/A2	22NOV2012	23MAR2013	15FEB2013	.	2.6	
305-0024/68/M/A2	15JAN2013	08AUG2013	12APR2013	.	2.9	
305-0033/37/F/A2	02JUL2013	19JUL2014	24SEP2013	.	2.8	
305-0035/60/M/A2	28AUG2013	29SEP2014	12FEB2014	.	5.6	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Duration of Progression-Free Survival is calculated as (date of death or disease progression — date of randomization + 1) / 30. Censored records are indicated with '+'. For censoring rules, refer to Table 2 in the Statistical Analysis Plan.

Listing 16.2.6.3
Progression-Free Survival
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
305-0046/60/M/A2	07NOV2014	.	23APR2015	.	5.3	
306-0004/46/M/A2	21FEB2012	07APR2012	06APR2012	.	1.4	
306-0010/69/M/A2	21MAR2012	30MAR2013	12JUN2012	.	2.6	
306-0013/42/M/A2	16APR2012	18JUN2012	.	13APR2012	0+	No post-treatment radiological assessment
306-0015/73/M/A2	17MAY2012	14MAY2013	02JUL2012	.	1.4	
306-0016/58/M/A2	25JUN2012	21SEP2013	17SEP2012	.	2.6	
306-0022/56/M/A2	13NOV2012	03FEB2014	30APR2013	.	5.5	
306-0028/53/M/A2	28MAR2013	23DEC2013	19JUN2013	13JUN2013	2.6+	No progression
306-0045/60/F/A1	20JUN2014	12JUN2015	09SEP2014	.	2.5	
307-0006/72/M/A2	29NOV2011	23DEC2011	.	08NOV2011	0+	No post-treatment radiological assessment

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Duration of Progression-Free Survival is calculated as (date of death or disease progression — date of randomization + 1) / 30. Censored records are indicated with '+'. For censoring rules, refer to Table 2 in the Statistical Analysis Plan.

Listing 16.2.6.3
Progression-Free Survival
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
307-0009/53/M/A2	03JAN2012	29MAR2012	.	28DEC2011	0+	No post-treatment radiological assessment
307-0012/42/M/A2	07FEB2012	10APR2012	.	03FEB2012	0+	No post-treatment radiological assessment
307-0015/75/M/A2	25APR2012	05MAR2013	05OCT2012	.	5.4	
307-0021/68/M/A2	21AUG2012	10FEB2013	.	08NOV2012	2.7+	No progression
307-0028/69/F/A2	14JAN2013	15JUN2013	08APR2013	.	2.6	
307-0034/48/M/A2	13AUG2013	04FEB2014	31OCT2013	.	2.6	
307-0036/76/M/A2	02OCT2013	30JUN2014	19DEC2013	.	2.6	
307-0042/55/M/A2	19JUN2014	.	27NOV2014	.	5.4	
308-0002/36/F/A2	31DEC2012	16FEB2014	26MAR2013	.	2.7	
308-0004/52/M/A2	05FEB2013	07APR2015	25APR2013	.	2.7	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Duration of Progression-Free Survival is calculated as (date of death or disease progression — date of randomization + 1) / 30. Censored records are indicated with '+'. For censoring rules, refer to Table 2 in the Statistical Analysis Plan.

Listing 16.2.6.3
Progression-Free Survival
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
308-0006/64/M/A2	14MAY2013	14NOV2014	27JUN2013	.	1.5	
308-0008/47/M/A2	23JUL2013	26DEC2013	08OCT2013	.	2.5	
308-0009/61/M/A2	19JUL2013	12SEP2013	.	.	1.9	
309-0006/56/M/A2	26NOV2012	24MAY2015	29JUL2013	.	8	
309-0007/58/M/A2	17DEC2012	12JUN2013	04MAR2013	.	2.4	
309-0013/45/M/A2	20JUN2013	17NOV2014	05SEP2013	.	2.4	
309-0014/39/M/A2	20JUN2013	18JAN2014	05SEP2013	.	2.4	
309-0019/68/M/A2	24JUN2014	.	.	12MAY2015	10.8+	No progression
309-0027/49/M/A2	03NOV2014	12JUN2015	19JAN2015	.	2.4	
309-0029/50/M/A2	01DEC2014	09APR2015	10FEB2015	.	2.4	
310-0004/50/F/A2	06FEB2013	01AUG2013	24APR2013	.	2.4	
310-0005/58/M/A2	27MAR2013	07DEC2013	10JUN2013	.	2.4	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Duration of Progression-Free Survival is calculated as (date of death or disease progression — date of randomization + 1) / 30. Censored records are indicated with '+'. For censoring rules, refer to Table 2 in the Statistical Analysis Plan.

Listing 16.2.6.3
Progression-Free Survival
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
310-0006/50/F/A2	01MAY2013	05OCT2014	27DEC2013	.	7.9	
310-0007/74/M/A2	13JUN2013	.	06MAY2014	.	10.8	
310-0009/46/M/A2	07AUG2013	10JAN2014	27SEP2013	.	1.7	
310-0010/34/F/A2	26AUG2013	11DEC2013	26SEP2013	.	1	
310-0011/52/M/A2	24OCT2013	.	08JAN2014	.	2.4	
310-0014/64/M/A2	24SEP2014	16JUN2015	03DEC2014	.	2.4	
311-0003/44/M/A2	25SEP2013	22NOV2014	11DEC2013	.	2.6	
311-0004/68/M/A2	30SEP2013	16NOV2013	.	26SEP2013	0+	No post-treatment radiological assessment
311-0005/58/M/A2	21OCT2013	03AUG2014	30DEC2013	.	2.4	
311-0006/73/F/A2	07NOV2013	16MAR2014	16JAN2014	.	2.4	
311-0009/51/F/A2	15JUL2014	.	30SEP2014	.	2.6	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Duration of Progression-Free Survival is calculated as (date of death or disease progression — date of randomization + 1) / 30. Censored records are indicated with '+'. For censoring rules, refer to Table 2 in the Statistical Analysis Plan.

Listing 16.2.6.3
Progression-Free Survival
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
311-0010/47/M/A2	02SEP2014	.	.	07MAY2015	8.3+	No progression
311-0011/46/M/A2	30OCT2014	.	31DEC2014	.	2.1	
311-0012/55/M/A2	29JAN2015	.	.	16APR2015	2.6+	No progression
401-0001/70/M/A7	04JUN2013	18AUG2013	.	03JUN2013	0+	No post-treatment radiological assessment
401-0002/55/M/A7	19JUN2013	21FEB2014	.	12JUN2013	0+	No post-treatment radiological assessment
402-0001/35/M/A7	22APR2013	03AUG2013	24JUN2013	.	1.7	
402-0002/58/M/A7	23APR2013	08MAY2014	09JUL2013	.	2.6	
402-0005/70/M/A7	09MAY2013	02OCT2013	01AUG2013	.	2.5	
402-0010/50/M/A7	20MAY2013	13JUL2013	08JUL2013	.	1.5	
402-0022/60/F/A7	19AUG2013	03MAR2014	18NOV2013	.	2.8	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Duration of Progression-Free Survival is calculated as (date of death or disease progression — date of randomization + 1) / 30. Censored records are indicated with '+'. For censoring rules, refer to Table 2 in the Statistical Analysis Plan.

Listing 16.2.6.3
Progression-Free Survival
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
402-0023/57/M/A7	02SEP2013	29DEC2013	26NOV2013	.	2.6	
402-0029/49/M/A7	11NOV2013	04JAN2014	06JAN2014	.	1.7	
402-0032/49/F/A7	06DEC2013	19JUN2014	27FEB2014	.	2.6	
402-0034/43/F/A7	19DEC2013	.	05JUN2014	.	5.4	
403-0004/37/M/A7	11JUL2013	01MAY2015	01OCT2013	.	2.6	
404-0003/53/M/A7	10SEP2013	20OCT2013	30SEP2013	.	0.7	
404-0004/61/F/A7	15OCT2013	25DEC2013	02DEC2013	.	1.6	
405-0001/55/M/A7	22APR2013	15MAR2014	10JUL2013	.	2.7	
405-0005/35/M/A6	24APR2013	01MAY2015	23DEC2013	.	8.1	
405-0012/72/M/A7	15MAY2013	02DEC2013	21OCT2013	.	5.3	
405-0019/61/M/A7	26JUN2013	11AUG2013	.	.	1.6	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Duration of Progression-Free Survival is calculated as (date of death or disease progression — date of randomization + 1) / 30. Censored records are indicated with '+'. For censoring rules, refer to Table 2 in the Statistical Analysis Plan.

Listing 16.2.6.3
Progression-Free Survival
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
405-0024/69/M/A7	03JUL2013	05AUG2013	.	21JUN2013	0+	No post-treatment radiological assessment
405-0026/67/M/A7	08JUL2013	13FEB2014	25SEP2013	.	2.7	
405-0036/70/M/A7	19AUG2013	15JAN2014	12NOV2013	.	2.9	
405-0041/57/M/A7	13SEP2013	.	02MAY2014	.	7.7	
501-0003/22/M/A1	11DEC2013	01JUL2014	25FEB2014	.	2.6	
501-0004/26/M/A1	18DEC2013	31JUL2014	05MAR2014	.	2.6	
501-0011/61/M/A1	25SEP2014	07JAN2015	12DEC2014	.	2.6	
502-0001/70/M/A1	13DEC2013	14JAN2014	.	.	1.1	
502-0003/48/M/A1	14JAN2014	10JUL2014	10APR2014	.	2.9	
503-0002/71/F/A1	20FEB2014	20APR2015	22OCT2014	.	8.4	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Duration of Progression-Free Survival is calculated as (date of death or disease progression — date of randomization + 1) / 30. Censored records are indicated with '+'. For censoring rules, refer to Table 2 in the Statistical Analysis Plan.

Listing 16.2.6.3
Progression-Free Survival
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
503-0003/47/F/A1	07MAR2014	01JUN2014	.	07MAR2014	0+	No post-treatment radiological assessment
503-0005/72/M/A1	25MAR2014	.	02MAR2015	.	11.4	
504-0003/53/M/A1	13MAR2014	16MAY2014	14APR2014	.	1	
504-0005/41/F/A1	03SEP2014	08NOV2014	.	.	2.2	
504-0006/51/M/A1	04SEP2014	13MAR2015	.	04SEP2014	0+	No post-treatment radiological assessment
506-0001/43/M/A1	15APR2014	29JUL2014	.	01APR2014	0+	No post-treatment radiological assessment
506-0005/24/M/A1	22DEC2014	20JAN2015	.	16DEC2014	0+	No post-treatment radiological assessment

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Duration of Progression-Free Survival is calculated as (date of death or disease progression — date of randomization + 1) / 30. Censored records are indicated with '+'. For censoring rules, refer to Table 2 in the Statistical Analysis Plan.

Listing 16.2.6.3
Progression-Free Survival
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
507-0001/51/M/A1	24JUL2014	.	14OCT2014	.	2.8	
507-0002/44/M/A1	29JUL2014	10NOV2014	17SEP2014	.	1.7	
508-0002/64/M/A1	19FEB2014	15APR2014	.	.	1.9	
508-0004/58/M/A1	27AUG2014	.	.	.	0+	Lost to follow-up and no post-treatment radio
509-0003/39/M/A1	24JUL2014	01JAN2015	09OCT2014	.	2.8	
510-0001/67/M/A1	26FEB2014	.	08DEC2014	.	9.5	
510-0003/43/M/A1	05JUN2014	20NOV2014	14AUG2014	.	2.4	
513-0003/46/M/A1	30APR2014	12JUN2014	.	24APR2014	0+	No post-treatment radiological assessment
515-0005/45/M/A1	23JUN2014	04OCT2014	09SEP2014	.	2.6	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Duration of Progression-Free Survival is calculated as (date of death or disease progression — date of randomization + 1) / 30. Censored records are indicated with '+'. For censoring rules, refer to Table 2 in the Statistical Analysis Plan.

Listing 16.2.6.3
Progression-Free Survival
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
517-0003/45/M/A1	14MAY2014	.	01AUG2014	01AUG2014	2.7+	Lost to follow-up
517-0010/67/M/A1	12NOV2014	24MAR2015	02FEB2015	.	2.8	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Duration of Progression-Free Survival is calculated as (date of death or disease progression — date of randomization + 1) / 30. Censored records are indicated with '+'. For censoring rules, refer to Table 2 in the Statistical Analysis Plan.

Listing 16.2.6.4
Best Overall Objective response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Visit	Date	Overall Response	Objective Response	Best Overall Objective Response[3]
101-0001/59/M/A2	WEEK 12	11OCT2011	SD	No	No
	WEEK 24	03JAN2012	PD	No	
101-0005/77/M/W2	WEEK 12	25OCT2011	PD	No	No
101-0006/62/M/W2	WEEK 12	12OCT2011	PD	No	No
101-0007/77/M/A1	WEEK 12	08NOV2011	PD	No	No
101-0008/83/M/BL	WEEK 12	12NOV2011	PD	No	No
101-0009/82/M/A1	WEEK 12	20DEC2011	PD	No	No
101-0011/75/F/W2	UNSCHEDULED	29NOV2011	PD	No	No
101-0012/68/M/W2	WEEK 12	18JAN2012	PD	No	No
101-0013/66/F/A5	WEEK 12	23MAR2012	PD	No	No
101-0016/61/M/A4	WEEK 12	28MAR2012	SD	No	No
	WEEK 24	22JUN2012	SD	No	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Best Overall Objective Response (BOOR) is calculated using the non-missing Objective Response across all visits. BOOR is 'Yes' if, at any visit, the Objective Response is 'Yes'. BOOR is 'No' if, for all visits, the Objective Response is 'No'.

Listing 16.2.6.4
Best Overall Objective response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Visit	Date	Overall Response	Objective Response	Best Overall Objective Response[3]
101-0016/61/M/A4	WEEK 36	11SEP2012	PD	No	
	WEEK 48	04DEC2012	PD	No	
	WEEK 60	05MAR2013	PD	No	
101-0018/51/M/A1		.			Missing
101-0019/68/M/W2	WEEK 12	15MAY2012	PD	No	No
101-0021/74/M/W2	WEEK 12	29MAY2012	PD	No	No
101-0022/55/M/BL	UNSCHEDULED	13APR2012	PD	No	No
101-0023/70/M/W2	WEEK 12	14JUN2012	SD	No	No
101-0024/35/F/A4	WEEK 12	10JUL2012	PD	No	No
101-0025/57/F/W2	UNSCHEDULED	15JUN2012	PD	No	No
101-0026/82/M/W2	WEEK 12	31JUL2012	SD	No	No
	WEEK 24	19OCT2012	SD	No	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Best Overall Objective Response (BOOR) is calculated using the non-missing Objective Response across all visits. BOOR is 'Yes' if, at any visit, the Objective Response is 'Yes'. BOOR is 'No' if, for all visits, the Objective Response is 'No'.

Listing 16.2.6.4
Best Overall Objective response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Visit	Date	Overall Response	Objective Response	Best Overall Objective Response[3]
101-0026/82/M/W2	UNSCHEDULED	11JAN2013	PD	No	
101-0028/60/M/W2	WEEK 12	07SEP2012	SD	No	No
101-0029/70/M/A1	WEEK 12	28AUG2012	PD	No	No
101-0030/51/M/W2	UNSCHEDULED	05SEP2012	PD	No	No
101-0032/84/M/W2	WEEK 12	09OCT2012	PR	Yes	Yes
101-0033/66/F/W2	WEEK 12	05OCT2012	SD	No	No
	WEEK 24	04JAN2013	PD	No	
101-0036/67/M/A4	UNSCHEDULED	12DEC2012	PD	No	No
101-0037/57/M/A1		.			Missing
101-0038/56/M/W2		.			Missing
101-0039/77/F/W2	WEEK 24	07SEP2010	SD	No	No
	WEEK 12	14JUN2013	SD	No	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Best Overall Objective Response (BOOR) is calculated using the non-missing Objective Response across all visits. BOOR is 'Yes' if, at any visit, the Objective Response is 'Yes'. BOOR is 'No' if, for all visits, the Objective Response is 'No'.

Listing 16.2.6.4
Best Overall Objective response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Visit	Date	Overall Response	Objective Response	Best Overall Objective Response[3]
101-0039/77/F/W2	WEEK 36	27NOV2013	PD	No	
101-0040/60/M/W2	WEEK 12	06AUG2013	PD	No	No
101-0041/54/M/W2		.			Missing
101-0042/64/M/W2		.			Missing
101-0044/78/M/W2	WEEK 12	27DEC2013	PD	No	No
101-0045/74/F/W2	WEEK 12	16JAN2014	PD	No	No
101-0046/70/M/OTH	WEEK 12	02JAN2014	PD	No	No
101-0047/52/M/W2	UNSCHEDULED	16DEC2013	PD	No	No
101-0048/66/F/W2	WEEK 12	30DEC2013	PD	No	No
101-0049/71/M/A8	WEEK 12	08JAN2014	PD	No	No
101-0050/59/M/W2	UNSCHEDULED	05DEC2013	PD	No	No
102-0001/53/M/BL	WEEK 12	07JUN2012	PD	No	No

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Best Overall Objective Response (BOOR) is calculated using the non-missing Objective Response across all visits. BOOR is 'Yes' if, at any visit, the Objective Response is 'Yes'. BOOR is 'No' if, for all visits, the Objective Response is 'No'.

Listing 16.2.6.4
Best Overall Objective response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Visit	Date	Overall Response	Objective Response	Best Overall Objective Response[3]
102-0003/63/M/BL	WEEK 12	23NOV2012	PD	No	No
102-0008/64/M/BL		.			Missing
102-0009/58/M/W2	UNSCHEDULED	09DEC2014	PD	No	No
103-0001/56/M/W2	WEEK 12	26JUL2012	PD	No	No
103-0003/66/M/W2	WEEK 12	29APR2013	No	No	No
	WEEK 24	23JUL2013	PD	No	
103-0004/40/F/A1	UNSCHEDULED	03JUN2014	PD	No	No
104-0003/56/F/W2		.			Missing
104-0004/74/M/W2		.			Missing
104-0008/55/M/PI	WEEK 12	29NOV2013	SD	No	No
104-0010/71/F/A8	WEEK 12	29MAR2014	SD	No	No
	WEEK 24	25JUN2014	SD	No	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Best Overall Objective Response (BOOR) is calculated using the non-missing Objective Response across all visits. BOOR is 'Yes' if, at any visit, the Objective Response is 'Yes'. BOOR is 'No' if, for all visits, the Objective Response is 'No'.

Listing 16.2.6.4
Best Overall Objective response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Visit	Date	Overall Response	Objective Response	Best Overall Objective Response[3]
104-0010/71/F/A8	WEEK 36	17SEP2014	PD	No	
104-0012/78/F/A2	UNSCHEDULED	29NOV2014	PD	No	No
106-0001/42/F/W2	WEEK 12	21MAY2012	SD	No	No
	WEEK 24	29JUN2012	PD	No	
107-0002/71/M/W2	WEEK 12	07NOV2012	PD	No	No
107-0003/73/M/BL		.			Missing
107-0004/63/M/W2	WEEK 12	21MAY2013	SD	No	No
107-0006/60/M/W2	WEEK 12	29JUL2013	PD	No	No
108-0001/60/F/W2	WEEK 12	04MAY2012	PD	No	No
108-0002/78/M/BL	UNSCHEDULED	05JUL2012	PD	No	No
108-0004/61/M/W2	UNSCHEDULED	16MAY2013	PD	No	No
108-0005/68/M/W2	UNSCHEDULED	14JUN2013	SD	No	No

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
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Listing 16.2.6.4
Best Overall Objective response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Visit	Date	Overall Response	Objective Response	Best Overall Objective Response[3]
108-0005/68/M/W2	WEEK 12	29JUL2013	PD	No	
108-0008/77/M/W2	UNSCHEDULED	17NOV2014	SD	No	No
	WEEK 12	29DEC2014	SD	No	
	WEEK 24	17MAR2015	PD	No	
109-0003/68/M/W2	WEEK 12	01JUL2013	PD	No	No
109-0004/57/M/W2	WEEK 12	07OCT2013	PD	No	No
109-0006/62/M/PI	WEEK 12	06NOV2013	PD	No	No
109-0007/55/M/W2	WEEK 12	30JAN2014	SD	No	No
	WEEK 24	23APR2014	PD	No	
109-0008/70/F/W2	WEEK 12	20AUG2014	SD	No	No
	WEEK 24	13NOV2014	PD	No	
109-0009/57/M/W2	WEEK 12	22SEP2014	PD	No	No

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Best Overall Objective Response (BOOR) is calculated using the non-missing Objective Response across all visits. BOOR is 'Yes' if, at any visit, the Objective Response is 'Yes'. BOOR is 'No' if, for all visits, the Objective Response is 'No'.

Listing 16.2.6.4
Best Overall Objective response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Visit	Date	Overall Response	Objective Response	Best Overall Objective Response[3]
109-0010/65/M/W2	WEEK 12	24SEP2014	PD	No	No
109-0011/64/M/A4	WEEK 12	09DEC2014	PD	No	No
109-0013/64/F/W2	WEEK 12	20JAN2015	SD	No	No
	WEEK 24	13APR2015	PD	No	
110-0003/63/M/OTH	WEEK 12	24SEP2012	SD	No	No
	WEEK 24	17DEC2012	SD	No	
110-0004/53/M/A4	WEEK 12	08JAN2013	SD	No	No
110-0005/77/M/W2	WEEK 12	24MAY2013	SD	No	No
110-0007/62/M/A4	WEEK 12	31JUL2013	SD	No	No
	WEEK 24	23OCT2013	SD	No	
	WEEK 36	13JAN2014	PD	No	
110-0008/63/F/BL		.			Missing

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
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Listing 16.2.6.4
Best Overall Objective response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Visit	Date	Overall Response	Objective Response	Best Overall Objective Response[3]
110-0011/77/M/A1	WEEK 12	07APR2015	PD	No	No
111-0001/37/M/A4	UNSCHEDULED	27JUL2012	PD	No	No
111-0004/64/M/W2	UNSCHEDULED	03JUL2013	SD	No	No
	UNSCHEDULED	31JUL2013	SD	No	
111-0006/59/M/W2	WEEK 12	06JAN2014	SD	No	No
	WEEK 24	26MAR2014	SD	No	
111-0007/55/M/W2	WEEK 12	14APR2014	PD	No	No
112-0006/58/M/W2	WEEK 12	03JUN2013	PD	No	No
112-0009/50/M/A8	WEEK 12	04SEP2013	PD	No	No
112-0011/56/M/A4	UNSCHEDULED	28FEB2014	PD	No	No
112-0012/71/M/W2	WEEK 12	08AUG2014	PD	No	No
112-0013/28/F/W2	UNSCHEDULED	12JUL2014	SD	No	No

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Listing 16.2.6.4
Best Overall Objective response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Visit	Date	Overall Response	Objective Response	Best Overall Objective Response[3]
112-0014/79/M/A8	UNSCHEDULED	18JUL2014	SD	No	No
	WEEK 12	22AUG2014	PD	No	
112-0015/66/M/A8	UNSCHEDULED	12DEC2014	PD	No	No
113-0001/60/M/W2	WEEK 12	08NOV2012	SD	No	No
	WEEK 24	06FEB2013	PD	No	
113-0002/64/F/W2	WEEK 12	22DEC2012	SD	No	No
	WEEK 24	18MAR2013	SD	No	
	WEEK 36	18JUN2013	PD	No	
113-0005/58/M/W2		.			Missing
113-0008/78/M/A8		.			Missing
113-0010/59/M/W2		.			Missing
113-0013/56/M/W2	WEEK 12	13JAN2015	PD	No	No

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
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Listing 16.2.6.4
Best Overall Objective response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Visit	Date	Overall Response	Objective Response	Best Overall Objective Response[3]
113-0016/72/M/A8	WEEK 12	22APR2015	PD	No	No
114-0003/59/M/W2	WEEK 12	13FEB2013	SD	No	No
	UNSCHEDULED	10APR2013	SD	No	
114-0005/73/M/W2	UNSCHEDULED	06FEB2014	SD	No	No
114-0007/60/F/W2	WEEK 12	04FEB2015	SD	No	No
	WEEK 24	01MAY2015	SD	No	
115-0001/59/F/A4	WEEK 12	11FEB2013	PD	No	No
115-0002/45/F/W2	UNSCHEDULED	10JAN2013	PD	No	No
115-0003/63/M/W2	WEEK 12	02APR2013	SD	No	No
	WEEK 24	24JUN2013	SD	No	
115-0008/51/M/A8		.			Missing
115-0009/85/M/W2	WEEK 12	21FEB2014	SD	No	No

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
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Listing 16.2.6.4
Best Overall Objective response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Visit	Date	Overall Response	Objective Response	Best Overall Objective Response[3]
115-0009/85/M/W2	UNSCHEDULED	03APR2014	SD	No	
	WEEK 24	21MAY2014	PD	No	
115-0011/56/M/W2	UNSCHEDULED	16JUL2014	SD	No	No
	WEEK 12	29AUG2014	PD	No	
115-0014/72/M/W2		.			Missing
116-0002/67/F/W2	WEEK 12	03JUN2013	SD	No	No
	WEEK 24	23AUG2013	SD	No	
	WEEK 36	15NOV2013	PD	No	
116-0003/66/M/BL	WEEK 12	21MAY2013	PD	No	No
117-0001/69/M/W2	UNSCHEDULED	25APR2013	SD	No	No
	WEEK 12	12JUN2013	PD	No	
118-0001/67/F/A8	WEEK 12	29OCT2013	PD	No	No

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Listing 16.2.6.4
Best Overall Objective response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Visit	Date	Overall Response	Objective Response	Best Overall Objective Response[3]
119-0001/80/M/A8		.			Missing
121-0001/62/M/W2	WEEK 12	06MAY2014	SD	No	No
121-0004/64/F/W2		.			Missing
201-0001/68/F/W2	WEEK 12	23APR2012	PD	No	No
201-0005/73/M/W2	WEEK 12	09OCT2012	PD	No	No
201-0008/79/M/W2	WEEK 12	29JUL2013	SD	No	No
201-0011/73/M/W2	WEEK 12	20SEP2013	PD	No	No
201-0012/79/M/W2	WEEK 12	11OCT2013	SD	No	No
	WEEK 24	07JAN2014	SD	No	
	WEEK 36	28MAR2014	SD	No	
	WEEK 48	23JUN2014	SD	No	
	WEEK 60	16SEP2014	PD	No	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
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Listing 16.2.6.4
Best Overall Objective response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Visit	Date	Overall Response	Objective Response	Best Overall Objective Response[3]
201-0013/67/F/W2	WEEK 12	11OCT2013	PD	No	No
201-0016/72/M/W2	WEEK 12	03FEB2014	SD	No	No
	WEEK 24	18APR2014	PD	No	
201-0017/82/M/W2		.			Missing
201-0018/78/F/W2		.			Missing
201-0019/68/M/W2	WEEK 12	07MAR2014	PD	No	No
201-0020/67/M/W2		.			Missing
201-0021/54/M/W2	WEEK 12	02MAY2014	PD	No	No
201-0024/74/M/W2	UNSCHEDULED	13MAR2015	PD	No	No
201-0025/75/M/W2		.			Missing
203-0001/61/F/W2		.			Missing
203-0002/72/M/W2		.			Missing

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
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Listing 16.2.6.4
Best Overall Objective response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Visit	Date	Overall Response	Objective Response	Best Overall Objective Response[3]
203-0005/53/M/W2	WEEK 12	09JUL2012	PD	No	No
203-0013/68/M/W2		.			Missing
203-0015/85/M/W2	WEEK 12	10APR2014	PD	No	No
203-0017/58/M/W2		.			Missing
203-0018/58/F/W2		.			Missing
205-0001/77/M/W2	WEEK 12	08MAY2012	SD	No	No
	WEEK 24	09AUG2012	SD	No	
	WEEK 36	23OCT2012	SD	No	
	WEEK 48	28JAN2013	SD	No	
	WEEK 60	16APR2013	SD	No	
	WEEK 72	09JUL2013	SD	No	
	WEEK 84	01OCT2013	PD	No	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Best Overall Objective Response (BOOR) is calculated using the non-missing Objective Response across all visits. BOOR is 'Yes' if, at any visit, the Objective Response is 'Yes'. BOOR is 'No' if, for all visits, the Objective Response is 'No'.

Listing 16.2.6.4
Best Overall Objective response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Visit	Date	Overall Response	Objective Response	Best Overall Objective Response[3]
205-0004/77/F/W2	WEEK 12	05JUN2012	PD	No	No
205-0008/76/M/W2		.			Missing
205-0012/73/F/W2		.			Missing
205-0015/71/M/W2		.			Missing
205-0016/70/M/W2	WEEK 12	10SEP2013	SD	No	No
	WEEK 24	10DEC2013	SD	No	
	WEEK 36	28MAR2014	SD	No	
	WEEK 48	20MAY2014	SD	No	
	WEEK 60	06AUG2014	SD	No	
	WEEK 72	28OCT2014	SD	No	
	WEEK 84	20JAN2015	SD	No	
	WEEK 96	21APR2015	SD	No	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Best Overall Objective Response (BOOR) is calculated using the non-missing Objective Response across all visits. BOOR is 'Yes' if, at any visit, the Objective Response is 'Yes'. BOOR is 'No' if, for all visits, the Objective Response is 'No'.

Listing 16.2.6.4
Best Overall Objective response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Visit	Date	Overall Response	Objective Response	Best Overall Objective Response[3]
205-0017/71/M/W2	WEEK 12	15OCT2013	SD	No	No
	WEEK 24	14JAN2014	PD	No	
205-0020/82/M/W2	WEEK 12	27DEC2013	PD	No	No
205-0022/67/M/W2		.			Missing
205-0024/80/M/W2	WEEK 12	25FEB2014	PD	No	No
205-0025/63/F/W2	WEEK 12	11FEB2014	PD	No	No
207-0001/81/F/W2		.			Missing
207-0005/74/M/W2		.			Missing
207-0006/73/M/W2	WEEK 12	14SEP2012	PD	No	No
207-0008/66/M/W2		.			Missing
207-0011/78/M/W2		.			Missing
207-0015/77/M/W2	WEEK 12	23OCT2013	PD	No	No

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Best Overall Objective Response (BOOR) is calculated using the non-missing Objective Response across all visits. BOOR is 'Yes' if, at any visit, the Objective Response is 'Yes'. BOOR is 'No' if, for all visits, the Objective Response is 'No'.

Listing 16.2.6.4
Best Overall Objective response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Visit	Date	Overall Response	Objective Response	Best Overall Objective Response[3]
207-0020/77/M/W2	WEEK 12	03SEP2014	PD	No	No
207-0021/74/M/W2	WEEK 12	03SEP2014	SD	No	No
	WEEK 24	25NOV2014	SD	No	
	WEEK 36	13FEB2015	PD	No	
207-0022/74/M/W2	WEEK 12	23SEP2014	SD	No	No
208-0001/59/M/W2	WEEK 12	05DEC2012	SD	No	No
	WEEK 24	01MAR2013	SD	No	
	WEEK 36	22MAY2013	SD	No	
	WEEK 48	19AUG2013	SD	No	
	WEEK 60	06NOV2013	SD	No	
	WEEK 72	29JAN2014	SD	No	
	WEEK 84	23APR2014	SD	No	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
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Listing 16.2.6.4
Best Overall Objective response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Visit	Date	Overall Response	Objective Response	Best Overall Objective Response[3]
208-0001/59/M/W2	WEEK 96	16JUL2014	SD	No	
	WEEK 108	08OCT2014	SD	No	
	WEEK 120	02JAN2015	SD	No	
	WEEK 132	01APR2015	SD	No	
	UNSCHEDULED	17JUN2015	SD	No	
208-0002/82/F/W2	WEEK 12	12DEC2012	PD	No	No
208-0006/69/F/W2	WEEK 12	13NOV2013	PD	No	No
208-0007/53/M/W2	WEEK 12	25SEP2014	PD	No	No
209-0001/66/M/W2	WEEK 12	31JAN2013	PD	No	No
209-0004/74/M/W2	WEEK 12	24JUN2013	PD	No	No
209-0008/66/M/W2	WEEK 12	30SEP2013	PD	No	No
209-0012/63/M/W2	WEEK 12	17FEB2014	SD	No	No

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Best Overall Objective Response (BOOR) is calculated using the non-missing Objective Response across all visits. BOOR is 'Yes' if, at any visit, the Objective Response is 'Yes'. BOOR is 'No' if, for all visits, the Objective Response is 'No'.

Listing 16.2.6.4
Best Overall Objective response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Visit	Date	Overall Response	Objective Response	Best Overall Objective Response[3]
209-0012/63/M/W2	WEEK 24	22MAY2014	PD	No	
209-0013/52/M/W2	WEEK 12	10MAR2014	PD	No	No
210-0001/67/M/W2	WEEK 12	11NOV2013	SD	No	No
	WEEK 24	05FEB2014	SD	No	
	UNSCHEDULED	25FEB2014	PD	No	
210-0002/80/M/W2	WEEK 12	19DEC2013	SD	No	No
	WEEK 24	13MAR2014	SD	No	
	WEEK 36	12JUN2014	SD	No	
	WEEK 48	04SEP2014	PD	No	
210-0007/72/M/W2	WEEK 12	18NOV2014	SD	No	No
	WEEK 24	16FEB2015	SD	No	
	WEEK 36	04JUN2015	SD	No	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
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Listing 16.2.6.4
Best Overall Objective response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Visit	Date	Overall Response	Objective Response	Best Overall Objective Response[3]
210-0009/49/F/W2	WEEK 12	27JAN2015	PD	No	No
210-0011/73/M/W2	WEEK 12	03FEB2015	PD	No	No
210-0012/47/F/W2	WEEK 12	17MAR2015	PD	No	No
210-0014/71/F/W2	WEEK 12	28APR2015	PD	No	No
251-0001/55/F/W2	WEEK 12	16OCT2012	SD	No	No
252-0002/76/M/W2		.			Missing
252-0003/68/M/W2	WEEK 12	19MAR2013	PD	No	No
252-0007/77/M/W2		.			Missing
252-0011/81/M/BL	WEEK 12	10FEB2015	SD	No	No
	WEEK 24	07MAY2015	SD	No	
253-0002/63/M/W2	WEEK 12	25MAY2012	PD	No	No
253-0010/76/M/W2	WEEK 12	22AUG2013	SD	No	No

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Listing 16.2.6.4
Best Overall Objective response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Visit	Date	Overall Response	Objective Response	Best Overall Objective Response[3]
253-0010/76/M/W2	WEEK 24	13NOV2013	PD	No	
254-0001/69/M/W2	WEEK 12	08AUG2012	PD	No	No
257-0001/47/M/A4		.			Missing
257-0002/56/M/W2		.			Missing
257-0007/80/M/W2	WEEK 12	09MAY2013	PD	No	No
257-0008/80/F/W2	WEEK 12	13JUN2013	PD	No	No
257-0010/42/M/BL	WEEK 12	05AUG2013	PD	No	No
257-0012/75/M/W2		.			Missing
257-0015/69/F/BL		.			Missing
257-0017/74/M/A8	WEEK 12	21JUL2014	PD	No	No
257-0018/53/M/A6		.			Missing
257-0022/60/M/W2	UNSCHEDULED	02FEB2015	PD	No	No

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[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
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Listing 16.2.6.4
Best Overall Objective response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Visit	Date	Overall Response	Objective Response	Best Overall Objective Response[3]
257-0024/75/M/W2		.			Missing
257-0025/69/M/BL	WEEK 12	09MAR2015	PD	No	No
257-0026/65/M/W2		.			Missing
257-0027/52/M/A6		.			Missing
258-0005/64/M/OTH	UNSCHEDULED	09OCT2013	SD	No	No
258-0007/74/M/W2		.			Missing
258-0008/70/M/W2		.			Missing
258-0009/64/M/W2	WEEK 12	06AUG2014	SD	No	No
	WEEK 24	29OCT2014	PD	No	
258-0010/53/M/W2	WEEK 12	20AUG2014	SD	No	No
	WEEK 24	12NOV2014	PD	No	
258-0012/66/F/W2	WEEK 12	01OCT2014	PD	No	No

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[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
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Listing 16.2.6.4
Best Overall Objective response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Visit	Date	Overall Response	Objective Response	Best Overall Objective Response[3]
258-0015/65/M/W2		.			Missing
259-0001/68/F/W2	WEEK 12	14AUG2013	SD	No	No
	WEEK 24	06NOV2013	SD	No	
	WEEK 36	05FEB2014	SD	No	
	WEEK 48	30APR2014	SD	No	
259-0002/54/F/W2	WEEK 12	27NOV2013	PD	No	No
260-0003/81/M/A7	WEEK 12	19JAN2015	SD	No	No
	WEEK 24	09APR2015	SD	No	
	WEEK 36	03JUL2015	SD	No	
301-0005/61/M/A2	WEEK 12	09AUG2012	PD	No	No
301-0007/55/F/A2		.			Missing
301-0009/55/M/A2	WEEK 12	28MAR2013	PD	No	No

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Listing 16.2.6.4
Best Overall Objective response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Visit	Date	Overall Response	Objective Response	Best Overall Objective Response[3]
302-0002/32/F/A2		.			Missing
302-0004/57/M/A2		.			Missing
302-0007/76/M/A2	WEEK 12	03MAY2012	PD	No	No
302-0008/37/M/A2	UNSCHEDULED	14MAY2012	PD	No	No
302-0010/45/M/A2	WEEK 12	05JUL2012	PD	No	No
302-0011/52/M/A2		.			Missing
302-0015/60/M/A2	WEEK 12	08JUL2013	PD	No	No
302-0016/60/M/A2	WEEK 12	02JUL2013	PD	No	No
302-0019/52/M/A2	WEEK 12	30JUL2013	PD	No	No
302-0022/65/M/A2	UNSCHEDULED	18SEP2013	PD	No	No
302-0023/68/M/A2		.			Missing
302-0024/66/F/A2	WEEK 12	10DEC2013	PD	No	No

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Listing 16.2.6.4
Best Overall Objective response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Visit	Date	Overall Response	Objective Response	Best Overall Objective Response[3]
302-0025/40/M/A2		.			Missing
302-0026/49/M/A2	WEEK 12	28JAN2014	SD	No	No
	WEEK 24	22APR2014	SD	No	
	WEEK 36	15JUL2014	PD	No	
303-0001/50/M/A2	WEEK 12	18APR2012	PD	No	No
303-0003/47/M/A2	WEEK 12	16FEB2013	PD	No	No
303-0004/18/M/A2	WEEK 12	23FEB2013	PD	No	No
303-0006/64/M/A2	UNSCHEDULED	22MAY2013	PD	No	No
303-0007/50/M/A2		.			Missing
304-0001/54/M/A2	UNSCHEDULED	13DEC2012	PD	No	No
304-0005/58/M/A2	UNSCHEDULED	28JUN2013	PD	No	No
305-0002/57/M/A2	UNSCHEDULED	24FEB2012	PD	No	No

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[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
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Listing 16.2.6.4
Best Overall Objective response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Visit	Date	Overall Response	Objective Response	Best Overall Objective Response[3]
305-0003/50/M/A2	WEEK 12	11MAY2012	SD	No	No
	WEEK 24	03AUG2012	PD	No	
305-0005/48/M/A2		.			Missing
305-0006/65/M/A2	WEEK 12	30MAY2012	SD	No	No
	WEEK 24	22AUG2012	PD	No	
305-0009/45/F/A2	WEEK 12	04JUL2012	SD	No	No
	WEEK 24	26SEP2012	PD	No	
305-0010/64/F/A2	WEEK 12	10JUL2012	PD	No	No
305-0011/68/M/A2	WEEK 12	20JUL2012	SD	No	No
	UNSCHEDULED	10AUG2012	PD	No	
305-0012/62/F/A2	WEEK 12	27JUL2012	PD	Yes	Yes
	UNSCHEDULED	07SEP2012	PR	Yes	

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[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
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Listing 16.2.6.4
Best Overall Objective response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Visit	Date	Overall Response	Objective Response	Best Overall Objective Response[3]
305-0012/62/F/A2	WEEK 24	19OCT2012	PR	Yes	
	WEEK 36	11JAN2013	PD	No	
305-0014/61/F/A2	WEEK 12	21SEP2012	PD	No	No
305-0019/35/M/A2		.			Missing
305-0023/54/M/A2	WEEK 12	26MAR2013	PD	No	No
305-0025/77/F/A2	WEEK 12	16APR2013	PD	No	No
305-0026/45/M/A2	WEEK 12	21MAY2013	SD	No	No
	WEEK 24	13AUG2013	SD	No	
305-0028/73/F/A2	WEEK 12	05JUN2013	PD	No	No
305-0030/61/M/A2		.			Missing
305-0031/29/M/A2		.			Missing
305-0034/53/M/A2	UNSCHEDULED	05AUG2013	PD	No	No

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Best Overall Objective Response (BOOR) is calculated using the non-missing Objective Response across all visits. BOOR is 'Yes' if, at any visit, the Objective Response is 'Yes'. BOOR is 'No' if, for all visits, the Objective Response is 'No'.

Listing 16.2.6.4
Best Overall Objective response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Visit	Date	Overall Response	Objective Response	Best Overall Objective Response[3]
305-0036/38/M/A2	WEEK 12	22NOV2013	PD	No	No
305-0037/50/M/A2	WEEK 12	09JAN2014	SD	No	No
305-0039/35/M/A2		.			Missing
305-0040/61/M/A2		.			Missing
305-0043/70/M/A2	WEEK 12	16SEP2014	PD	No	No
305-0044/67/M/A2	WEEK 12	30SEP2014	PD	No	No
305-0045/65/M/A2		.			Missing
305-0047/58/M/A2		.			Missing
305-0048/55/M/A2	WEEK 12	12MAY2015	PD	No	No
306-0001/56/M/A2	WEEK 12	04MAY2012	PD	No	No
306-0002/73/M/A2	WEEK 12	02MAY2012	PD	No	No
306-0005/69/F/A2	UNSCHEDULED	25APR2012	PD	No	No

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Best Overall Objective Response (BOOR) is calculated using the non-missing Objective Response across all visits. BOOR is 'Yes' if, at any visit, the Objective Response is 'Yes'. BOOR is 'No' if, for all visits, the Objective Response is 'No'.

Listing 16.2.6.4
Best Overall Objective response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Visit	Date	Overall Response	Objective Response	Best Overall Objective Response[3]
306-0006/43/M/A2	UNSCHEDULED	11APR2012	PD	No	No
306-0007/56/M/A2	UNSCHEDULED	23APR2012	PD	No	No
306-0008/40/M/A2		.			Missing
306-0011/47/M/A2	WEEK 12	31MAY2012	PD	No	No
306-0012/61/M/A2	WEEK 12	19JUN2012	SD	No	No
	WEEK 24	11SEP2012	SD	No	
306-0014/47/M/A2		.			Missing
306-0017/49/M/A2	UNSCHEDULED	23AUG2012	PD	No	No
306-0019/78/M/A2	WEEK 12	05NOV2012	PD	No	No
306-0020/63/M/A2	WEEK 12	20DEC2012	PD	No	No
306-0023/68/M/A2	UNSCHEDULED	03JAN2013	PD	No	No
306-0026/58/M/A2	WEEK 12	25APR2013	SD	No	No

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
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Listing 16.2.6.4
Best Overall Objective response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Visit	Date	Overall Response	Objective Response	Best Overall Objective Response[3]
306-0026/58/M/A2	WEEK 24	18JUL2013	SD	No	
	WEEK 36	11OCT2013	PD	No	
306-0027/67/M/A2	UNSCHEDULED	25APR2013	SD	No	No
	WEEK 24	01AUG2013	SD	No	
	UNSCHEDULED	26SEP2013	SD	No	
	WEEK 36	24OCT2013	SD	No	
	WEEK 48	16JAN2014	SD	No	
	WEEK 60	10APR2014	SD	No	
	WEEK 72	02JUL2014	PD	No	
306-0030/63/M/A2		.			Missing
306-0031/40/M/A2	UNSCHEDULED	18JUL2013	PD	No	No
306-0034/65/M/A2	UNSCHEDULED	25JUL2013	PD	No	No

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Best Overall Objective Response (BOOR) is calculated using the non-missing Objective Response across all visits. BOOR is 'Yes' if, at any visit, the Objective Response is 'Yes'. BOOR is 'No' if, for all visits, the Objective Response is 'No'.

Listing 16.2.6.4
Best Overall Objective response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Visit	Date	Overall Response	Objective Response	Best Overall Objective Response[3]
306-0035/48/M/A2	UNSCHEDULED	22AUG2013	PD	No	No
306-0036/73/M/A2	UNSCHEDULED	09SEP2013	PD	No	No
306-0038/66/M/A2	WEEK 12	31OCT2013	PD	No	No
306-0039/62/M/A2	WEEK 12	31OCT2013	PD	No	No
306-0040/44/F/A2	UNSCHEDULED	14NOV2013	SD	No	No
	WEEK 12	12DEC2013	SD	No	
	WEEK 24	06MAR2014	PD	No	
306-0041/62/M/A2	WEEK 12	16JAN2014	SD	No	No
	UNSCHEDULED	21FEB2014	PD	No	
306-0043/56/M/A2	WEEK 12	04AUG2014	PD	No	No
307-0002/61/M/A2	WEEK 12	20JAN2012	PD	No	No
307-0003/68/M/A2	WEEK 12	31JAN2012	SD	No	No

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Best Overall Objective Response (BOOR) is calculated using the non-missing Objective Response across all visits. BOOR is 'Yes' if, at any visit, the Objective Response is 'Yes'. BOOR is 'No' if, for all visits, the Objective Response is 'No'.

Listing 16.2.6.4
Best Overall Objective response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Visit	Date	Overall Response	Objective Response	Best Overall Objective Response[3]
307-0003/68/M/A2	WEEK 24	16APR2012	SD	No	
	WEEK 36	10JUL2012	SD	No	
307-0004/60/M/A2	UNSCHEDULED	19JAN2012	PD	No	No
307-0008/58/M/A2	WEEK 12	08MAR2012	PD	No	No
307-0011/75/M/A2		.			Missing
307-0014/61/M/A2	WEEK 12	08MAY2012	SD	No	No
	WEEK 24	26JUL2012	PD	No	
307-0018/70/M/A2	WEEK 12	30AUG2012	SD	No	No
	WEEK 24	22NOV2012	SD	No	
	WEEK 36	14FEB2013	SD	No	
	WEEK 48	09MAY2013	PD	No	
307-0020/68/F/A2	WEEK 12	30OCT2012	PD	No	No

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
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Listing 16.2.6.4
Best Overall Objective response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Visit	Date	Overall Response	Objective Response	Best Overall Objective Response[3]
307-0022/59/M/A2	WEEK 12	14FEB2013	PD	No	No
307-0025/68/M/A2	WEEK 12	07MAR2013	SD	No	No
	WEEK 24	30MAY2013	PD	No	
307-0026/65/M/A2	WEEK 12	12MAR2013	SD	No	No
	WEEK 24	04JUN2013	PD	No	
307-0030/53/M/A2	UNSCHEDULED	13MAY2013	PD	No	No
307-0031/60/M/A2	WEEK 12	30MAY2013	SD	No	No
	WEEK 24	22AUG2013	SD	No	
	WEEK 36	14NOV2013	PD	No	
307-0032/74/F/A2		.			Missing
307-0037/61/M/A2		.			Missing
307-0039/51/M/A2	WEEK 12	21JAN2014	PD	No	No

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
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Listing 16.2.6.4
Best Overall Objective response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Visit	Date	Overall Response	Objective Response	Best Overall Objective Response[3]
307-0040/65/M/A2		.			Missing
307-0043/54/M/A2	WEEK 12	09SEP2014	SD	No	No
307-0044/53/M/A2		.			Missing
307-0045/48/M/A2	WEEK 12	22SEP2014	PD	No	No
307-0046/46/M/A2		.			Missing
308-0003/54/M/A2	WEEK 12	18APR2013	SD	No	No
	WEEK 24	11JUL2013	SD	No	
	WEEK 36	03OCT2013	PD	No	
308-0005/68/F/A2	WEEK 12	18JUL2013	PD	No	No
309-0001/46/M/A2	WEEK 12	21AUG2012	PD	No	No
309-0002/56/M/A2	UNSCHEDULED	21JUN2012	PD	No	No
309-0003/52/F/A2	WEEK 12	29AUG2012	PD	No	No

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
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Listing 16.2.6.4
Best Overall Objective response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Visit	Date	Overall Response	Objective Response	Best Overall Objective Response[3]
309-0004/55/M/A2		.			Missing
309-0008/38/M/A2	WEEK 12	02MAY2013	PD	No	No
309-0010/47/M/A2	WEEK 12	03JUN2013	PD	No	Yes
	WEEK 24	26AUG2013	PR	Yes	
	WEEK 36	20NOV2013	PR	Yes	
	WEEK 48	10FEB2014	PR	Yes	
	WEEK 60	05MAY2014	PR	Yes	
	WEEK 72	28JUL2014	PR	Yes	
	WEEK 84	20OCT2014	PD	No	
309-0011/59/M/A2	WEEK 12	17JUN2013	PD	No	No
309-0012/82/M/A2	WEEK 12	01AUG2013	PD	No	No
309-0015/62/M/A2	WEEK 12	02SEP2013	PD	No	No

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
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Listing 16.2.6.4
Best Overall Objective response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Visit	Date	Overall Response	Objective Response	Best Overall Objective Response[3]
309-0016/72/F/A2	WEEK 12	14NOV2013	PD	No	No
309-0017/73/F/A2	WEEK 12	10FEB2014	PD	No	No
309-0018/82/M/A2	WEEK 12	25AUG2014	PD	No	No
309-0021/54/F/A2	UNSCHEDULED	16SEP2014	PD	No	No
309-0025/49/M/A2		.			Missing
309-0026/41/M/A2	UNSCHEDULED	04NOV2014	SD	No	No
	WEEK 12	01DEC2014	SD	No	
	UNSCHEDULED	28JAN2015	PD	No	
309-0028/62/M/A2	WEEK 12	12JAN2015	SD	No	No
	WEEK 24	08APR2015	PD	No	
309-0030/33/M/A2	UNSCHEDULED	08FEB2015	PD	No	No
309-0031/34/M/A2	WEEK 12	05MAR2015	PD	No	No

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
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Listing 16.2.6.4
Best Overall Objective response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Visit	Date	Overall Response	Objective Response	Best Overall Objective Response[3]
309-0031/34/M/A2	UNSCHEDULED	12MAR2015	PD	No	
309-0032/63/M/A2	WEEK 12	19MAR2015	PD	No	No
309-0033/78/F/A2	WEEK 12	16APR2015	SD	No	No
	WEEK 24	02JUL2015	PD	No	
310-0001/61/M/A2	UNSCHEDULED	21AUG2012	PD	No	No
310-0002/55/M/A2		.			Missing
310-0003/61/M/A2	WEEK 12	24APR2013	PD	No	No
310-0008/49/M/A2		.			Missing
310-0012/73/M/A2	WEEK 12	16JAN2014	SD	No	No
	WEEK 24	10APR2014	PD	No	
310-0013/54/M/A2	WEEK 12	12NOV2014	PD	No	No
311-0002/60/M/A2	UNSCHEDULED	10OCT2013	PD	No	No

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Best Overall Objective Response (BOOR) is calculated using the non-missing Objective Response across all visits. BOOR is 'Yes' if, at any visit, the Objective Response is 'Yes'. BOOR is 'No' if, for all visits, the Objective Response is 'No'.

Listing 16.2.6.4
Best Overall Objective response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Visit	Date	Overall Response	Objective Response	Best Overall Objective Response[3]
311-0007/55/M/A2	WEEK 12	27JAN2014	PD	No	No
311-0008/71/M/A2	UNSCHEDULED	09JUL2014	PD	No	No
401-0003/36/M/A7	UNSCHEDULED	03SEP2013	PD	No	No
401-0005/58/M/A7	UNSCHEDULED	18DEC2013	PD	No	No
402-0003/75/M/A7	WEEK 12	16JUL2013	SD	No	No
	WEEK 24	08OCT2013	PD	No	
402-0006/71/M/A7	WEEK 12	22JUL2013	PD	No	No
402-0008/43/M/A7	UNSCHEDULED	04JUN2013	PD	No	No
402-0009/70/M/A7	UNSCHEDULED	04JUL2013	PD	No	No
402-0011/64/M/A7	WEEK 12	04JUL2013	PD	No	No
402-0017/50/M/A7		.			Missing
402-0018/48/M/A7	WEEK 12	09SEP2013	PD	No	No

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Best Overall Objective Response (BOOR) is calculated using the non-missing Objective Response across all visits. BOOR is 'Yes' if, at any visit, the Objective Response is 'Yes'. BOOR is 'No' if, for all visits, the Objective Response is 'No'.

Listing 16.2.6.4
Best Overall Objective response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Visit	Date	Overall Response	Objective Response	Best Overall Objective Response[3]
402-0019/54/M/A7	WEEK 12	16SEP2013	PD	No	No
402-0021/64/M/A7	WEEK 12	29OCT2013	SD	No	No
	WEEK 24	21JAN2014	SD	No	
	WEEK 36	09APR2014	SD	No	
	WEEK 48	08JUL2014	SD	No	
	WEEK 60	29SEP2014	PD	No	
402-0024/57/M/A7	UNSCHEDULED	05NOV2013	PD	No	No
402-0025/58/M/A7	WEEK 12	12DEC2013	PD	No	No
402-0027/52/M/A7	UNSCHEDULED	21NOV2013	PD	No	No
402-0028/60/M/A7		.			Missing
402-0031/65/M/A7	WEEK 12	29JAN2014	PD	No	No
402-0033/63/F/A7	UNSCHEDULED	27JAN2014	PD	No	No

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Best Overall Objective Response (BOOR) is calculated using the non-missing Objective Response across all visits. BOOR is 'Yes' if, at any visit, the Objective Response is 'Yes'. BOOR is 'No' if, for all visits, the Objective Response is 'No'.

Listing 16.2.6.4
Best Overall Objective response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Visit	Date	Overall Response	Objective Response	Best Overall Objective Response[3]
402-0035/44/M/A7		.			Missing
403-0001/55/M/A7	UNSCHEDULED	01JUL2013	PD	No	No
403-0002/52/M/A7	UNSCHEDULED	21AUG2013	PD	No	No
403-0005/50/F/A7	UNSCHEDULED	01AUG2013	PD	No	No
403-0006/66/M/A7	WEEK 12	17OCT2013	PD	No	No
403-0007/64/M/MIX	UNSCHEDULED	01OCT2013	SD	No	No
	WEEK 12	07NOV2013	PD	No	
404-0001/71/M/A7	UNSCHEDULED	12AUG2013	PD	No	No
404-0002/56/F/A7	UNSCHEDULED	12SEP2013	PD	No	No
405-0002/46/M/A7		.			Missing
405-0004/38/M/A7	WEEK 12	10JUL2013	PD	No	No
405-0006/62/M/A7		.			Missing

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Best Overall Objective Response (BOOR) is calculated using the non-missing Objective Response across all visits. BOOR is 'Yes' if, at any visit, the Objective Response is 'Yes'. BOOR is 'No' if, for all visits, the Objective Response is 'No'.

Listing 16.2.6.4
Best Overall Objective response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Visit	Date	Overall Response	Objective Response	Best Overall Objective Response[3]
405-0007/53/M/A7	UNSCHEDULED	25JUN2013	SD	No	No
	WEEK 12	23JUL2013	SD	No	
405-0009/50/M/A7	UNSCHEDULED	10JUN2013	SD	No	No
405-0010/39/M/A7	WEEK 12	06AUG2013	PD	No	No
405-0011/63/M/A7	UNSCHEDULED	01JUL2013	SD	No	No
	WEEK 12	29JUL2013	SD	No	
	WEEK 24	21OCT2013	PD	No	
405-0013/45/M/A7	UNSCHEDULED	08JUL2013	SD	No	No
	WEEK 12	05AUG2013	SD	No	
405-0014/35/M/A7	UNSCHEDULED	30JUN2013	PD	No	No
405-0016/41/M/A7	UNSCHEDULED	25JUN2013	PD	No	No
405-0018/70/F/A7	UNSCHEDULED	03JUL2013	PD	No	No

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Best Overall Objective Response (BOOR) is calculated using the non-missing Objective Response across all visits. BOOR is 'Yes' if, at any visit, the Objective Response is 'Yes'. BOOR is 'No' if, for all visits, the Objective Response is 'No'.

Listing 16.2.6.4
Best Overall Objective response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Visit	Date	Overall Response	Objective Response	Best Overall Objective Response[3]
405-0020/69/M/A7	WEEK 12	04SEP2013	SD	No	No
	WEEK 24	27NOV2013	SD	No	
	WEEK 36	19FEB2014	SD	No	
	WEEK 48	14MAY2014	PD	No	
405-0021/47/M/A7	WEEK 12	05SEP2013	SD	No	No
	UNSCHEDULED	11OCT2013	SD	No	
	WEEK 24	27NOV2013	SD	No	
	WEEK 36	18FEB2014	SD	No	
	WEEK 48	14MAY2014	SD	No	
	UNSCHEDULED	04JUL2014	SD	No	
	UNSCHEDULED	06AUG2014	PD	No	
405-0022/65/M/A7	UNSCHEDULED	26AUG2013	SD	No	No

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Best Overall Objective Response (BOOR) is calculated using the non-missing Objective Response across all visits. BOOR is 'Yes' if, at any visit, the Objective Response is 'Yes'. BOOR is 'No' if, for all visits, the Objective Response is 'No'.

Listing 16.2.6.4
Best Overall Objective response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Visit	Date	Overall Response	Objective Response	Best Overall Objective Response[3]
405-0022/65/M/A7	WEEK 12	16SEP2013	SD	No	
	WEEK 24	11DEC2013	PD	No	
405-0023/46/M/A7	WEEK 12	05SEP2013	PD	No	No
405-0025/47/M/A7	UNSCHEDULED	17JUL2013	PD	No	No
405-0028/67/M/A7	WEEK 12	07OCT2013	PD	No	No
405-0030/35/M/A7	UNSCHEDULED	25SEP2013	PD	No	No
405-0032/69/M/A7	WEEK 12	08OCT2013	SD	No	No
	WEEK 24	30DEC2013	SD	No	
	WEEK 36	24MAR2014	SD	No	
	WEEK 48	16JUN2014	SD	No	
	WEEK 60	05SEP2014	PD	No	
405-0033/43/M/A7	WEEK 12	23OCT2013	PD	No	No

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Best Overall Objective Response (BOOR) is calculated using the non-missing Objective Response across all visits. BOOR is 'Yes' if, at any visit, the Objective Response is 'Yes'. BOOR is 'No' if, for all visits, the Objective Response is 'No'.

Listing 16.2.6.4
Best Overall Objective response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Visit	Date	Overall Response	Objective Response	Best Overall Objective Response[3]
405-0034/61/M/A7	WEEK 12	23OCT2013	PD	No	No
405-0035/66/M/A7	UNSCHEDULED	11OCT2014	PD	No	No
405-0039/73/M/A7	UNSCHEDULED	05NOV2013	SD	No	No
	WEEK 12	03DEC2013	PD	No	
405-0040/65/M/A7	WEEK 12	09DEC2013	PD	No	No
405-0042/53/M/A7	UNSCHEDULED	27NOV2013	PD	No	No
405-0043/49/M/A7	UNSCHEDULED	05DEC2013	PD	No	No
405-0044/56/M/A7	UNSCHEDULED	13NOV2013	PD	No	No
501-0001/59/M/A1	WEEK 12	23JAN2014	PD	No	No
501-0002/36/F/A1	WEEK 12	19FEB2014	PD	No	No
501-0005/80/M/A1	WEEK 12	10APR2014	SD	No	No
	WEEK 24	03JUL2014	SD	No	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
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Listing 16.2.6.4
Best Overall Objective response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Visit	Date	Overall Response	Objective Response	Best Overall Objective Response[3]
501-0005/80/M/A1	WEEK 36	24SEP2014	SD	No	
	WEEK 48	20DEC2014	SD	No	
	WEEK 60	12MAR2015	SD	No	
	WEEK 72	04JUN2015	PD	No	
501-0006/60/M/A1	WEEK 12	28APR2014	PD	No	No
501-0007/43/M/A1	WEEK 12	19MAY2014	PD	No	No
501-0008/76/F/A1	WEEK 12	02JUL2014	PD	No	No
501-0009/62/M/A1	WEEK 12	29SEP2014	PD	No	No
501-0010/65/M/A1	WEEK 12	26NOV2014	PD	No	No
502-0002/65/M/A1		.			Missing
503-0001/32/M/A1	UNSCHEDULED	06JAN2014	PD	No	No
503-0004/49/M/A1		.			Missing

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
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Listing 16.2.6.4
Best Overall Objective response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Visit	Date	Overall Response	Objective Response	Best Overall Objective Response[3]
503-0006/54/M/A1	WEEK 12	23OCT2014	SD	No	No
	WEEK 24	14JAN2015	SD	No	
503-0007/57/M/A1	WEEK 12	14JAN2015	PD	No	No
503-0008/50/M/A1		.			Missing
503-0009/57/M/A1		.			Missing
504-0001/47/M/A1	WEEK 12	06MAY2014	SD	No	No
504-0007/32/M/A1		.			Missing
505-0001/70/M/A1	UNSCHEDULED	28SEP2014	PD	No	No
506-0002/54/M/A1	UNSCHEDULED	12JUN2014	SD	No	No
	WEEK 12	31JUL2014	SD	No	
	WEEK 24	22OCT2014	SD	No	
	WEEK 36	14JAN2015	SD	No	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
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Listing 16.2.6.4
Best Overall Objective response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Visit	Date	Overall Response	Objective Response	Best Overall Objective Response[3]
506-0002/54/M/A1	WEEK 48	10APR2015	PD	No	
506-0003/66/M/A1	UNSCHEDULED	27OCT2014	PD	No	No
506-0004/49/M/A1	UNSCHEDULED	24DEC2014	PD	No	No
508-0001/36/M/A1	UNSCHEDULED	08FEB2014	PD	No	No
508-0003/49/F/A1		.			Missing
509-0001/45/M/A1	WEEK 12	18JUL2014	PD	No	No
509-0002/51/M/A1		.			Missing
510-0002/50/M/A1		.			Missing
510-0004/72/M/A1	WEEK 12	15OCT2014	PD	No	No
511-0001/35/M/A1	UNSCHEDULED	26FEB2014	PD	No	No
511-0002/49/M/A1	WEEK 12	27MAY2014	SD	No	No
	WEEK 24	20AUG2014	PD	No	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Best Overall Objective Response (BOOR) is calculated using the non-missing Objective Response across all visits. BOOR is 'Yes' if, at any visit, the Objective Response is 'Yes'. BOOR is 'No' if, for all visits, the Objective Response is 'No'.

Listing 16.2.6.4
Best Overall Objective response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Visit	Date	Overall Response	Objective Response	Best Overall Objective Response[3]
512-0001/59/M/A1	WEEK 12	24MAY2014	SD	No	No
513-0001/28/M/A1	UNSCHEDULED	26MAY2014	PD	No	No
513-0004/46/M/A1	UNSCHEDULED	16JUL2014	PD	No	No
513-0005/61/M/A1	WEEK 12	20JAN2015	PD	No	No
515-0001/64/M/A1	WEEK 12	07MAY2014	PD	No	No
515-0003/69/M/A1	WEEK 12	29JUL2014	PD	No	No
515-0004/52/M/A1	WEEK 12	11AUG2014	SD	No	No
515-0006/47/M/A1	WEEK 12	20OCT2014	PD	No	No
515-0007/39/M/A1		.			Missing
515-0008/60/M/A1	WEEK 12	11FEB2015	PD	No	No
516-0001/45/M/A1	WEEK 12	25OCT2014	SD	No	No
	WEEK 24	16JAN2015	PD	No	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Best Overall Objective Response (BOOR) is calculated using the non-missing Objective Response across all visits. BOOR is 'Yes' if, at any visit, the Objective Response is 'Yes'. BOOR is 'No' if, for all visits, the Objective Response is 'No'.

Listing 16.2.6.4
Best Overall Objective response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./Age[1]/ Gender/Race[2]	Visit	Date	Overall Response	Objective Response	Best Overall Objective Response[3]
517-0001/42/M/A1	UNSCHEDULED	27JAN2014	PD	No	No
517-0002/43/M/A1	WEEK 12	12JUN2014	SD	No	No
	WEEK 24	04SEP2014	PD	No	
517-0005/46/M/MIX		.			Missing
517-0006/67/F/A1	WEEK 12	12NOV2014	SD	No	No
	WEEK 24	02FEB2015	SD	No	
	WEEK 36	23APR2015	PD	No	
517-0007/66/M/A1		.			Missing
517-0008/59/M/A1		.			Missing
517-0009/23/M/A1	WEEK 12	10DEC2014	PD	No	No

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Best Overall Objective Response (BOOR) is calculated using the non-missing Objective Response across all visits. BOOR is 'Yes' if, at any visit, the Objective Response is 'Yes'. BOOR is 'No' if, for all visits, the Objective Response is 'No'.

Listing 16.2.6.4
Best Overall Objective response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./Age[1]/ Gender/Race[2]	Visit	Date	Overall Response	Objective Response	Best Overall Objective Response[3]
101-0002/70/M/OTH	WEEK 12	14OCT2011	PD	No	No
101-0004/78/F/A2	WEEK 12	21OCT2011	SD	No	No

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Best Overall Objective Response (BOOR) is calculated using the non-missing Objective Response across all visits. BOOR is 'Yes' if, at any visit, the Objective Response is 'Yes'. BOOR is 'No' if, for all visits, the Objective Response is 'No'.

Listing 16.2.6.4
Best Overall Objective response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./Age[1]/ Gender/Race[2]	Visit	Date	Overall Response	Objective Response	Best Overall Objective Response[3]
101-0004/78/F/A2	WEEK 24	13JAN2012	PD	No	
	WEEK 36	10APR2012	PD	No	
	WEEK 48	29JUN2012	PD	No	
	WEEK 60	21SEP2012	PD	No	
101-0010/43/M/BL		.			Missing
101-0014/61/M/W2	WEEK 12	16MAR2012	SD	No	No
101-0015/65/M/A4	WEEK 12	22MAR2012	PD	No	No
101-0017/60/M/W2	WEEK 12	01MAY2012	PD	No	No
101-0020/86/M/W2	WEEK 12	05JUN2012	SD	No	No
	WEEK 24	21AUG2012	PD	No	
101-0027/72/M/W2		.			Missing
101-0031/69/F/W2	WEEK 12	29SEP2012	PD	No	No

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Best Overall Objective Response (BOOR) is calculated using the non-missing Objective Response across all visits. BOOR is 'Yes' if, at any visit, the Objective Response is 'Yes'. BOOR is 'No' if, for all visits, the Objective Response is 'No'.

Listing 16.2.6.4
Best Overall Objective response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./Age[1]/ Gender/Race[2]	Visit	Date	Overall Response	Objective Response	Best Overall Objective Response[3]
101-0034/44/M/OTH	UNSCHEDULED	02NOV2012	SD	No	No
101-0035/37/M/A6		.			Missing
101-0043/69/M/W1	WEEK 12	02JAN2014	SD	No	No
101-0051/70/F/W2		.			Missing
102-0006/66/M/BL	WEEK 12	23FEB2014	PD	No	No
102-0007/61/M/W2	WEEK 12	19MAR2014	SD	No	No
103-0002/74/M/W2	WEEK 12	25FEB2013	SD	No	No
	WEEK 24	20MAY2013	PD	No	
103-0006/57/M/W2	WEEK 12	04FEB2015	PD	No	No
104-0002/80/M/W2	WEEK 12	26JUL2012	SD	No	No
	WEEK 24	20OCT2012	SD	No	
	WEEK 36	12JAN2013	SD	No	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
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Listing 16.2.6.4
Best Overall Objective response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./Age[1]/ Gender/Race[2]	Visit	Date	Overall Response	Objective Response	Best Overall Objective Response[3]
104-0007/89/M/A1	WEEK 12	24OCT2013	SD	No	No
	WEEK 24	17JAN2014	SD	No	
	WEEK 36	11APR2014	SD	No	
	WEEK 48	09JUL2014	SD	No	
	WEEK 60	24SEP2014	SD	No	
	WEEK 72	19DEC2014	SD	No	
	WEEK 84	17MAR2015	SD	No	
	WEEK 96	05JUN2015	SD	No	
105-0003/57/M/W2	WEEK 12	22JAN2014	SD	No	No
	WEEK 24	24APR2014	SD	No	
	WEEK 36	08JUL2014	SD	No	
	WEEK 48	03OCT2014	SD	No	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
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Listing 16.2.6.4
Best Overall Objective response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./Age[1]/ Gender/Race[2]	Visit	Date	Overall Response	Objective Response	Best Overall Objective Response[3]
105-0006/60/F/BL	WEEK 12	17MAR2015	SD	No	No
	WEEK 24	11JUN2015	PD	No	
108-0003/85/M/W2	WEEK 12	31DEC2012	PD	No	No
109-0002/63/M/W2	WEEK 12	07JUN2013	SD	No	No
	WEEK 24	30AUG2013	PD	No	
109-0005/64/F/W2		.			Missing
109-0012/21/F/W2	UNSCHEDULED	18NOV2014	SD	No	No
109-0014/50/F/W2	UNSCHEDULED	13MAR2015	PD	No	No
111-0003/37/M/A1	UNSCHEDULED	13MAR2013	PD	No	No
112-0010/56/F/W2	WEEK 12	21FEB2014	PD	No	No
113-0007/74/M/W2	WEEK 12	09APR2014	SD	No	No
	WEEK 24	02JUL2014	SD	No	

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Listing 16.2.6.4
Best Overall Objective response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./Age[1]/ Gender/Race[2]	Visit	Date	Overall Response	Objective Response	Best Overall Objective Response[3]
113-0015/58/F/BL		.			Missing
114-0001/25/F/OTH	WEEK 12	27SEP2012	PD	No	No
114-0004/54/F/A1	UNSCHEDULED	27MAR2013	SD	No	No
115-0005/60/M/W2		.			Missing
115-0006/62/M/W2	WEEK 12	25JUN2013	SD	No	No
115-0007/57/M/W2	UNSCHEDULED	16MAY2013	PD	No	No
115-0010/54/M/A4	WEEK 12	20JUN2014	PD	No	No
121-0003/65/M/BL	UNSCHEDULED	27AUG2014	SD	No	No
201-0002/76/M/W2	WEEK 12	04JUN2012	SD	No	No
	WEEK 24	24AUG2012	SD	No	
	WEEK 36	16NOV2012	SD	No	
	WEEK 48	11FEB2013	PD	No	

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[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
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Listing 16.2.6.4
Best Overall Objective response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./Age[1]/ Gender/Race[2]	Visit	Date	Overall Response	Objective Response	Best Overall Objective Response[3]
201-0006/71/M/W2	WEEK 12	28SEP2012	SD	No	No
	WEEK 24	19DEC2012	PD	No	
201-0007/71/M/W2	WEEK 12	12OCT2012	PD	No	Yes
	WEEK 24	04JAN2013	PR	Yes	
	WEEK 36	29MAR2013	PD	No	
201-0009/64/M/W2	WEEK 12	06SEP2013	SD	No	No
	WEEK 24	29NOV2013	SD	No	
	WEEK 36	21FEB2014	SD	No	
	WEEK 48	19MAY2014	SD	No	
	WEEK 60	04AUG2014	SD	No	
	WEEK 72	04NOV2014	SD	No	
	WEEK 84	26JAN2015	SD	No	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
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Listing 16.2.6.4
Best Overall Objective response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./Age[1]/ Gender/Race[2]	Visit	Date	Overall Response	Objective Response	Best Overall Objective Response[3]
201-0009/64/M/W2	WEEK 96	20APR2015	SD	No	
201-0010/81/F/W2	WEEK 12	13SEP2013	PD	No	No
201-0014/73/M/W2	WEEK 12	04OCT2013	PD	No	No
201-0015/49/M/W2	WEEK 12	25OCT2013	SD	No	No
	WEEK 24	17JAN2014	SD	No	
	WEEK 36	14MAR2014	PD	No	
201-0022/80/F/W2	WEEK 12	25JUL2014	SD	No	No
	WEEK 24	27OCT2014	PD	No	
203-0004/81/M/W2	WEEK 12	28JUN2012	SD	No	No
	WEEK 24	20SEP2012	SD	No	
	WEEK 36	13DEC2012	PD	No	
203-0006/76/M/W2		.			Missing

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
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Best Overall Objective response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./Age[1]/ Gender/Race[2]	Visit	Date	Overall Response	Objective Response	Best Overall Objective Response[3]
203-0007/59/M/W2		.			Missing
203-0009/73/M/W2	WEEK 12	20DEC2012	SD	No	No
	WEEK 24	04APR2013	SD	No	
	WEEK 36	01AUG2013	SD	No	
	WEEK 48	31OCT2013	PD	No	
203-0010/74/M/W2	WEEK 12	13DEC2012	SD	No	Yes
	WEEK 24	21MAR2013	SD	No	
	WEEK 36	20JUN2013	SD	No	
	WEEK 48	26SEP2013	SD	No	
	WEEK 60	09JAN2014	SD	No	
	WEEK 72	17APR2014	PR	Yes	
	WEEK 84	17JUL2014	PR	Yes	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
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Listing 16.2.6.4
Best Overall Objective response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./Age[1]/ Gender/Race[2]	Visit	Date	Overall Response	Objective Response	Best Overall Objective Response[3]
203-0010/74/M/W2	WEEK 96	02OCT2014	PR	Yes	
203-0014/73/M/W2		.			Missing
203-0016/57/M/W2	WEEK 12	24APR2014	SD	No	No
	WEEK 24	31JUL2014	PD	No	
203-0019/68/M/W2	WEEK 12	04JUL2014	PD	No	No
204-0003/64/M/W2	WEEK 12	30SEP2013	PD	No	No
204-0004/76/F/W2	WEEK 12	17DEC2013	PD	No	No
205-0002/71/M/W2	WEEK 12	08MAY2012	PD	No	No
205-0003/79/M/W2	WEEK 12	12JUN2012	SD	No	No
	WEEK 24	11SEP2012	SD	No	
	WEEK 36	04DEC2012	PD	No	
205-0005/71/M/W2	WEEK 12	05JUN2012	PD	No	No

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Listing 16.2.6.4
Best Overall Objective response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./Age[1]/ Gender/Race[2]	Visit	Date	Overall Response	Objective Response	Best Overall Objective Response[3]
205-0014/70/M/W2		.			Missing
205-0023/72/M/W2	WEEK 12	21JAN2014	PD	No	No
205-0026/61/F/W2	WEEK 12	28APR2015	PD	No	No
205-0028/73/F/W2		.			Missing
207-0002/71/M/W2	WEEK 12	07JUN2012	PD	No	No
207-0007/71/M/W2	WEEK 12	18SEP2012	PD	No	No
207-0012/66/M/W2	WEEK 12	13JUN2013	SD	No	No
	WEEK 24	05SEP2013	SD	No	
	WEEK 36	29NOV2013	SD	No	
	WEEK 48	19FEB2014	PD	No	
207-0016/82/F/W2	WEEK 12	03JAN2014	SD	No	No
207-0017/81/F/W2	WEEK 12	19FEB2014	PD	No	No

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Listing 16.2.6.4
Best Overall Objective response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./Age[1]/ Gender/Race[2]	Visit	Date	Overall Response	Objective Response	Best Overall Objective Response[3]
207-0019/55/M/W2		.			Missing
209-0006/68/M/W2	WEEK 12	19JUL2013	SD	No	No
	WEEK 24	15OCT2013	SD	No	
	WEEK 36	08JAN2014	PD	No	
209-0011/69/M/W2	WEEK 12	17FEB2014	PD	No	No
209-0014/79/M/W2	WEEK 12	03JUN2014	SD	No	No
	WEEK 24	25AUG2014	PD	No	
210-0003/74/M/W2		.			Missing
210-0004/71/M/W2	WEEK 12	27MAR2014	PD	No	No
210-0005/53/M/W2	WEEK 12	07MAY2014	PD	No	No
210-0006/45/M/W2	WEEK 12	18SEP2014	PD	No	No
251-0002/69/M/W2	WEEK 12	16OCT2013	PD	No	No

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Listing 16.2.6.4
Best Overall Objective response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./Age[1]/ Gender/Race[2]	Visit	Date	Overall Response	Objective Response	Best Overall Objective Response[3]
251-0003/68/M/W2	WEEK 12	21JAN2014	SD	No	No
	WEEK 24	15APR2014	PD	No	
252-0001/65/M/A3		.			Missing
252-0004/50/M/A1	UNSCHEDULED	25JUL2013	PD	No	No
252-0006/64/M/W2	WEEK 12	17DEC2013	SD	No	No
	WEEK 24	11MAR2014	SD	No	
252-0008/76/M/W2	WEEK 12	12AUG2014	PD	No	No
252-0010/56/F/W2	WEEK 12	20JAN2015	PD	No	No
253-0003/75/M/W2	WEEK 12	31AUG2012	SD	No	No
	WEEK 24	16NOV2012	SD	No	
	WEEK 36	13FEB2013	PD	No	
253-0004/79/M/W2	WEEK 12	19NOV2012	PD	No	No

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Listing 16.2.6.4
Best Overall Objective response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./Age[1]/ Gender/Race[2]	Visit	Date	Overall Response	Objective Response	Best Overall Objective Response[3]
253-0005/74/F/W2		.			Missing
253-0006/63/M/A3	WEEK 12	15MAR2013	SD	No	No
	UNSCHEDULED	17MAY2013	PD	No	
253-0011/67/M/W2	WEEK 12	22DEC2014	SD	No	Yes
	WEEK 24	16MAR2015	PR	Yes	
	WEEK 36	08JUN2015	PR	Yes	
253-0012/67/M/W2		.			Missing
257-0005/66/M/W2	WEEK 12	18MAR2013	PD	No	No
257-0013/63/M/W2		.			Missing
257-0020/72/M/A1	UNSCHEDULED	20NOV2014	PD	No	No
258-0002/69/F/W2	WEEK 12	26JUN2013	SD	No	No
	WEEK 24	18SEP2013	SD	No	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Best Overall Objective Response (BOOR) is calculated using the non-missing Objective Response across all visits. BOOR is 'Yes' if, at any visit, the Objective Response is 'Yes'. BOOR is 'No' if, for all visits, the Objective Response is 'No'.

Listing 16.2.6.4
Best Overall Objective response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./Age[1]/ Gender/Race[2]	Visit	Date	Overall Response	Objective Response	Best Overall Objective Response[3]
258-0002/69/F/W2	WEEK 36	11DEC2013	PD	No	
258-0003/67/F/W2	WEEK 12	31JUL2013	SD	No	No
	WEEK 24	23OCT2013	PD	No	
258-0004/65/M/W2		.			Missing
258-0006/69/M/W2		.			Missing
258-0013/59/M/W2	WEEK 12	28JAN2015	PD	No	No
259-0003/73/M/W2	WEEK 12	20AUG2014	SD	No	No
	WEEK 24	12NOV2014	SD	No	
	WEEK 36	04FEB2015	SD	No	
	WEEK 48	29APR2015	SD	No	
259-0004/52/M/W2		.			Missing
260-0002/66/M/W2	UNSCHEDULED	15NOV2013	PD	No	No

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Best Overall Objective Response (BOOR) is calculated using the non-missing Objective Response across all visits. BOOR is 'Yes' if, at any visit, the Objective Response is 'Yes'. BOOR is 'No' if, for all visits, the Objective Response is 'No'.

Listing 16.2.6.4
Best Overall Objective response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./Age[1]/ Gender/Race[2]	Visit	Date	Overall Response	Objective Response	Best Overall Objective Response[3]
301-0001/47/F/A2	WEEK 12	17JAN2012	PD	No	No
301-0003/61/F/A2	WEEK 12	17MAY2012	PD	No	No
301-0008/53/M/A2	WEEK 12	22MAR2013	PD	No	No
302-0006/49/M/A2		.			Missing
302-0009/73/M/A2		.			Missing
302-0012/62/M/A2	WEEK 12	12JUL2012	PD	No	No
302-0013/62/M/A2		.			Missing
302-0020/52/M/A2		.			Missing
302-0021/75/F/A2	WEEK 12	27AUG2013	SD	No	No
	WEEK 24	19NOV2013	PD	No	
304-0003/56/F/A2	WEEK 12	03JUN2013	PD	No	No
304-0004/69/M/A2		.			Missing

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
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Listing 16.2.6.4
Best Overall Objective response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./Age[1]/ Gender/Race[2]	Visit	Date	Overall Response	Objective Response	Best Overall Objective Response[3]
304-0007/72/M/A2	WEEK 12	29JAN2014	PD	No	No
305-0001/79/M/A2		.			Missing
305-0004/79/M/A2	WEEK 12	07MAY2012	SD	No	No
305-0007/67/M/A2	WEEK 12	01JUN2012	SD	No	No
	WEEK 24	24AUG2012	PD	No	
305-0015/84/M/A2	WEEK 12	17SEP2012	PD	No	No
305-0016/78/M/A2	UNSCHEDULED	16AUG2012	PD	Yes	Yes
	WEEK 12	25SEP2012	PD	No	
305-0021/83/F/A2	WEEK 12	08FEB2013	PD	No	No
305-0024/68/M/A2	WEEK 12	12APR2013	PD	No	No
305-0033/37/F/A2	WEEK 12	24SEP2013	PD	No	No
305-0035/60/M/A2	WEEK 12	20NOV2013	SD	No	No

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Best Overall Objective Response (BOOR) is calculated using the non-missing Objective Response across all visits. BOOR is 'Yes' if, at any visit, the Objective Response is 'Yes'. BOOR is 'No' if, for all visits, the Objective Response is 'No'.

Listing 16.2.6.4
Best Overall Objective response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./Age[1]/ Gender/Race[2]	Visit	Date	Overall Response	Objective Response	Best Overall Objective Response[3]
305-0035/60/M/A2	WEEK 24	12FEB2014	PD	No	
305-0046/60/M/A2	WEEK 12	24JAN2015	SD	No	No
	WEEK 24	14APR2015	PD	No	
306-0004/46/M/A2	UNSCHEDULED	03APR2012	PD	No	No
306-0010/69/M/A2	WEEK 12	06JUN2012	PD	No	No
306-0013/42/M/A2		.			Missing
306-0015/73/M/A2	UNSCHEDULED	28JUN2012	PD	No	No
306-0016/58/M/A2	WEEK 12	11SEP2012	PD	No	No
306-0022/56/M/A2	WEEK 12	24JAN2013	SD	No	No
	WEEK 24	25APR2013	PD	No	
306-0028/53/M/A2	WEEK 12	13JUN2013	SD	No	No
306-0045/60/F/A1	UNSCHEDULED	15AUG2014	SD	No	No

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
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Listing 16.2.6.4
Best Overall Objective response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./Age[1]/ Gender/Race[2]	Visit	Date	Overall Response	Objective Response	Best Overall Objective Response[3]
306-0045/60/F/A1	WEEK 12	02SEP2014	PD	No	
307-0006/72/M/A2		.			Missing
307-0009/53/M/A2		.			Missing
307-0012/42/M/A2		.			Missing
307-0015/75/M/A2	WEEK 12	11JUL2012	SD	No	No
	WEEK 24	04OCT2012	PD	No	
307-0021/68/M/A2	WEEK 12	08NOV2012	SD	No	No
307-0028/69/F/A2	WEEK 12	01APR2013	PD	No	No
307-0034/48/M/A2	WEEK 12	29OCT2013	PD	No	No
307-0036/76/M/A2	WEEK 12	18DEC2013	PD	No	No
307-0042/55/M/A2	WEEK 12	04SEP2014	SD	No	No
	WEEK 24	27NOV2014	PD	No	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
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Listing 16.2.6.4
Best Overall Objective response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./Age[1]/ Gender/Race[2]	Visit	Date	Overall Response	Objective Response	Best Overall Objective Response[3]
308-0002/36/F/A2	WEEK 12	21MAR2013	PD	No	No
308-0004/52/M/A2	WEEK 12	25APR2013	PD	No	No
308-0006/64/M/A2	UNSCHEDULED	27JUN2013	PD	No	No
308-0008/47/M/A2	WEEK 12	04OCT2013	PD	No	No
308-0009/61/M/A2		.			Missing
309-0006/56/M/A2	WEEK 12	04FEB2013	SD	No	No
	WEEK 24	29APR2013	SD	No	
	WEEK 36	22JUL2013	PD	No	
309-0007/58/M/A2	WEEK 12	25FEB2013	PD	No	No
309-0013/45/M/A2	WEEK 12	29AUG2013	PD	No	No
309-0014/39/M/A2	WEEK 12	29AUG2013	PD	No	No
309-0019/68/M/A2	UNSCHEDULED	19AUG2014	SD	No	No

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
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Listing 16.2.6.4
Best Overall Objective response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./Age[1]/ Gender/Race[2]	Visit	Date	Overall Response	Objective Response	Best Overall Objective Response[3]
309-0019/68/M/A2	WEEK 24	25NOV2014	SD	No	
	WEEK 36	17FEB2015	SD	No	
	WEEK 48	12MAY2015	SD	No	
309-0027/49/M/A2	WEEK 12	12JAN2015	PD	No	No
309-0029/50/M/A2	WEEK 12	09FEB2015	PD	No	No
310-0004/50/F/A2	WEEK 12	17APR2013	PD	No	No
310-0005/58/M/A2	WEEK 12	05JUN2013	PD	No	No
310-0006/50/F/A2	WEEK 12	10JUL2013	SD	No	No
	WEEK 24	09OCT2013	SD	No	
	WEEK 36	23DEC2013	PD	No	
310-0007/74/M/A2	WEEK 12	22AUG2013	SD	No	No
	WEEK 24	14NOV2013	SD	No	

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[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
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Listing 16.2.6.4
Best Overall Objective response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./Age[1]/ Gender/Race[2]	Visit	Date	Overall Response	Objective Response	Best Overall Objective Response[3]
310-0007/74/M/A2	WEEK 36	06FEB2014	SD	No	
	WEEK 48	01MAY2014	PD	No	
310-0009/46/M/A2	UNSCHEDULED	27SEP2013	PD	No	No
310-0010/34/F/A2	UNSCHEDULED	25SEP2013	PD	No	No
310-0011/52/M/A2	WEEK 12	02JAN2014	PD	No	No
310-0014/64/M/A2	WEEK 12	03DEC2014	PD	No	No
311-0003/44/M/A2	WEEK 12	10DEC2013	PD	No	No
311-0004/68/M/A2		.			Missing
311-0005/58/M/A2	WEEK 12	30DEC2013	PD	No	No
311-0006/73/F/A2	WEEK 12	16JAN2014	PD	No	No
311-0009/51/F/A2	WEEK 12	30SEP2014	PD	No	No
311-0010/47/M/A2	WEEK 12	18NOV2014	PR	Yes	Yes

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
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Listing 16.2.6.4
Best Overall Objective response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./Age[1]/ Gender/Race[2]	Visit	Date	Overall Response	Objective Response	Best Overall Objective Response[3]
311-0010/47/M/A2	WEEK 24	12FEB2015	PR	Yes	
	WEEK 36	07MAY2015	PR	Yes	
311-0011/46/M/A2	UNSCHEDULED	30DEC2014	PD	No	No
311-0012/55/M/A2	WEEK 12	16APR2015	SD	No	No
401-0001/70/M/A7		.			Missing
401-0002/55/M/A7		.			Missing
402-0001/35/M/A7	UNSCHEDULED	10JUN2013	PD	No	No
402-0002/58/M/A7	WEEK 12	09JUL2013	PD	No	No
402-0005/70/M/A7	WEEK 12	23JUL2013	PD	No	No
402-0010/50/M/A7	UNSCHEDULED	02JUL2013	PD	No	No
402-0022/60/F/A7	WEEK 12	11NOV2013	PD	No	No
402-0023/57/M/A7	WEEK 12	19NOV2013	PD	No	No

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
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Listing 16.2.6.4
Best Overall Objective response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./Age[1]/ Gender/Race[2]	Visit	Date	Overall Response	Objective Response	Best Overall Objective Response[3]
402-0029/49/M/A7	UNSCHEDULED	30DEC2013	PD	No	No
402-0032/49/F/A7	WEEK 12	20FEB2014	PD	No	No
402-0034/43/F/A7	WEEK 12	06MAR2014	SD	No	No
	WEEK 24	29MAY2014	PD	No	
403-0004/37/M/A7	WEEK 12	25SEP2013	PD	No	No
404-0003/53/M/A7	UNSCHEDULED	30SEP2013	PD	No	No
404-0004/61/F/A7	UNSCHEDULED	02DEC2013	PD	No	No
405-0001/55/M/A7	WEEK 12	10JUL2013	PD	No	No
405-0005/35/M/A6	WEEK 12	10JUL2013	SD	No	No
	WEEK 24	02OCT2013	SD	No	
	WEEK 36	23DEC2013	PD	No	
405-0012/72/M/A7	WEEK 12	29JUL2013	SD	No	No

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Best Overall Objective Response (BOOR) is calculated using the non-missing Objective Response across all visits. BOOR is 'Yes' if, at any visit, the Objective Response is 'Yes'. BOOR is 'No' if, for all visits, the Objective Response is 'No'.

Listing 16.2.6.4
Best Overall Objective response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./Age[1]/ Gender/Race[2]	Visit	Date	Overall Response	Objective Response	Best Overall Objective Response[3]
405-0012/72/M/A7	WEEK 24	21OCT2013	PD	No	
405-0019/61/M/A7		.			Missing
405-0024/69/M/A7		.			Missing
405-0026/67/M/A7	WEEK 12	25SEP2013	PD	No	No
405-0036/70/M/A7	UNSCHEDULED	16OCT2013	SD	No	No
	WEEK 12	12NOV2013	PD	No	
405-0041/57/M/A7	WEEK 12	25NOV2013	SD	No	No
	WEEK 24	17FEB2014	SD	No	
	WEEK 36	02MAY2014	PD	No	
501-0003/22/M/A1	WEEK 12	25FEB2014	PD	No	No
501-0004/26/M/A1	WEEK 12	05MAR2014	PD	No	No
501-0011/61/M/A1	WEEK 12	12DEC2014	PD	No	No

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Best Overall Objective Response (BOOR) is calculated using the non-missing Objective Response across all visits. BOOR is 'Yes' if, at any visit, the Objective Response is 'Yes'. BOOR is 'No' if, for all visits, the Objective Response is 'No'.

Listing 16.2.6.4
Best Overall Objective response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./Age[1]/ Gender/Race[2]	Visit	Date	Overall Response	Objective Response	Best Overall Objective Response[3]
502-0001/70/M/A1		.			Missing
502-0003/48/M/A1	WEEK 12	10APR2014	PD	No	No
503-0002/71/F/A1	WEEK 12	13MAY2014	SD	No	No
	WEEK 24	04AUG2014	SD	No	
	WEEK 36	28OCT2014	PD	No	
503-0003/47/F/A1		.			Missing
503-0005/72/M/A1	WEEK 12	17JUN2014	SD	No	No
	WEEK 24	11SEP2014	SD	No	
	WEEK 36	25NOV2014	SD	No	
	WEEK 48	02MAR2015	PD	No	
504-0003/53/M/A1	UNSCHEDULED	11APR2014	PD	No	No
504-0005/41/F/A1		.			Missing

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Best Overall Objective Response (BOOR) is calculated using the non-missing Objective Response across all visits. BOOR is 'Yes' if, at any visit, the Objective Response is 'Yes'. BOOR is 'No' if, for all visits, the Objective Response is 'No'.

Listing 16.2.6.4
Best Overall Objective response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./Age[1]/ Gender/Race[2]	Visit	Date	Overall Response	Objective Response	Best Overall Objective Response[3]
504-0006/51/M/A1		.			Missing
506-0001/43/M/A1		.			Missing
506-0005/24/M/A1		.			Missing
507-0001/51/M/A1	WEEK 12	14OCT2014	PD	No	No
507-0002/44/M/A1	UNSCHEDULED	17SEP2014	PD	No	No
508-0002/64/M/A1		.			Missing
508-0004/58/M/A1		.			Missing
509-0003/39/M/A1	WEEK 12	14OCT2014	PD	No	No
510-0001/67/M/A1	WEEK 12	15MAY2014	PD	Yes	Yes
	WEEK 24	06AUG2014	PR	Yes	
	WEEK 36	30OCT2014	PR	Yes	
	UNSCHEDULED	08DEC2014	PD	No	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Best Overall Objective Response (BOOR) is calculated using the non-missing Objective Response across all visits. BOOR is 'Yes' if, at any visit, the Objective Response is 'Yes'. BOOR is 'No' if, for all visits, the Objective Response is 'No'.

Listing 16.2.6.4
Best Overall Objective response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./Age[1]/ Gender/Race[2]	Visit	Date	Overall Response	Objective Response	Best Overall Objective Response[3]
510-0003/43/M/A1	UNSCHEDULED	14AUG2014	PD	No	No
513-0003/46/M/A1		.			Missing
515-0005/45/M/A1	WEEK 12	09SEP2014	PD	No	No
517-0003/45/M/A1	WEEK 12	01AUG2014	PD	No	No
517-0010/67/M/A1	WEEK 12	02FEB2015	PD	No	No

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Best Overall Objective Response (BOOR) is calculated using the non-missing Objective Response across all visits. BOOR is 'Yes' if, at any visit, the Objective Response is 'Yes'. BOOR is 'No' if, for all visits, the Objective Response is 'No'.

Listing 16.2.6.5
Best Overall Tumor Response and Best Overall Disease Control
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Date	Overall Response	Best Overall Tumor Response	Disease Control	Best Overall Disease Control[3]
101-0001/59/M/A2	WEEK 12	11OCT2011	SD	SD	Yes	Yes
	WEEK 24	03JAN2012	PD	SD	No	Yes
101-0005/77/M/W2	WEEK 12	25OCT2011	PD	PD	No	No
101-0006/62/M/W2	WEEK 12	12OCT2011	PD	PD	No	No
101-0007/77/M/A1	WEEK 12	08NOV2011	PD	PD	No	No
101-0008/83/M/BL	WEEK 12	12NOV2011	PD	PD	No	No
101-0009/82/M/A1	WEEK 12	20DEC2011	PD	PD	No	No
101-0011/75/F/W2	UNSCHEDULED	29NOV2011	PD	PD	No	No
101-0012/68/M/W2	WEEK 12	18JAN2012	PD	PD	No	No
101-0013/66/F/A5	WEEK 12	23MAR2012	PD	PD	No	No
101-0016/61/M/A4	WEEK 12	28MAR2012	SD	SD	Yes	Yes
	WEEK 24	22JUN2012	SD	SD	Yes	Yes
	WEEK 36	11SEP2012	PD	SD	No	Yes
	WEEK 48	04DEC2012	PD	SD	No	Yes
	WEEK 60	05MAR2013	PD	SD	No	Yes
101-0018/51/M/A1		.		Missing		Missing
101-0019/68/M/W2	WEEK 12	15MAY2012	PD	PD	No	No

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Best Overall Disease Control (BODC) is calculated using the non-missing Objective Response across all visits. BODC is 'Yes' if, at any visit, the Disease Control is 'Yes'. BOOR is 'No' if, for all visits, the Disease Control is 'No'.

Listing 16.2.6.5
Best Overall Tumor Response and Best Overall Disease Control
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Date	Overall Response	Best Overall Tumor Response	Disease Control	Best Overall Disease Control[3]
101-0021/74/M/W2	WEEK 12	29MAY2012	PD	PD	No	No
101-0022/55/M/BL	UNSCHEDULED	13APR2012	PD	PD	No	No
101-0023/70/M/W2	WEEK 12	14JUN2012	SD	SD	Yes	Yes
101-0024/35/F/A4	WEEK 12	10JUL2012	PD	PD	No	No
101-0025/57/F/W2	UNSCHEDULED	15JUN2012	PD	PD	No	No
101-0026/82/M/W2	WEEK 12	31JUL2012	SD	SD	Yes	Yes
	WEEK 24	19OCT2012	SD	SD	Yes	Yes
	UNSCHEDULED	11JAN2013	PD	SD	No	Yes
101-0028/60/M/W2	WEEK 12	07SEP2012	SD	SD	Yes	Yes
101-0029/70/M/A1	WEEK 12	28AUG2012	PD	PD	No	No
101-0030/51/M/W2	UNSCHEDULED	05SEP2012	PD	PD	No	No
101-0032/84/M/W2	WEEK 12	09OCT2012	PR	PR	Yes	Yes
101-0033/66/F/W2	WEEK 12	05OCT2012	SD	SD	Yes	Yes
	WEEK 24	04JAN2013	PD	SD	No	Yes
101-0036/67/M/A4	UNSCHEDULED	12DEC2012	PD	PD	No	No
101-0037/57/M/A1		.		Missing		Missing
101-0038/56/M/W2		.		Missing		Missing

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Best Overall Disease Control (BODC) is calculated using the non-missing Objective Response across all visits. BODC is 'Yes' if, at any visit, the Disease Control is 'Yes'. BOOR is 'No' if, for all visits, the Disease Control is 'No'.

Listing 16.2.6.5
Best Overall Tumor Response and Best Overall Disease Control
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Date	Overall Response	Best Overall Tumor Response	Disease Control	Best Overall Disease Control[3]
101-0039/77/F/W2	WEEK 24	07SEP2010	SD	SD	Yes	Yes
	WEEK 12	14JUN2013	SD	SD	Yes	Yes
	WEEK 36	27NOV2013	PD	SD	No	Yes
101-0040/60/M/W2	WEEK 12	06AUG2013	PD	PD	No	No
101-0041/54/M/W2		.		Missing		Missing
101-0042/64/M/W2		.		Missing		Missing
101-0044/78/M/W2	WEEK 12	27DEC2013	PD	PD	No	No
101-0045/74/F/W2	WEEK 12	16JAN2014	PD	PD	No	No
101-0046/70/M/OTH	WEEK 12	02JAN2014	PD	PD	No	No
101-0047/52/M/W2	UNSCHEDULED	16DEC2013	PD	PD	No	No
101-0048/66/F/W2	WEEK 12	30DEC2013	PD	PD	No	No
101-0049/71/M/A8	WEEK 12	08JAN2014	PD	PD	No	No
101-0050/59/M/W2	UNSCHEDULED	05DEC2013	PD	PD	No	No
102-0001/53/M/BL	WEEK 12	07JUN2012	PD	PD	No	No
102-0003/63/M/BL	WEEK 12	23NOV2012	PD	PD	No	No
102-0008/64/M/BL		.		Missing		Missing
102-0009/58/M/W2	UNSCHEDULED	09DEC2014	PD	PD	No	No

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Best Overall Disease Control (BODC) is calculated using the non-missing Objective Response across all visits. BODC is 'Yes' if, at any visit, the Disease Control is 'Yes'. BOOR is 'No' if, for all visits, the Disease Control is 'No'.

Listing 16.2.6.5
Best Overall Tumor Response and Best Overall Disease Control
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Date	Overall Response	Best Overall Tumor Response	Disease Control	Best Overall Disease Control[3]
103-0001/56/M/W2	WEEK 12	26JUL2012	PD	PD	No	No
103-0003/66/M/W2	WEEK 12	29APR2013	No	PD	No	No
	WEEK 24	23JUL2013	PD	PD	No	No
103-0004/40/F/A1	UNSCHEDULED	03JUN2014	PD	PD	No	No
104-0003/56/F/W2		.		Missing		Missing
104-0004/74/M/W2		.		Missing		Missing
104-0008/55/M/PI	WEEK 12	29NOV2013	SD	SD	Yes	Yes
104-0010/71/F/A8	WEEK 12	29MAR2014	SD	SD	Yes	Yes
	WEEK 24	25JUN2014	SD	SD	Yes	Yes
	WEEK 36	17SEP2014	PD	SD	No	Yes
104-0012/78/F/A2	UNSCHEDULED	29NOV2014	PD	PD	No	No
106-0001/42/F/W2	WEEK 12	21MAY2012	SD	SD	Yes	Yes
	WEEK 24	29JUN2012	PD	SD	No	Yes
107-0002/71/M/W2	WEEK 12	07NOV2012	PD	PD	No	No
107-0003/73/M/BL		.		Missing		Missing
107-0004/63/M/W2	WEEK 12	21MAY2013	SD	SD	Yes	Yes
107-0006/60/M/W2	WEEK 12	29JUL2013	PD	PD	No	No

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Best Overall Disease Control (BODC) is calculated using the non-missing Objective Response across all visits. BODC is 'Yes' if, at any visit, the Disease Control is 'Yes'. BOOR is 'No' if, for all visits, the Disease Control is 'No'.

Listing 16.2.6.5
Best Overall Tumor Response and Best Overall Disease Control
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Date	Overall Response	Best Overall Tumor Response	Disease Control	Best Overall Disease Control[3]
108-0001/60/F/W2	WEEK 12	04MAY2012	PD	PD	No	No
108-0002/78/M/BL	UNSCHEDULED	05JUL2012	PD	PD	No	No
108-0004/61/M/W2	UNSCHEDULED	16MAY2013	PD	PD	No	No
108-0005/68/M/W2	UNSCHEDULED	14JUN2013	SD	SD	Yes	Yes
	WEEK 12	29JUL2013	PD	SD	No	Yes
108-0008/77/M/W2	UNSCHEDULED	17NOV2014	SD	SD	Yes	Yes
	WEEK 12	29DEC2014	SD	SD	Yes	Yes
	WEEK 24	17MAR2015	PD	SD	No	Yes
109-0003/68/M/W2	WEEK 12	01JUL2013	PD	PD	No	No
109-0004/57/M/W2	WEEK 12	07OCT2013	PD	PD	No	No
109-0006/62/M/PI	WEEK 12	06NOV2013	PD	PD	No	No
109-0007/55/M/W2	WEEK 12	30JAN2014	SD	SD	Yes	Yes
	WEEK 24	23APR2014	PD	SD	No	Yes
109-0008/70/F/W2	WEEK 12	20AUG2014	SD	SD	Yes	Yes
	WEEK 24	13NOV2014	PD	SD	No	Yes
109-0009/57/M/W2	WEEK 12	22SEP2014	PD	PD	No	No
109-0010/65/M/W2	WEEK 12	24SEP2014	PD	PD	No	No

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Best Overall Disease Control (BODC) is calculated using the non-missing Objective Response across all visits. BODC is 'Yes' if, at any visit, the Disease Control is 'Yes'. BOOR is 'No' if, for all visits, the Disease Control is 'No'.

Listing 16.2.6.5
Best Overall Tumor Response and Best Overall Disease Control
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Date	Overall Response	Best Overall Tumor Response	Disease Control	Best Overall Disease Control[3]
109-0011/64/M/A4	WEEK 12	09DEC2014	PD	PD	No	No
109-0013/64/F/W2	WEEK 12	20JAN2015	SD	SD	Yes	Yes
	WEEK 24	13APR2015	PD	SD	No	Yes
110-0003/63/M/OTH	WEEK 12	24SEP2012	SD	SD	Yes	Yes
	WEEK 24	17DEC2012	SD	SD	Yes	Yes
110-0004/53/M/A4	WEEK 12	08JAN2013	SD	SD	Yes	Yes
110-0005/77/M/W2	WEEK 12	24MAY2013	SD	SD	Yes	Yes
110-0007/62/M/A4	WEEK 12	31JUL2013	SD	SD	Yes	Yes
	WEEK 24	23OCT2013	SD	SD	Yes	Yes
	WEEK 36	13JAN2014	PD	SD	No	Yes
110-0008/63/F/BL		.		Missing		Missing
110-0011/77/M/A1	WEEK 12	07APR2015	PD	PD	No	No
111-0001/37/M/A4	UNSCHEDULED	27JUL2012	PD	PD	No	No
111-0004/64/M/W2	UNSCHEDULED	03JUL2013	SD	SD	Yes	Yes
	UNSCHEDULED	31JUL2013	SD	SD	Yes	Yes
111-0006/59/M/W2	WEEK 12	06JAN2014	SD	SD	Yes	Yes
	WEEK 24	26MAR2014	SD	SD	Yes	Yes

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Best Overall Disease Control (BODC) is calculated using the non-missing Objective Response across all visits. BODC is 'Yes' if, at any visit, the Disease Control is 'Yes'. BOOR is 'No' if, for all visits, the Disease Control is 'No'.

Listing 16.2.6.5
Best Overall Tumor Response and Best Overall Disease Control
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Date	Overall Response	Best Overall Tumor Response	Disease Control	Best Overall Disease Control[3]
111-0007/55/M/W2	WEEK 12	14APR2014	PD	PD	No	No
112-0006/58/M/W2	WEEK 12	03JUN2013	PD	PD	No	No
112-0009/50/M/A8	WEEK 12	04SEP2013	PD	PD	No	No
112-0011/56/M/A4	UNSCHEDULED	28FEB2014	PD	PD	No	No
112-0012/71/M/W2	WEEK 12	08AUG2014	PD	PD	No	No
112-0013/28/F/W2	UNSCHEDULED	12JUL2014	SD	SD	Yes	Yes
112-0014/79/M/A8	UNSCHEDULED	18JUL2014	SD	SD	Yes	Yes
	WEEK 12	22AUG2014	PD	SD	No	Yes
112-0015/66/M/A8	UNSCHEDULED	12DEC2014	PD	PD	No	No
113-0001/60/M/W2	WEEK 12	08NOV2012	SD	SD	Yes	Yes
	WEEK 24	06FEB2013	PD	SD	No	Yes
113-0002/64/F/W2	WEEK 12	22DEC2012	SD	SD	Yes	Yes
	WEEK 24	18MAR2013	SD	SD	Yes	Yes
	WEEK 36	18JUN2013	PD	SD	No	Yes
113-0005/58/M/W2		.		Missing		Missing
113-0008/78/M/A8		.		Missing		Missing
113-0010/59/M/W2		.		Missing		Missing

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Best Overall Disease Control (BODC) is calculated using the non-missing Objective Response across all visits. BODC is 'Yes' if, at any visit, the Disease Control is 'Yes'. BOOR is 'No' if, for all visits, the Disease Control is 'No'.

Listing 16.2.6.5
Best Overall Tumor Response and Best Overall Disease Control
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Date	Overall Response	Best Overall Tumor Response	Disease Control	Best Overall Disease Control[3]
113-0013/56/M/W2	WEEK 12	13JAN2015	PD	PD	No	No
113-0016/72/M/A8	WEEK 12	22APR2015	PD	PD	No	No
114-0003/59/M/W2	WEEK 12	13FEB2013	SD	SD	Yes	Yes
	UNSCHEDULED	10APR2013	SD	SD	Yes	Yes
114-0005/73/M/W2	UNSCHEDULED	06FEB2014	SD	SD	Yes	Yes
114-0007/60/F/W2	WEEK 12	04FEB2015	SD	SD	Yes	Yes
	WEEK 24	01MAY2015	SD	SD	Yes	Yes
115-0001/59/F/A4	WEEK 12	11FEB2013	PD	PD	No	No
115-0002/45/F/W2	UNSCHEDULED	10JAN2013	PD	PD	No	No
115-0003/63/M/W2	WEEK 12	02APR2013	SD	SD	Yes	Yes
	WEEK 24	24JUN2013	SD	SD	Yes	Yes
115-0008/51/M/A8		.		Missing		Missing
115-0009/85/M/W2	WEEK 12	21FEB2014	SD	SD	Yes	Yes
	UNSCHEDULED	03APR2014	SD	SD	Yes	Yes
	WEEK 24	21MAY2014	PD	SD	No	Yes
115-0011/56/M/W2	UNSCHEDULED	16JUL2014	SD	SD	Yes	Yes
	WEEK 12	29AUG2014	PD	SD	No	Yes

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Best Overall Disease Control (BODC) is calculated using the non-missing Objective Response across all visits. BODC is 'Yes' if, at any visit, the Disease Control is 'Yes'. BOOR is 'No' if, for all visits, the Disease Control is 'No'.

Listing 16.2.6.5
Best Overall Tumor Response and Best Overall Disease Control
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Date	Overall Response	Best Overall Tumor Response	Disease Control	Best Overall Disease Control[3]
115-0014/72/M/W2		.		Missing		Missing
116-0002/67/F/W2	WEEK 12	03JUN2013	SD	SD	Yes	Yes
	WEEK 24	23AUG2013	SD	SD	Yes	Yes
	WEEK 36	15NOV2013	PD	SD	No	Yes
116-0003/66/M/BL	WEEK 12	21MAY2013	PD	PD	No	No
117-0001/69/M/W2	UNSCHEDULED	25APR2013	SD	SD	Yes	Yes
	WEEK 12	12JUN2013	PD	SD	No	Yes
118-0001/67/F/A8	WEEK 12	29OCT2013	PD	PD	No	No
119-0001/80/M/A8		.		Missing		Missing
121-0001/62/M/W2	WEEK 12	06MAY2014	SD	SD	Yes	Yes
121-0004/64/F/W2		.		Missing		Missing
201-0001/68/F/W2	WEEK 12	23APR2012	PD	PD	No	No
201-0005/73/M/W2	WEEK 12	09OCT2012	PD	PD	No	No
201-0008/79/M/W2	WEEK 12	29JUL2013	SD	SD	Yes	Yes
201-0011/73/M/W2	WEEK 12	20SEP2013	PD	PD	No	No
201-0012/79/M/W2	WEEK 12	11OCT2013	SD	SD	Yes	Yes
	WEEK 24	07JAN2014	SD	SD	Yes	Yes

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Best Overall Disease Control (BODC) is calculated using the non-missing Objective Response across all visits. BODC is 'Yes' if, at any visit, the Disease Control is 'Yes'. BOOR is 'No' if, for all visits, the Disease Control is 'No'.

Listing 16.2.6.5
Best Overall Tumor Response and Best Overall Disease Control
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Date	Overall Response	Best Overall Tumor Response	Disease Control	Best Overall Disease Control[3]
	WEEK 36	28MAR2014	SD	SD	Yes	Yes
	WEEK 48	23JUN2014	SD	SD	Yes	Yes
	WEEK 60	16SEP2014	PD	SD	No	Yes
201-0013/67/F/W2	WEEK 12	11OCT2013	PD	PD	No	No
201-0016/72/M/W2	WEEK 12	03FEB2014	SD	SD	Yes	Yes
	WEEK 24	18APR2014	PD	SD	No	Yes
201-0017/82/M/W2		.		Missing		Missing
201-0018/78/F/W2		.		Missing		Missing
201-0019/68/M/W2	WEEK 12	07MAR2014	PD	PD	No	No
201-0020/67/M/W2		.		Missing		Missing
201-0021/54/M/W2	WEEK 12	02MAY2014	PD	PD	No	No
201-0024/74/M/W2	UNSCHEDULED	13MAR2015	PD	PD	No	No
201-0025/75/M/W2		.		Missing		Missing
203-0001/61/F/W2		.		Missing		Missing
203-0002/72/M/W2		.		Missing		Missing
203-0005/53/M/W2	WEEK 12	09JUL2012	PD	PD	No	No
203-0013/68/M/W2		.		Missing		Missing

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Best Overall Disease Control (BODC) is calculated using the non-missing Objective Response across all visits. BODC is 'Yes' if, at any visit, the Disease Control is 'Yes'. BOOR is 'No' if, for all visits, the Disease Control is 'No'.

Listing 16.2.6.5
Best Overall Tumor Response and Best Overall Disease Control
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Date	Overall Response	Best Overall Tumor Response	Disease Control	Best Overall Disease Control[3]
203-0015/85/M/W2	WEEK 12	10APR2014	PD	PD	No	No
203-0017/58/M/W2		.		Missing		Missing
203-0018/58/F/W2		.		Missing		Missing
205-0001/77/M/W2	WEEK 12	08MAY2012	SD	SD	Yes	Yes
	WEEK 24	09AUG2012	SD	SD	Yes	Yes
	WEEK 36	23OCT2012	SD	SD	Yes	Yes
	WEEK 48	28JAN2013	SD	SD	Yes	Yes
	WEEK 60	16APR2013	SD	SD	Yes	Yes
	WEEK 72	09JUL2013	SD	SD	Yes	Yes
	WEEK 84	01OCT2013	PD	SD	No	Yes
205-0004/77/F/W2	WEEK 12	05JUN2012	PD	PD	No	No
205-0008/76/M/W2		.		Missing		Missing
205-0012/73/F/W2		.		Missing		Missing
205-0015/71/M/W2		.		Missing		Missing
205-0016/70/M/W2	WEEK 12	10SEP2013	SD	SD	Yes	Yes
	WEEK 24	10DEC2013	SD	SD	Yes	Yes
	WEEK 36	28MAR2014	SD	SD	Yes	Yes

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Best Overall Disease Control (BODC) is calculated using the non-missing Objective Response across all visits. BODC is 'Yes' if, at any visit, the Disease Control is 'Yes'. BOOR is 'No' if, for all visits, the Disease Control is 'No'.

Listing 16.2.6.5
Best Overall Tumor Response and Best Overall Disease Control
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Date	Overall Response	Best Overall Tumor Response	Disease Control	Best Overall Disease Control[3]
	WEEK 48	20MAY2014	SD	SD	Yes	Yes
	WEEK 60	06AUG2014	SD	SD	Yes	Yes
	WEEK 72	28OCT2014	SD	SD	Yes	Yes
	WEEK 84	20JAN2015	SD	SD	Yes	Yes
	WEEK 96	21APR2015	SD	SD	Yes	Yes
205-0017/71/M/W2	WEEK 12	15OCT2013	SD	SD	Yes	Yes
	WEEK 24	14JAN2014	PD	SD	No	Yes
205-0020/82/M/W2	WEEK 12	27DEC2013	PD	PD	No	No
205-0022/67/M/W2		.		Missing		Missing
205-0024/80/M/W2	WEEK 12	25FEB2014	PD	PD	No	No
205-0025/63/F/W2	WEEK 12	11FEB2014	PD	PD	No	No
207-0001/81/F/W2		.		Missing		Missing
207-0005/74/M/W2		.		Missing		Missing
207-0006/73/M/W2	WEEK 12	14SEP2012	PD	PD	No	No
207-0008/66/M/W2		.		Missing		Missing
207-0011/78/M/W2		.		Missing		Missing
207-0015/77/M/W2	WEEK 12	23OCT2013	PD	PD	No	No

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Best Overall Disease Control (BODC) is calculated using the non-missing Objective Response across all visits. BODC is 'Yes' if, at any visit, the Disease Control is 'Yes'. BOOR is 'No' if, for all visits, the Disease Control is 'No'.

Listing 16.2.6.5
Best Overall Tumor Response and Best Overall Disease Control
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Date	Overall Response	Best Overall Tumor Response	Disease Control	Best Overall Disease Control[3]
207-0020/77/M/W2	WEEK 12	03SEP2014	PD	PD	No	No
207-0021/74/M/W2	WEEK 12	03SEP2014	SD	SD	Yes	Yes
	WEEK 24	25NOV2014	SD	SD	Yes	Yes
	WEEK 36	13FEB2015	PD	SD	No	Yes
207-0022/74/M/W2	WEEK 12	23SEP2014	SD	SD	Yes	Yes
208-0001/59/M/W2	WEEK 12	05DEC2012	SD	SD	Yes	Yes
	WEEK 24	01MAR2013	PR	SD	Yes	Yes
	WEEK 36	22MAY2013	SD	SD	Yes	Yes
	WEEK 48	19AUG2013	SD	SD	Yes	Yes
	WEEK 60	06NOV2013	SD	SD	Yes	Yes
	WEEK 72	29JAN2014	SD	SD	Yes	Yes
	WEEK 84	23APR2014	SD	SD	Yes	Yes
	WEEK 96	16JUL2014	SD	SD	Yes	Yes
	WEEK 108	08OCT2014	SD	SD	Yes	Yes
	WEEK 120	02JAN2015	SD	SD	Yes	Yes
	WEEK 132	01APR2015	SD	SD	Yes	Yes
	UNSCHEDULED	17JUN2015	SD	SD	Yes	Yes

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Listing 16.2.6.5
Best Overall Tumor Response and Best Overall Disease Control
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Date	Overall Response	Best Overall Tumor Response	Disease Control	Best Overall Disease Control[3]
208-0002/82/F/W2	WEEK 12	12DEC2012	PD	PD	No	No
208-0006/69/F/W2	WEEK 12	13NOV2013	PD	PD	No	No
208-0007/53/M/W2	WEEK 12	25SEP2014	PD	PD	No	No
209-0001/66/M/W2	WEEK 12	31JAN2013	PD	PD	No	No
209-0004/74/M/W2	WEEK 12	24JUN2013	PD	PD	No	No
209-0008/66/M/W2	WEEK 12	30SEP2013	PD	PD	No	No
209-0012/63/M/W2	WEEK 12	17FEB2014	SD	SD	Yes	Yes
	WEEK 24	22MAY2014	PD	SD	No	Yes
209-0013/52/M/W2	WEEK 12	10MAR2014	PD	PD	No	No
210-0001/67/M/W2	WEEK 12	11NOV2013	SD	SD	Yes	Yes
	WEEK 24	05FEB2014	SD	SD	Yes	Yes
	UNSCHEDULED	25FEB2014	PD	SD	No	Yes
210-0002/80/M/W2	WEEK 12	19DEC2013	SD	SD	Yes	Yes
	WEEK 24	13MAR2014	SD	SD	Yes	Yes
	WEEK 36	12JUN2014	SD	SD	Yes	Yes
	WEEK 48	04SEP2014	PD	SD	No	Yes
210-0007/72/M/W2	WEEK 12	18NOV2014	SD	SD	Yes	Yes

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Listing 16.2.6.5
Best Overall Tumor Response and Best Overall Disease Control
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Date	Overall Response	Best Overall Tumor Response	Disease Control	Best Overall Disease Control[3]
	WEEK 24	16FEB2015	SD	SD	Yes	Yes
	WEEK 36	04JUN2015	SD	SD	Yes	Yes
210-0009/49/F/W2	WEEK 12	27JAN2015	PD	PD	No	No
210-0011/73/M/W2	WEEK 12	03FEB2015	PD	PD	No	No
210-0012/47/F/W2	WEEK 12	17MAR2015	PD	PD	No	No
210-0014/71/F/W2	WEEK 12	28APR2015	PD	PD	No	No
251-0001/55/F/W2	WEEK 12	16OCT2012	SD	SD	Yes	Yes
252-0002/76/M/W2		.		Missing		Missing
252-0003/68/M/W2	WEEK 12	19MAR2013	PD	PD	No	No
252-0007/77/M/W2		.		Missing		Missing
252-0011/81/M/BL	WEEK 12	10FEB2015	SD	SD	Yes	Yes
	WEEK 24	07MAY2015	SD	SD	Yes	Yes
253-0002/63/M/W2	WEEK 12	25MAY2012	PD	PD	No	No
253-0010/76/M/W2	WEEK 12	22AUG2013	SD	SD	Yes	Yes
	WEEK 24	13NOV2013	PD	SD	No	Yes
254-0001/69/M/W2	WEEK 12	08AUG2012	PD	PD	No	No
257-0001/47/M/A4		.		Missing		Missing

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[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Best Overall Disease Control (BODC) is calculated using the non-missing Objective Response across all visits. BODC is 'Yes' if, at any visit, the Disease Control is 'Yes'. BOOR is 'No' if, for all visits, the Disease Control is 'No'.

Listing 16.2.6.5
Best Overall Tumor Response and Best Overall Disease Control
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Date	Overall Response	Best Overall Tumor Response	Disease Control	Best Overall Disease Control[3]
257-0002/56/M/W2		.		Missing		Missing
257-0007/80/M/W2	WEEK 12	09MAY2013	PD	PD	No	No
257-0008/80/F/W2	WEEK 12	13JUN2013	PD	PD	No	No
257-0010/42/M/BL	WEEK 12	05AUG2013	PD	PD	No	No
257-0012/75/M/W2		.		Missing		Missing
257-0015/69/F/BL		.		Missing		Missing
257-0017/74/M/A8	WEEK 12	21JUL2014	PD	PD	No	No
257-0018/53/M/A6		.		Missing		Missing
257-0022/60/M/W2	UNSCHEDULED	02FEB2015	PD	PD	No	No
257-0024/75/M/W2		.		Missing		Missing
257-0025/69/M/BL	WEEK 12	09MAR2015	PD	PD	No	No
257-0026/65/M/W2		.		Missing		Missing
257-0027/52/M/A6		.		Missing		Missing
258-0005/64/M/OTH	UNSCHEDULED	09OCT2013	SD	SD	Yes	Yes
258-0007/74/M/W2		.		Missing		Missing
258-0008/70/M/W2		.		Missing		Missing
258-0009/64/M/W2	WEEK 12	06AUG2014	SD	SD	Yes	Yes

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
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[3] Best Overall Disease Control (BODC) is calculated using the non-missing Objective Response across all visits. BODC is 'Yes' if, at any visit, the Disease Control is 'Yes'. BOOR is 'No' if, for all visits, the Disease Control is 'No'.

Listing 16.2.6.5
Best Overall Tumor Response and Best Overall Disease Control
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Date	Overall Response	Best Overall Tumor Response	Disease Control	Best Overall Disease Control[3]
	WEEK 24	29OCT2014	PD	SD	No	Yes
258-0010/53/M/W2	WEEK 12	20AUG2014	SD	SD	Yes	Yes
	WEEK 24	12NOV2014	PD	SD	No	Yes
258-0012/66/F/W2	WEEK 12	01OCT2014	PD	PD	No	No
258-0015/65/M/W2		.		Missing		Missing
259-0001/68/F/W2	WEEK 12	14AUG2013	SD	SD	Yes	Yes
	WEEK 24	06NOV2013	SD	SD	Yes	Yes
	WEEK 36	05FEB2014	SD	SD	Yes	Yes
	WEEK 48	30APR2014	SD	SD	Yes	Yes
259-0002/54/F/W2	WEEK 12	27NOV2013	PD	PD	No	No
260-0003/81/M/A7	WEEK 12	19JAN2015	SD	SD	Yes	Yes
	WEEK 24	09APR2015	SD	SD	Yes	Yes
	WEEK 36	03JUL2015	SD	SD	Yes	Yes
301-0005/61/M/A2	WEEK 12	09AUG2012	PD	PD	No	No
301-0007/55/F/A2		.		Missing		Missing
301-0009/55/M/A2	WEEK 12	28MAR2013	PD	PD	No	No
302-0002/32/F/A2		.		Missing		Missing

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Best Overall Disease Control (BODC) is calculated using the non-missing Objective Response across all visits. BODC is 'Yes' if, at any visit, the Disease Control is 'Yes'. BOOR is 'No' if, for all visits, the Disease Control is 'No'.

Listing 16.2.6.5
Best Overall Tumor Response and Best Overall Disease Control
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Date	Overall Response	Best Overall Tumor Response	Disease Control	Best Overall Disease Control[3]
302-0004/57/M/A2		.		Missing		Missing
302-0007/76/M/A2	WEEK 12	03MAY2012	PD	PD	No	No
302-0008/37/M/A2	UNSCHEDULED	14MAY2012	PD	PD	No	No
302-0010/45/M/A2	WEEK 12	05JUL2012	PD	PD	No	No
302-0011/52/M/A2		.		Missing		Missing
302-0015/60/M/A2	WEEK 12	08JUL2013	PD	PD	No	No
302-0016/60/M/A2	WEEK 12	02JUL2013	PD	PD	No	No
302-0019/52/M/A2	WEEK 12	30JUL2013	PD	PD	No	No
302-0022/65/M/A2	UNSCHEDULED	18SEP2013	PD	PD	No	No
302-0023/68/M/A2		.		Missing		Missing
302-0024/66/F/A2	WEEK 12	10DEC2013	PD	PD	No	No
302-0025/40/M/A2		.		Missing		Missing
302-0026/49/M/A2	WEEK 12	28JAN2014	SD	SD	Yes	Yes
	WEEK 24	22APR2014	SD	SD	Yes	Yes
	WEEK 36	15JUL2014	PD	SD	No	Yes
303-0001/50/M/A2	WEEK 12	18APR2012	PD	PD	No	No
303-0003/47/M/A2	WEEK 12	16FEB2013	PD	PD	No	No

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Best Overall Disease Control (BODC) is calculated using the non-missing Objective Response across all visits. BODC is 'Yes' if, at any visit, the Disease Control is 'Yes'. BOOR is 'No' if, for all visits, the Disease Control is 'No'.

Listing 16.2.6.5
Best Overall Tumor Response and Best Overall Disease Control
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Date	Overall Response	Best Overall Tumor Response	Disease Control	Best Overall Disease Control[3]
303-0004/18/M/A2	WEEK 12	23FEB2013	PD	PD	No	No
303-0006/64/M/A2	UNSCHEDULED	22MAY2013	PD	PD	No	No
303-0007/50/M/A2		.		Missing		Missing
304-0001/54/M/A2	UNSCHEDULED	13DEC2012	PD	PD	No	No
304-0005/58/M/A2	UNSCHEDULED	28JUN2013	PD	PD	No	No
305-0002/57/M/A2	UNSCHEDULED	24FEB2012	PD	PD	No	No
305-0003/50/M/A2	WEEK 12	11MAY2012	SD	SD	Yes	Yes
	WEEK 24	03AUG2012	PD	SD	No	Yes
305-0005/48/M/A2		.		Missing		Missing
305-0006/65/M/A2	WEEK 12	30MAY2012	SD	SD	Yes	Yes
	WEEK 24	22AUG2012	PD	SD	No	Yes
305-0009/45/F/A2	WEEK 12	04JUL2012	SD	SD	Yes	Yes
	WEEK 24	26SEP2012	PD	SD	No	Yes
305-0010/64/F/A2	WEEK 12	10JUL2012	PD	PD	No	No
305-0011/68/M/A2	WEEK 12	20JUL2012	SD	SD	Yes	Yes
	UNSCHEDULED	10AUG2012	PD	SD	No	Yes
305-0012/62/F/A2	WEEK 12	27JUL2012	PR	PR	Yes	Yes

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
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[3] Best Overall Disease Control (BODC) is calculated using the non-missing Objective Response across all visits. BODC is 'Yes' if, at any visit, the Disease Control is 'Yes'. BOOR is 'No' if, for all visits, the Disease Control is 'No'.

Listing 16.2.6.5
Best Overall Tumor Response and Best Overall Disease Control
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Date	Overall Response	Best Overall Tumor Response	Disease Control	Best Overall Disease Control[3]
	UNSCHEDULED	07SEP2012	PR	PR	Yes	Yes
	WEEK 24	19OCT2012	PR	PR	Yes	Yes
	WEEK 36	11JAN2013	PD	PR	No	Yes
305-0014/61/F/A2	WEEK 12	21SEP2012	PD	PD	No	No
305-0019/35/M/A2		.		Missing		Missing
305-0023/54/M/A2	WEEK 12	26MAR2013	PD	PD	No	No
305-0025/77/F/A2	WEEK 12	16APR2013	PD	PD	No	No
305-0026/45/M/A2	WEEK 12	21MAY2013	SD	SD	Yes	Yes
	WEEK 24	13AUG2013	SD	SD	Yes	Yes
305-0028/73/F/A2	WEEK 12	05JUN2013	PD	PD	No	No
305-0030/61/M/A2		.		Missing		Missing
305-0031/29/M/A2		.		Missing		Missing
305-0034/53/M/A2	UNSCHEDULED	05AUG2013	PD	PD	No	No
305-0036/38/M/A2	WEEK 12	22NOV2013	PD	PD	No	No
305-0037/50/M/A2	WEEK 12	09JAN2014	SD	SD	Yes	Yes
305-0039/35/M/A2		.		Missing		Missing
305-0040/61/M/A2		.		Missing		Missing

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Best Overall Disease Control (BODC) is calculated using the non-missing Objective Response across all visits. BODC is 'Yes' if, at any visit, the Disease Control is 'Yes'. BOOR is 'No' if, for all visits, the Disease Control is 'No'.

Listing 16.2.6.5
Best Overall Tumor Response and Best Overall Disease Control
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Date	Overall Response	Best Overall Tumor Response	Disease Control	Best Overall Disease Control[3]
305-0043/70/M/A2	WEEK 12	16SEP2014	PD	PD	No	No
305-0044/67/M/A2	WEEK 12	30SEP2014	PD	PD	No	No
305-0045/65/M/A2		.		Missing		Missing
305-0047/58/M/A2		.		Missing		Missing
305-0048/55/M/A2	WEEK 12	12MAY2015	PD	PD	No	No
306-0001/56/M/A2	WEEK 12	04MAY2012	PD	PD	No	No
306-0002/73/M/A2	WEEK 12	02MAY2012	PD	PD	No	No
306-0005/69/F/A2	UNSCHEDULED	25APR2012	PD	PD	No	No
306-0006/43/M/A2	UNSCHEDULED	11APR2012	PD	PD	No	No
306-0007/56/M/A2	UNSCHEDULED	23APR2012	PD	PD	No	No
306-0008/40/M/A2		.		Missing		Missing
306-0011/47/M/A2	WEEK 12	31MAY2012	PD	PD	No	No
306-0012/61/M/A2	WEEK 12	19JUN2012	SD	SD	Yes	Yes
	WEEK 24	11SEP2012	SD	SD	Yes	Yes
306-0014/47/M/A2		.		Missing		Missing
306-0017/49/M/A2	UNSCHEDULED	23AUG2012	PD	PD	No	No
306-0019/78/M/A2	WEEK 12	05NOV2012	PD	PD	No	No

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[3] Best Overall Disease Control (BODC) is calculated using the non-missing Objective Response across all visits. BODC is 'Yes' if, at any visit, the Disease Control is 'Yes'. BOOR is 'No' if, for all visits, the Disease Control is 'No'.

Listing 16.2.6.5
Best Overall Tumor Response and Best Overall Disease Control
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Date	Overall Response	Best Overall Tumor Response	Disease Control	Best Overall Disease Control[3]
306-0020/63/M/A2	WEEK 12	20DEC2012	PD	PD	No	No
306-0023/68/M/A2	UNSCHEDULED	03JAN2013	PD	PD	No	No
306-0026/58/M/A2	WEEK 12	25APR2013	SD	SD	Yes	Yes
	WEEK 24	18JUL2013	SD	SD	Yes	Yes
	WEEK 36	11OCT2013	PD	SD	No	Yes
306-0027/67/M/A2	UNSCHEDULED	25APR2013	SD	SD	Yes	Yes
	WEEK 24	01AUG2013	SD	SD	Yes	Yes
	UNSCHEDULED	26SEP2013	SD	SD	Yes	Yes
	WEEK 36	24OCT2013	SD	SD	Yes	Yes
	WEEK 48	16JAN2014	SD	SD	Yes	Yes
	WEEK 60	10APR2014	SD	SD	Yes	Yes
	WEEK 72	02JUL2014	PD	SD	No	Yes
306-0030/63/M/A2		.		Missing		Missing
306-0031/40/M/A2	UNSCHEDULED	18JUL2013	PD	PD	No	No
306-0034/65/M/A2	UNSCHEDULED	25JUL2013	PD	PD	No	No
306-0035/48/M/A2	UNSCHEDULED	22AUG2013	PD	PD	No	No
306-0036/73/M/A2	UNSCHEDULED	09SEP2013	PD	PD	No	No

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
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Listing 16.2.6.5
Best Overall Tumor Response and Best Overall Disease Control
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Date	Overall Response	Best Overall Tumor Response	Disease Control	Best Overall Disease Control[3]
306-0038/66/M/A2	WEEK 12	31OCT2013	PD	PD	No	No
306-0039/62/M/A2	WEEK 12	31OCT2013	PD	PD	No	No
306-0040/44/F/A2	UNSCHEDULED	14NOV2013	SD	SD	Yes	Yes
	WEEK 12	12DEC2013	SD	SD	Yes	Yes
	WEEK 24	06MAR2014	PD	SD	No	Yes
306-0041/62/M/A2	WEEK 12	16JAN2014	SD	SD	Yes	Yes
	UNSCHEDULED	21FEB2014	PD	SD	No	Yes
306-0043/56/M/A2	WEEK 12	04AUG2014	PD	PD	No	No
307-0002/61/M/A2	WEEK 12	20JAN2012	PD	PD	No	No
307-0003/68/M/A2	WEEK 12	31JAN2012	SD	SD	Yes	Yes
	WEEK 24	16APR2012	SD	SD	Yes	Yes
	WEEK 36	10JUL2012	SD	SD	Yes	Yes
307-0004/60/M/A2	UNSCHEDULED	19JAN2012	PD	PD	No	No
307-0008/58/M/A2	WEEK 12	08MAR2012	PD	PD	No	No
307-0011/75/M/A2		.		Missing		Missing
307-0014/61/M/A2	WEEK 12	08MAY2012	SD	SD	Yes	Yes
	WEEK 24	26JUL2012	PD	SD	No	Yes

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Listing 16.2.6.5
Best Overall Tumor Response and Best Overall Disease Control
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Date	Overall Response	Best Overall Tumor Response	Disease Control	Best Overall Disease Control[3]
307-0018/70/M/A2	WEEK 12	30AUG2012	SD	SD	Yes	Yes
	WEEK 24	22NOV2012	SD	SD	Yes	Yes
	WEEK 36	14FEB2013	SD	SD	Yes	Yes
	WEEK 48	09MAY2013	PD	SD	No	Yes
307-0020/68/F/A2	WEEK 12	30OCT2012	PD	PD	No	No
307-0022/59/M/A2	WEEK 12	14FEB2013	PD	PD	No	No
307-0025/68/M/A2	WEEK 12	07MAR2013	SD	SD	Yes	Yes
	WEEK 24	30MAY2013	PD	SD	No	Yes
307-0026/65/M/A2	WEEK 12	12MAR2013	SD	SD	Yes	Yes
	WEEK 24	04JUN2013	PD	SD	No	Yes
307-0030/53/M/A2	UNSCHEDULED	13MAY2013	PD	PD	No	No
307-0031/60/M/A2	WEEK 12	30MAY2013	SD	SD	Yes	Yes
	WEEK 24	22AUG2013	SD	SD	Yes	Yes
	WEEK 36	14NOV2013	PD	SD	No	Yes
307-0032/74/F/A2		.		Missing		Missing
307-0037/61/M/A2		.		Missing		Missing
307-0039/51/M/A2	WEEK 12	21JAN2014	PD	PD	No	No

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Listing 16.2.6.5
Best Overall Tumor Response and Best Overall Disease Control
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Date	Overall Response	Best Overall Tumor Response	Disease Control	Best Overall Disease Control[3]
307-0040/65/M/A2		.		Missing		Missing
307-0043/54/M/A2	WEEK 12	09SEP2014	SD	SD	Yes	Yes
307-0044/53/M/A2		.		Missing		Missing
307-0045/48/M/A2	WEEK 12	22SEP2014	PD	PD	No	No
307-0046/46/M/A2		.		Missing		Missing
308-0003/54/M/A2	WEEK 12	18APR2013	SD	SD	Yes	Yes
	WEEK 24	11JUL2013	SD	SD	Yes	Yes
	WEEK 36	03OCT2013	PD	SD	No	Yes
308-0005/68/F/A2	WEEK 12	18JUL2013	PD	PD	No	No
309-0001/46/M/A2	WEEK 12	21AUG2012	PD	PD	No	No
309-0002/56/M/A2	UNSCHEDULED	21JUN2012	PD	PD	No	No
309-0003/52/F/A2	WEEK 12	29AUG2012	PD	PD	No	No
309-0004/55/M/A2		.		Missing		Missing
309-0008/38/M/A2	WEEK 12	02MAY2013	PD	PD	No	No
309-0010/47/M/A2	WEEK 12	03JUN2013	SD	PR	Yes	Yes
	WEEK 24	26AUG2013	PR	PR	Yes	Yes
	WEEK 36	20NOV2013	PR	PR	Yes	Yes

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Listing 16.2.6.5
Best Overall Tumor Response and Best Overall Disease Control
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Date	Overall Response	Best Overall Tumor Response	Disease Control	Best Overall Disease Control[3]
	WEEK 48	10FEB2014	PR	PR	Yes	Yes
	WEEK 60	05MAY2014	PR	PR	Yes	Yes
	WEEK 72	28JUL2014	PR	PR	Yes	Yes
	WEEK 84	20OCT2014	PD	PR	No	Yes
309-0011/59/M/A2	WEEK 12	17JUN2013	PD	PD	No	No
309-0012/82/M/A2	WEEK 12	01AUG2013	PD	PD	No	No
309-0015/62/M/A2	WEEK 12	02SEP2013	PD	PD	No	No
309-0016/72/F/A2	WEEK 12	14NOV2013	PD	PD	No	No
309-0017/73/F/A2	WEEK 12	10FEB2014	PD	PD	No	No
309-0018/82/M/A2	WEEK 12	25AUG2014	PD	PD	No	No
309-0021/54/F/A2	UNSCHEDULED	16SEP2014	PD	PD	No	No
309-0025/49/M/A2		.		Missing		Missing
309-0026/41/M/A2	UNSCHEDULED	04NOV2014	SD	SD	Yes	Yes
	WEEK 12	01DEC2014	SD	SD	Yes	Yes
	UNSCHEDULED	28JAN2015	PD	SD	No	Yes
309-0028/62/M/A2	WEEK 12	12JAN2015	SD	SD	Yes	Yes
	WEEK 24	08APR2015	PD	SD	No	Yes

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
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Listing 16.2.6.5
Best Overall Tumor Response and Best Overall Disease Control
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Date	Overall Response	Best Overall Tumor Response	Disease Control	Best Overall Disease Control[3]
309-0030/33/M/A2	UNSCHEDULED	08FEB2015	PD	PD	No	No
309-0031/34/M/A2	WEEK 12	05MAR2015	PD	PD	No	No
	UNSCHEDULED	12MAR2015	PD	PD	No	No
309-0032/63/M/A2	WEEK 12	19MAR2015	PD	PD	No	No
309-0033/78/F/A2	WEEK 12	16APR2015	SD	SD	Yes	Yes
	WEEK 24	02JUL2015	PD	SD	No	Yes
310-0001/61/M/A2	UNSCHEDULED	21AUG2012	PD	PD	No	No
310-0002/55/M/A2		.		Missing		Missing
310-0003/61/M/A2	WEEK 12	24APR2013	PD	PD	No	No
310-0008/49/M/A2		.		Missing		Missing
310-0012/73/M/A2	WEEK 12	16JAN2014	SD	SD	Yes	Yes
	WEEK 24	10APR2014	PD	SD	No	Yes
310-0013/54/M/A2	WEEK 12	12NOV2014	PD	PD	No	No
311-0002/60/M/A2	UNSCHEDULED	10OCT2013	PD	PD	No	No
311-0007/55/M/A2	WEEK 12	27JAN2014	PD	PD	No	No
311-0008/71/M/A2	UNSCHEDULED	09JUL2014	PD	PD	No	No
401-0003/36/M/A7	UNSCHEDULED	03SEP2013	PD	PD	No	No

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
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Listing 16.2.6.5
Best Overall Tumor Response and Best Overall Disease Control
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Date	Overall Response	Best Overall Tumor Response	Disease Control	Best Overall Disease Control[3]
401-0005/58/M/A7	UNSCHEDULED	18DEC2013	PD	PD	No	No
402-0003/75/M/A7	WEEK 12	16JUL2013	SD	SD	Yes	Yes
	WEEK 24	08OCT2013	PD	SD	No	Yes
402-0006/71/M/A7	WEEK 12	22JUL2013	PD	PD	No	No
402-0008/43/M/A7	UNSCHEDULED	04JUN2013	PD	PD	No	No
402-0009/70/M/A7	UNSCHEDULED	04JUL2013	PD	PD	No	No
402-0011/64/M/A7	WEEK 12	04JUL2013	PD	PD	No	No
402-0017/50/M/A7		.		Missing		Missing
402-0018/48/M/A7	WEEK 12	09SEP2013	PD	PD	No	No
402-0019/54/M/A7	WEEK 12	16SEP2013	PD	PD	No	No
402-0021/64/M/A7	WEEK 12	29OCT2013	SD	SD	Yes	Yes
	WEEK 24	21JAN2014	SD	SD	Yes	Yes
	WEEK 36	09APR2014	SD	SD	Yes	Yes
	WEEK 48	08JUL2014	SD	SD	Yes	Yes
	WEEK 60	29SEP2014	PD	SD	No	Yes
402-0024/57/M/A7	UNSCHEDULED	05NOV2013	PD	PD	No	No
402-0025/58/M/A7	WEEK 12	12DEC2013	PD	PD	No	No

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Best Overall Disease Control (BODC) is calculated using the non-missing Objective Response across all visits. BODC is 'Yes' if, at any visit, the Disease Control is 'Yes'. BOOR is 'No' if, for all visits, the Disease Control is 'No'.

Listing 16.2.6.5
Best Overall Tumor Response and Best Overall Disease Control
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Date	Overall Response	Best Overall Tumor Response	Disease Control	Best Overall Disease Control[3]
402-0027/52/M/A7	UNSCHEDULED	21NOV2013	PD	PD	No	No
402-0028/60/M/A7		.		Missing		Missing
402-0031/65/M/A7	WEEK 12	29JAN2014	PD	PD	No	No
402-0033/63/F/A7	UNSCHEDULED	27JAN2014	PD	PD	No	No
402-0035/44/M/A7		.		Missing		Missing
403-0001/55/M/A7	UNSCHEDULED	01JUL2013	PD	PD	No	No
403-0002/52/M/A7	UNSCHEDULED	21AUG2013	PD	PD	No	No
403-0005/50/F/A7	UNSCHEDULED	01AUG2013	PD	PD	No	No
403-0006/66/M/A7	WEEK 12	17OCT2013	PD	PD	No	No
403-0007/64/M/MIX	UNSCHEDULED	01OCT2013	SD	SD	Yes	Yes
	WEEK 12	07NOV2013	PD	SD	No	Yes
404-0001/71/M/A7	UNSCHEDULED	12AUG2013	PD	PD	No	No
404-0002/56/F/A7	UNSCHEDULED	12SEP2013	PD	PD	No	No
405-0002/46/M/A7		.		Missing		Missing
405-0004/38/M/A7	WEEK 12	10JUL2013	PD	PD	No	No
405-0006/62/M/A7		.		Missing		Missing
405-0007/53/M/A7	UNSCHEDULED	25JUN2013	SD	SD	Yes	Yes

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Best Overall Disease Control (BODC) is calculated using the non-missing Objective Response across all visits. BODC is 'Yes' if, at any visit, the Disease Control is 'Yes'. BOOR is 'No' if, for all visits, the Disease Control is 'No'.

Listing 16.2.6.5
Best Overall Tumor Response and Best Overall Disease Control
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Date	Overall Response	Best Overall Tumor Response	Disease Control	Best Overall Disease Control[3]
	WEEK 12	23JUL2013	SD	SD	Yes	Yes
405-0009/50/M/A7	UNSCHEDULED	10JUN2013	SD	SD	Yes	Yes
405-0010/39/M/A7	WEEK 12	06AUG2013	PD	PD	No	No
405-0011/63/M/A7	UNSCHEDULED	01JUL2013	SD	SD	Yes	Yes
	WEEK 12	29JUL2013	SD	SD	Yes	Yes
	WEEK 24	21OCT2013	PD	SD	No	Yes
405-0013/45/M/A7	UNSCHEDULED	08JUL2013	SD	SD	Yes	Yes
	WEEK 12	05AUG2013	SD	SD	Yes	Yes
405-0014/35/M/A7	UNSCHEDULED	30JUN2013	PD	PD	No	No
405-0016/41/M/A7	UNSCHEDULED	25JUN2013	PD	PD	No	No
405-0018/70/F/A7	UNSCHEDULED	03JUL2013	PD	PD	No	No
405-0020/69/M/A7	WEEK 12	04SEP2013	SD	SD	Yes	Yes
	WEEK 24	27NOV2013	SD	SD	Yes	Yes
	WEEK 36	19FEB2014	SD	SD	Yes	Yes
	WEEK 48	14MAY2014	PD	SD	No	Yes
405-0021/47/M/A7	WEEK 12	05SEP2013	SD	SD	Yes	Yes
	UNSCHEDULED	11OCT2013	SD	SD	Yes	Yes

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Best Overall Disease Control (BODC) is calculated using the non-missing Objective Response across all visits. BODC is 'Yes' if, at any visit, the Disease Control is 'Yes'. BOOR is 'No' if, for all visits, the Disease Control is 'No'.

Listing 16.2.6.5
Best Overall Tumor Response and Best Overall Disease Control
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Date	Overall Response	Best Overall Tumor Response	Disease Control	Best Overall Disease Control[3]
	WEEK 24	27NOV2013	SD	SD	Yes	Yes
	WEEK 36	18FEB2014	SD	SD	Yes	Yes
	WEEK 48	14MAY2014	SD	SD	Yes	Yes
	UNSCHEDULED	04JUL2014	SD	SD	Yes	Yes
	UNSCHEDULED	06AUG2014	PD	SD	No	Yes
405-0022/65/M/A7	UNSCHEDULED	26AUG2013	SD	SD	Yes	Yes
	WEEK 12	16SEP2013	SD	SD	Yes	Yes
	WEEK 24	11DEC2013	PD	SD	No	Yes
405-0023/46/M/A7	WEEK 12	05SEP2013	PD	PD	No	No
405-0025/47/M/A7	UNSCHEDULED	17JUL2013	PD	PD	No	No
405-0028/67/M/A7	WEEK 12	07OCT2013	PD	PD	No	No
405-0030/35/M/A7	UNSCHEDULED	25SEP2013	PD	PD	No	No
405-0032/69/M/A7	WEEK 12	08OCT2013	SD	SD	Yes	Yes
	WEEK 24	30DEC2013	SD	SD	Yes	Yes
	WEEK 36	24MAR2014	SD	SD	Yes	Yes
	WEEK 48	16JUN2014	SD	SD	Yes	Yes
	WEEK 60	05SEP2014	PD	SD	No	Yes

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Best Overall Disease Control (BODC) is calculated using the non-missing Objective Response across all visits. BODC is 'Yes' if, at any visit, the Disease Control is 'Yes'. BOOR is 'No' if, for all visits, the Disease Control is 'No'.

Listing 16.2.6.5
Best Overall Tumor Response and Best Overall Disease Control
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Date	Overall Response	Best Overall Tumor Response	Disease Control	Best Overall Disease Control[3]
405-0033/43/M/A7	WEEK 12	23OCT2013	PD	PD	No	No
405-0034/61/M/A7	WEEK 12	23OCT2013	PD	PD	No	No
405-0035/66/M/A7	UNSCHEDULED	11OCT2014	PD	PD	No	No
405-0039/73/M/A7	UNSCHEDULED	05NOV2013	SD	SD	Yes	Yes
	WEEK 12	03DEC2013	PD	SD	No	Yes
405-0040/65/M/A7	WEEK 12	09DEC2013	PD	PD	No	No
405-0042/53/M/A7	UNSCHEDULED	27NOV2013	PD	PD	No	No
405-0043/49/M/A7	UNSCHEDULED	05DEC2013	PD	PD	No	No
405-0044/56/M/A7	UNSCHEDULED	13NOV2013	PD	PD	No	No
501-0001/59/M/A1	WEEK 12	23JAN2014	PD	PD	No	No
501-0002/36/F/A1	WEEK 12	19FEB2014	PD	PD	No	No
501-0005/80/M/A1	WEEK 12	10APR2014	SD	SD	Yes	Yes
	WEEK 24	03JUL2014	SD	SD	Yes	Yes
	WEEK 36	24SEP2014	SD	SD	Yes	Yes
	WEEK 48	20DEC2014	SD	SD	Yes	Yes
	WEEK 60	12MAR2015	SD	SD	Yes	Yes
	WEEK 72	04JUN2015	PD	SD	No	Yes

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
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[3] Best Overall Disease Control (BODC) is calculated using the non-missing Objective Response across all visits. BODC is 'Yes' if, at any visit, the Disease Control is 'Yes'. BOOR is 'No' if, for all visits, the Disease Control is 'No'.

Listing 16.2.6.5
Best Overall Tumor Response and Best Overall Disease Control
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Date	Overall Response	Best Overall Tumor Response	Disease Control	Best Overall Disease Control[3]
501-0006/60/M/A1	WEEK 12	28APR2014	PD	PD	No	No
501-0007/43/M/A1	WEEK 12	19MAY2014	PD	PD	No	No
501-0008/76/F/A1	WEEK 12	02JUL2014	PD	PD	No	No
501-0009/62/M/A1	WEEK 12	29SEP2014	PD	PD	No	No
501-0010/65/M/A1	WEEK 12	26NOV2014	PD	PD	No	No
502-0002/65/M/A1		.		Missing		Missing
503-0001/32/M/A1	UNSCHEDULED	06JAN2014	PD	PD	No	No
503-0004/49/M/A1		.		Missing		Missing
503-0006/54/M/A1	WEEK 12	23OCT2014	SD	SD	Yes	Yes
	WEEK 24	14JAN2015	SD	SD	Yes	Yes
503-0007/57/M/A1	WEEK 12	14JAN2015	PD	PD	No	No
503-0008/50/M/A1		.		Missing		Missing
503-0009/57/M/A1		.		Missing		Missing
504-0001/47/M/A1	WEEK 12	06MAY2014	SD	SD	Yes	Yes
504-0007/32/M/A1		.		Missing		Missing
505-0001/70/M/A1	UNSCHEDULED	28SEP2014	PD	PD	No	No
506-0002/54/M/A1	UNSCHEDULED	12JUN2014	SD	SD	Yes	Yes

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[3] Best Overall Disease Control (BODC) is calculated using the non-missing Objective Response across all visits. BODC is 'Yes' if, at any visit, the Disease Control is 'Yes'. BOOR is 'No' if, for all visits, the Disease Control is 'No'.

Listing 16.2.6.5
Best Overall Tumor Response and Best Overall Disease Control
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Date	Overall Response	Best Overall Tumor Response	Disease Control	Best Overall Disease Control[3]
	WEEK 12	31JUL2014	SD	SD	Yes	Yes
	WEEK 24	22OCT2014	SD	SD	Yes	Yes
	WEEK 36	14JAN2015	SD	SD	Yes	Yes
	WEEK 48	10APR2015	PD	SD	No	Yes
506-0003/66/M/A1	UNSCHEDULED	27OCT2014	PD	PD	No	No
506-0004/49/M/A1	UNSCHEDULED	24DEC2014	PD	PD	No	No
508-0001/36/M/A1	UNSCHEDULED	08FEB2014	PD	PD	No	No
508-0003/49/F/A1		.		Missing		Missing
509-0001/45/M/A1	WEEK 12	18JUL2014	PD	PD	No	No
509-0002/51/M/A1		.		Missing		Missing
510-0002/50/M/A1		.		Missing		Missing
510-0004/72/M/A1	WEEK 12	15OCT2014	PD	PD	No	No
511-0001/35/M/A1	UNSCHEDULED	26FEB2014	PD	PD	No	No
511-0002/49/M/A1	WEEK 12	27MAY2014	SD	SD	Yes	Yes
	WEEK 24	20AUG2014	PD	SD	No	Yes
512-0001/59/M/A1	WEEK 12	24MAY2014	SD	SD	Yes	Yes
513-0001/28/M/A1	UNSCHEDULED	26MAY2014	PD	PD	No	No

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Best Overall Disease Control (BODC) is calculated using the non-missing Objective Response across all visits. BODC is 'Yes' if, at any visit, the Disease Control is 'Yes'. BOOR is 'No' if, for all visits, the Disease Control is 'No'.

Listing 16.2.6.5
Best Overall Tumor Response and Best Overall Disease Control
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Date	Overall Response	Best Overall Tumor Response	Disease Control	Best Overall Disease Control[3]
513-0004/46/M/A1	UNSCHEDULED	16JUL2014	PD	PD	No	No
513-0005/61/M/A1	WEEK 12	20JAN2015	PD	PD	No	No
515-0001/64/M/A1	WEEK 12	07MAY2014	PD	PD	No	No
515-0003/69/M/A1	WEEK 12	29JUL2014	PD	PD	No	No
515-0004/52/M/A1	WEEK 12	11AUG2014	SD	SD	Yes	Yes
515-0006/47/M/A1	WEEK 12	20OCT2014	PD	PD	No	No
515-0007/39/M/A1		.		Missing		Missing
515-0008/60/M/A1	WEEK 12	11FEB2015	PD	PD	No	No
516-0001/45/M/A1	WEEK 12	25OCT2014	SD	SD	Yes	Yes
	WEEK 24	16JAN2015	PD	SD	No	Yes
517-0001/42/M/A1	UNSCHEDULED	27JAN2014	PD	PD	No	No
517-0002/43/M/A1	WEEK 12	12JUN2014	SD	SD	Yes	Yes
	WEEK 24	04SEP2014	PD	SD	No	Yes
517-0005/46/M/MIX		.		Missing		Missing
517-0006/67/F/A1	WEEK 12	12NOV2014	SD	SD	Yes	Yes
	WEEK 24	02FEB2015	SD	SD	Yes	Yes
	WEEK 36	23APR2015	PD	SD	No	Yes

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Best Overall Disease Control (BODC) is calculated using the non-missing Objective Response across all visits. BODC is 'Yes' if, at any visit, the Disease Control is 'Yes'. BOOR is 'No' if, for all visits, the Disease Control is 'No'.

Listing 16.2.6.5
Best Overall Tumor Response and Best Overall Disease Control
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Date	Overall Response	Best Overall Tumor Response	Disease Control	Best Overall Disease Control[3]
517-0007/66/M/A1		.		Missing		Missing
517-0008/59/M/A1		.		Missing		Missing
517-0009/23/M/A1	WEEK 12	10DEC2014	PD	PD	No	No

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Best Overall Disease Control (BODC) is calculated using the non-missing Objective Response across all visits. BODC is 'Yes' if, at any visit, the Disease Control is 'Yes'. BOOR is 'No' if, for all visits, the Disease Control is 'No'.

Listing 16.2.6.5
Best Overall Tumor Response and Best Overall Disease Control
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Date	Overall Response	Best Overall Tumor Response	Disease Control	Best Overall Disease Control[3]
101-0002/70/M/OTH	WEEK 12	14OCT2011	PD	PD	No	No
101-0004/78/F/A2	WEEK 12	21OCT2011	SD	SD	Yes	Yes
	WEEK 24	13JAN2012	PD	SD	No	Yes
	WEEK 36	10APR2012	PD	SD	No	Yes
	WEEK 48	29JUN2012	PD	SD	No	Yes
	WEEK 60	21SEP2012	PD	SD	No	Yes
101-0010/43/M/BL		.		Missing		Missing
101-0014/61/M/W2	WEEK 12	16MAR2012	SD	SD	Yes	Yes
101-0015/65/M/A4	WEEK 12	22MAR2012	PD	PD	No	No
101-0017/60/M/W2	WEEK 12	01MAY2012	PD	PD	No	No
101-0020/86/M/W2	WEEK 12	05JUN2012	SD	SD	Yes	Yes
	WEEK 24	21AUG2012	PD	SD	No	Yes
101-0027/72/M/W2		.		Missing		Missing
101-0031/69/F/W2	WEEK 12	29SEP2012	PD	PD	No	No
101-0034/44/M/OTH	UNSCHEDULED	02NOV2012	SD	SD	Yes	Yes
101-0035/37/M/A6		.		Missing		Missing
101-0043/69/M/W1	WEEK 12	02JAN2014	SD	SD	Yes	Yes

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Best Overall Disease Control (BODC) is calculated using the non-missing Objective Response across all visits. BODC is 'Yes' if, at any visit, the Disease Control is 'Yes'. BOOR is 'No' if, for all visits, the Disease Control is 'No'.

Listing 16.2.6.5
Best Overall Tumor Response and Best Overall Disease Control
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Date	Overall Response	Best Overall Tumor Response	Disease Control	Best Overall Disease Control[3]
101-0051/70/F/W2		.		Missing		Missing
102-0006/66/M/BL	WEEK 12	23FEB2014	PD	PD	No	No
102-0007/61/M/W2	WEEK 12	19MAR2014	SD	SD	Yes	Yes
103-0002/74/M/W2	WEEK 12	25FEB2013	SD	SD	Yes	Yes
	WEEK 24	20MAY2013	PD	SD	No	Yes
103-0006/57/M/W2	WEEK 12	04FEB2015	PD	PD	No	No
104-0002/80/M/W2	WEEK 12	26JUL2012	SD	SD	Yes	Yes
	WEEK 24	20OCT2012	SD	SD	Yes	Yes
	WEEK 36	12JAN2013	SD	SD	Yes	Yes
104-0007/89/M/A1	WEEK 12	24OCT2013	SD	SD	Yes	Yes
	WEEK 24	17JAN2014	SD	SD	Yes	Yes
	WEEK 36	11APR2014	SD	SD	Yes	Yes
	WEEK 48	09JUL2014	SD	SD	Yes	Yes
	WEEK 60	24SEP2014	SD	SD	Yes	Yes
	WEEK 72	19DEC2014	SD	SD	Yes	Yes
	WEEK 84	17MAR2015	SD	SD	Yes	Yes
	WEEK 96	05JUN2015	SD	SD	Yes	Yes

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Best Overall Disease Control (BODC) is calculated using the non-missing Objective Response across all visits. BODC is 'Yes' if, at any visit, the Disease Control is 'Yes'. BOOR is 'No' if, for all visits, the Disease Control is 'No'.

Listing 16.2.6.5
Best Overall Tumor Response and Best Overall Disease Control
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Date	Overall Response	Best Overall Tumor Response	Disease Control	Best Overall Disease Control[3]
105-0003/57/M/W2	WEEK 12	22JAN2014	SD	SD	Yes	Yes
	WEEK 24	24APR2014	SD	SD	Yes	Yes
	WEEK 36	08JUL2014	SD	SD	Yes	Yes
	WEEK 48	03OCT2014	SD	SD	Yes	Yes
105-0006/60/F/BL	WEEK 12	17MAR2015	SD	SD	Yes	Yes
	WEEK 24	11JUN2015	PD	SD	No	Yes
108-0003/85/M/W2	WEEK 12	31DEC2012	PD	PD	No	No
109-0002/63/M/W2	WEEK 12	07JUN2013	SD	SD	Yes	Yes
	WEEK 24	30AUG2013	PD	SD	No	Yes
109-0005/64/F/W2		.		Missing		Missing
109-0012/21/F/W2	UNSCHEDULED	18NOV2014	SD	SD	Yes	Yes
109-0014/50/F/W2	UNSCHEDULED	13MAR2015	PD	PD	No	No
111-0003/37/M/A1	UNSCHEDULED	13MAR2013	PD	PD	No	No
112-0010/56/F/W2	WEEK 12	21FEB2014	PD	PD	No	No
113-0007/74/M/W2	WEEK 12	09APR2014	SD	SD	Yes	Yes
	WEEK 24	02JUL2014	SD	SD	Yes	Yes
113-0015/58/F/BL		.		Missing		Missing

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
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Listing 16.2.6.5
Best Overall Tumor Response and Best Overall Disease Control
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Date	Overall Response	Best Overall Tumor Response	Disease Control	Best Overall Disease Control[3]
114-0001/25/F/OTH	WEEK 12	27SEP2012	PD	PD	No	No
114-0004/54/F/A1	UNSCHEDULED	27MAR2013	SD	SD	Yes	Yes
115-0005/60/M/W2		.		Missing		Missing
115-0006/62/M/W2	WEEK 12	25JUN2013	SD	SD	Yes	Yes
115-0007/57/M/W2	UNSCHEDULED	16MAY2013	PD	PD	No	No
115-0010/54/M/A4	WEEK 12	20JUN2014	PD	PD	No	No
121-0003/65/M/BL	UNSCHEDULED	27AUG2014	SD	SD	Yes	Yes
201-0002/76/M/W2	WEEK 12	04JUN2012	SD	SD	Yes	Yes
	WEEK 24	24AUG2012	SD	SD	Yes	Yes
	WEEK 36	16NOV2012	SD	SD	Yes	Yes
	WEEK 48	11FEB2013	PD	SD	No	Yes
201-0006/71/M/W2	WEEK 12	28SEP2012	SD	SD	Yes	Yes
	WEEK 24	19DEC2012	PD	SD	No	Yes
201-0007/71/M/W2	WEEK 12	12OCT2012	SD	PR	Yes	Yes
	WEEK 24	04JAN2013	PR	PR	Yes	Yes
	WEEK 36	29MAR2013	PD	PR	No	Yes
201-0009/64/M/W2	WEEK 12	06SEP2013	SD	SD	Yes	Yes

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
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Listing 16.2.6.5
Best Overall Tumor Response and Best Overall Disease Control
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Date	Overall Response	Best Overall Tumor Response	Disease Control	Best Overall Disease Control[3]
	WEEK 24	29NOV2013	SD	SD	Yes	Yes
	WEEK 36	21FEB2014	SD	SD	Yes	Yes
	WEEK 48	19MAY2014	SD	SD	Yes	Yes
	WEEK 60	04AUG2014	SD	SD	Yes	Yes
	WEEK 72	04NOV2014	SD	SD	Yes	Yes
	WEEK 84	26JAN2015	SD	SD	Yes	Yes
	WEEK 96	20APR2015	SD	SD	Yes	Yes
201-0010/81/F/W2	WEEK 12	13SEP2013	PD	PD	No	No
201-0014/73/M/W2	WEEK 12	04OCT2013	PD	PD	No	No
201-0015/49/M/W2	WEEK 12	25OCT2013	SD	SD	Yes	Yes
	WEEK 24	17JAN2014	SD	SD	Yes	Yes
	WEEK 36	14MAR2014	PD	SD	No	Yes
201-0022/80/F/W2	WEEK 12	25JUL2014	SD	SD	Yes	Yes
	WEEK 24	27OCT2014	PD	SD	No	Yes
203-0004/81/M/W2	WEEK 12	28JUN2012	SD	SD	Yes	Yes
	WEEK 24	20SEP2012	SD	SD	Yes	Yes
	WEEK 36	13DEC2012	PD	SD	No	Yes

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
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[3] Best Overall Disease Control (BODC) is calculated using the non-missing Objective Response across all visits. BODC is 'Yes' if, at any visit, the Disease Control is 'Yes'. BOOR is 'No' if, for all visits, the Disease Control is 'No'.

Listing 16.2.6.5
Best Overall Tumor Response and Best Overall Disease Control
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Date	Overall Response	Best Overall Tumor Response	Disease Control	Best Overall Disease Control[3]
203-0006/76/M/W2		.		Missing		Missing
203-0007/59/M/W2		.		Missing		Missing
203-0009/73/M/W2	WEEK 12	20DEC2012	SD	SD	Yes	Yes
	WEEK 24	04APR2013	SD	SD	Yes	Yes
	WEEK 36	01AUG2013	SD	SD	Yes	Yes
	WEEK 48	31OCT2013	PD	SD	No	Yes
203-0010/74/M/W2	WEEK 12	13DEC2012	SD	PR	Yes	Yes
	WEEK 24	21MAR2013	SD	PR	Yes	Yes
	WEEK 36	20JUN2013	SD	PR	Yes	Yes
	WEEK 48	26SEP2013	SD	PR	Yes	Yes
	WEEK 60	09JAN2014	SD	PR	Yes	Yes
	WEEK 72	17APR2014	PR	PR	Yes	Yes
	WEEK 84	17JUL2014	PR	PR	Yes	Yes
	WEEK 96	02OCT2014	PR	PR	Yes	Yes
203-0014/73/M/W2		.		Missing		Missing
203-0016/57/M/W2	WEEK 12	24APR2014	SD	SD	Yes	Yes
	WEEK 24	31JUL2014	PD	SD	No	Yes

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
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[3] Best Overall Disease Control (BODC) is calculated using the non-missing Objective Response across all visits. BODC is 'Yes' if, at any visit, the Disease Control is 'Yes'. BOOR is 'No' if, for all visits, the Disease Control is 'No'.

Listing 16.2.6.5
Best Overall Tumor Response and Best Overall Disease Control
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Date	Overall Response	Best Overall Tumor Response	Disease Control	Best Overall Disease Control[3]
203-0019/68/M/W2	WEEK 12	04JUL2014	PD	PD	No	No
204-0003/64/M/W2	WEEK 12	30SEP2013	PD	PD	No	No
204-0004/76/F/W2	WEEK 12	17DEC2013	PD	PD	No	No
205-0002/71/M/W2	WEEK 12	08MAY2012	PD	PD	No	No
205-0003/79/M/W2	WEEK 12	12JUN2012	SD	SD	Yes	Yes
	WEEK 24	11SEP2012	SD	SD	Yes	Yes
	WEEK 36	04DEC2012	PD	SD	No	Yes
205-0005/71/M/W2	WEEK 12	05JUN2012	PD	PD	No	No
205-0014/70/M/W2		.		Missing		Missing
205-0023/72/M/W2	WEEK 12	21JAN2014	PD	PD	No	No
205-0026/61/F/W2	WEEK 12	28APR2015	PD	PD	No	No
205-0028/73/F/W2		.		Missing		Missing
207-0002/71/M/W2	WEEK 12	07JUN2012	PD	PD	No	No
207-0007/71/M/W2	WEEK 12	18SEP2012	PD	PD	No	No
207-0012/66/M/W2	WEEK 12	13JUN2013	SD	SD	Yes	Yes
	WEEK 24	05SEP2013	SD	SD	Yes	Yes
	WEEK 36	29NOV2013	SD	SD	Yes	Yes

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[3] Best Overall Disease Control (BODC) is calculated using the non-missing Objective Response across all visits. BODC is 'Yes' if, at any visit, the Disease Control is 'Yes'. BOOR is 'No' if, for all visits, the Disease Control is 'No'.

Listing 16.2.6.5
Best Overall Tumor Response and Best Overall Disease Control
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Date	Overall Response	Best Overall Tumor Response	Disease Control	Best Overall Disease Control[3]
	WEEK 48	19FEB2014	PD	SD	No	Yes
207-0016/82/F/W2	WEEK 12	03JAN2014	SD	SD	Yes	Yes
207-0017/81/F/W2	WEEK 12	19FEB2014	PD	PD	No	No
207-0019/55/M/W2		.		Missing		Missing
209-0006/68/M/W2	WEEK 12	19JUL2013	SD	SD	Yes	Yes
	WEEK 24	15OCT2013	SD	SD	Yes	Yes
	WEEK 36	08JAN2014	PD	SD	No	Yes
209-0011/69/M/W2	WEEK 12	17FEB2014	PD	PD	No	No
209-0014/79/M/W2	WEEK 12	03JUN2014	SD	SD	Yes	Yes
	WEEK 24	25AUG2014	PD	SD	No	Yes
210-0003/74/M/W2		.		Missing		Missing
210-0004/71/M/W2	WEEK 12	27MAR2014	PD	PD	No	No
210-0005/53/M/W2	WEEK 12	07MAY2014	PD	PD	No	No
210-0006/45/M/W2	WEEK 12	18SEP2014	PD	PD	No	No
251-0002/69/M/W2	WEEK 12	16OCT2013	PD	PD	No	No
251-0003/68/M/W2	WEEK 12	21JAN2014	SD	SD	Yes	Yes
	WEEK 24	15APR2014	PD	SD	No	Yes

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Best Overall Disease Control (BODC) is calculated using the non-missing Objective Response across all visits. BODC is 'Yes' if, at any visit, the Disease Control is 'Yes'. BOOR is 'No' if, for all visits, the Disease Control is 'No'.

Listing 16.2.6.5
Best Overall Tumor Response and Best Overall Disease Control
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Date	Overall Response	Best Overall Tumor Response	Disease Control	Best Overall Disease Control[3]
252-0001/65/M/A3		.		Missing		Missing
252-0004/50/M/A1	UNSCHEDULED	25JUL2013	PD	PD	No	No
252-0006/64/M/W2	WEEK 12	17DEC2013	SD	SD	Yes	Yes
	WEEK 24	11MAR2014	SD	SD	Yes	Yes
252-0008/76/M/W2	WEEK 12	12AUG2014	PD	PD	No	No
252-0010/56/F/W2	WEEK 12	20JAN2015	PD	PD	No	No
253-0003/75/M/W2	WEEK 12	31AUG2012	SD	SD	Yes	Yes
	WEEK 24	16NOV2012	SD	SD	Yes	Yes
	WEEK 36	13FEB2013	PD	SD	No	Yes
253-0004/79/M/W2	WEEK 12	19NOV2012	PD	PD	No	No
253-0005/74/F/W2		.		Missing		Missing
253-0006/63/M/A3	WEEK 12	15MAR2013	SD	SD	Yes	Yes
	UNSCHEDULED	17MAY2013	PD	SD	No	Yes
253-0011/67/M/W2	WEEK 12	22DEC2014	SD	PR	Yes	Yes
	WEEK 24	16MAR2015	PR	PR	Yes	Yes
	WEEK 36	08JUN2015	PR	PR	Yes	Yes
253-0012/67/M/W2		.		Missing		Missing

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[3] Best Overall Disease Control (BODC) is calculated using the non-missing Objective Response across all visits. BODC is 'Yes' if, at any visit, the Disease Control is 'Yes'. BOOR is 'No' if, for all visits, the Disease Control is 'No'.

Listing 16.2.6.5
Best Overall Tumor Response and Best Overall Disease Control
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Date	Overall Response	Best Overall Tumor Response	Disease Control	Best Overall Disease Control[3]
257-0005/66/M/W2	WEEK 12	18MAR2013	PD	PD	No	No
257-0013/63/M/W2		.		Missing		Missing
257-0020/72/M/A1	UNSCHEDULED	20NOV2014	PD	PD	No	No
258-0002/69/F/W2	WEEK 12	26JUN2013	SD	SD	Yes	Yes
	WEEK 24	18SEP2013	SD	SD	Yes	Yes
	WEEK 36	11DEC2013	PD	SD	No	Yes
258-0003/67/F/W2	WEEK 12	31JUL2013	SD	SD	Yes	Yes
	WEEK 24	23OCT2013	PD	SD	No	Yes
258-0004/65/M/W2		.		Missing		Missing
258-0006/69/M/W2		.		Missing		Missing
258-0013/59/M/W2	WEEK 12	28JAN2015	PD	PD	No	No
259-0003/73/M/W2	WEEK 12	20AUG2014	SD	SD	Yes	Yes
	WEEK 24	12NOV2014	SD	SD	Yes	Yes
	WEEK 36	04FEB2015	SD	SD	Yes	Yes
	WEEK 48	29APR2015	SD	SD	Yes	Yes
259-0004/52/M/W2		.		Missing		Missing
260-0002/66/M/W2	UNSCHEDULED	15NOV2013	PD	PD	No	No

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Listing 16.2.6.5
Best Overall Tumor Response and Best Overall Disease Control
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Date	Overall Response	Best Overall Tumor Response	Disease Control	Best Overall Disease Control[3]
301-0001/47/F/A2	WEEK 12	17JAN2012	PD	PD	No	No
301-0003/61/F/A2	WEEK 12	17MAY2012	PD	PD	No	No
301-0008/53/M/A2	WEEK 12	22MAR2013	PD	PD	No	No
302-0006/49/M/A2		.		Missing		Missing
302-0009/73/M/A2		.		Missing		Missing
302-0012/62/M/A2	WEEK 12	12JUL2012	PD	PD	No	No
302-0013/62/M/A2		.		Missing		Missing
302-0020/52/M/A2		.		Missing		Missing
302-0021/75/F/A2	WEEK 12	27AUG2013	SD	SD	Yes	Yes
	WEEK 24	19NOV2013	PD	SD	No	Yes
304-0003/56/F/A2	WEEK 12	03JUN2013	PD	PD	No	No
304-0004/69/M/A2		.		Missing		Missing
304-0007/72/M/A2	WEEK 12	29JAN2014	PD	PD	No	No
305-0004/79/M/A2	WEEK 12	07MAY2012	SD	SD	Yes	Yes
305-0007/67/M/A2	WEEK 12	01JUN2012	SD	SD	Yes	Yes
	WEEK 24	24AUG2012	PD	SD	No	Yes
305-0015/84/M/A2	WEEK 12	17SEP2012	PD	PD	No	No

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
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Listing 16.2.6.5
Best Overall Tumor Response and Best Overall Disease Control
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Date	Overall Response	Best Overall Tumor Response	Disease Control	Best Overall Disease Control[3]
305-0016/78/M/A2	UNSCHEDULED	16AUG2012	PR	PR	Yes	Yes
	WEEK 12	25SEP2012	PD	PR	No	Yes
305-0021/83/F/A2	WEEK 12	08FEB2013	PD	PD	No	No
305-0024/68/M/A2	WEEK 12	12APR2013	PD	PD	No	No
305-0033/37/F/A2	WEEK 12	24SEP2013	PD	PD	No	No
305-0035/60/M/A2	WEEK 12	20NOV2013	SD	SD	Yes	Yes
	WEEK 24	12FEB2014	PD	SD	No	Yes
305-0046/60/M/A2	WEEK 12	24JAN2015	SD	SD	Yes	Yes
	WEEK 24	14APR2015	PD	SD	No	Yes
306-0004/46/M/A2	UNSCHEDULED	03APR2012	PD	PD	No	No
306-0010/69/M/A2	WEEK 12	06JUN2012	PD	PD	No	No
306-0013/42/M/A2		.		Missing		Missing
306-0015/73/M/A2	UNSCHEDULED	28JUN2012	PD	PD	No	No
306-0016/58/M/A2	WEEK 12	11SEP2012	PD	PD	No	No
306-0022/56/M/A2	WEEK 12	24JAN2013	SD	SD	Yes	Yes
	WEEK 24	25APR2013	PD	SD	No	Yes
306-0028/53/M/A2	WEEK 12	13JUN2013	SD	SD	Yes	Yes

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Best Overall Disease Control (BODC) is calculated using the non-missing Objective Response across all visits. BODC is 'Yes' if, at any visit, the Disease Control is 'Yes'. BOOR is 'No' if, for all visits, the Disease Control is 'No'.

Listing 16.2.6.5
Best Overall Tumor Response and Best Overall Disease Control
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Date	Overall Response	Best Overall Tumor Response	Disease Control	Best Overall Disease Control[3]
306-0045/60/F/A1	UNSCHEDULED	15AUG2014	SD	SD	Yes	Yes
	WEEK 12	02SEP2014	PD	SD	No	Yes
307-0006/72/M/A2		.		Missing		Missing
307-0009/53/M/A2		.		Missing		Missing
307-0012/42/M/A2		.		Missing		Missing
307-0015/75/M/A2	WEEK 12	11JUL2012	SD	SD	Yes	Yes
	WEEK 24	04OCT2012	PD	SD	No	Yes
307-0021/68/M/A2	WEEK 12	08NOV2012	SD	SD	Yes	Yes
307-0028/69/F/A2	WEEK 12	01APR2013	PD	PD	No	No
307-0034/48/M/A2	WEEK 12	29OCT2013	PD	PD	No	No
307-0036/76/M/A2	WEEK 12	18DEC2013	PD	PD	No	No
307-0042/55/M/A2	WEEK 12	04SEP2014	SD	SD	Yes	Yes
	WEEK 24	27NOV2014	PD	SD	No	Yes
308-0002/36/F/A2	WEEK 12	21MAR2013	PD	PD	No	No
308-0004/52/M/A2	WEEK 12	25APR2013	PD	PD	No	No
308-0006/64/M/A2	UNSCHEDULED	27JUN2013	PD	PD	No	No
308-0008/47/M/A2	WEEK 12	04OCT2013	PD	PD	No	No

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Best Overall Disease Control (BODC) is calculated using the non-missing Objective Response across all visits. BODC is 'Yes' if, at any visit, the Disease Control is 'Yes'. BOOR is 'No' if, for all visits, the Disease Control is 'No'.

Listing 16.2.6.5
Best Overall Tumor Response and Best Overall Disease Control
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Date	Overall Response	Best Overall Tumor Response	Disease Control	Best Overall Disease Control[3]
308-0009/61/M/A2		.		Missing		Missing
309-0006/56/M/A2	WEEK 12	04FEB2013	SD	SD	Yes	Yes
	WEEK 24	29APR2013	SD	SD	Yes	Yes
	WEEK 36	22JUL2013	PD	SD	No	Yes
309-0007/58/M/A2	WEEK 12	25FEB2013	PD	PD	No	No
309-0013/45/M/A2	WEEK 12	29AUG2013	PD	PD	No	No
309-0014/39/M/A2	WEEK 12	29AUG2013	PD	PD	No	No
309-0019/68/M/A2	UNSCHEDULED	19AUG2014	SD	SD	Yes	Yes
	WEEK 24	25NOV2014	SD	SD	Yes	Yes
	WEEK 36	17FEB2015	SD	SD	Yes	Yes
	WEEK 48	12MAY2015	SD	SD	Yes	Yes
309-0027/49/M/A2	WEEK 12	12JAN2015	PD	PD	No	No
309-0029/50/M/A2	WEEK 12	09FEB2015	PD	PD	No	No
310-0004/50/F/A2	WEEK 12	17APR2013	PD	PD	No	No
310-0005/58/M/A2	WEEK 12	05JUN2013	PD	PD	No	No
310-0006/50/F/A2	WEEK 12	10JUL2013	SD	SD	Yes	Yes
	WEEK 24	09OCT2013	SD	SD	Yes	Yes

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Best Overall Disease Control (BODC) is calculated using the non-missing Objective Response across all visits. BODC is 'Yes' if, at any visit, the Disease Control is 'Yes'. BOOR is 'No' if, for all visits, the Disease Control is 'No'.

Listing 16.2.6.5
Best Overall Tumor Response and Best Overall Disease Control
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Date	Overall Response	Best Overall Tumor Response	Disease Control	Best Overall Disease Control[3]
	WEEK 36	23DEC2013	PD	SD	No	Yes
310-0007/74/M/A2	WEEK 12	22AUG2013	SD	SD	Yes	Yes
	WEEK 24	14NOV2013	SD	SD	Yes	Yes
	WEEK 36	06FEB2014	SD	SD	Yes	Yes
	WEEK 48	01MAY2014	PD	SD	No	Yes
310-0009/46/M/A2	UNSCHEDULED	27SEP2013	PD	PD	No	No
310-0010/34/F/A2	UNSCHEDULED	25SEP2013	PD	PD	No	No
310-0011/52/M/A2	WEEK 12	02JAN2014	PD	PD	No	No
310-0014/64/M/A2	WEEK 12	03DEC2014	PD	PD	No	No
311-0003/44/M/A2	WEEK 12	10DEC2013	PD	PD	No	No
311-0004/68/M/A2		.		Missing		Missing
311-0005/58/M/A2	WEEK 12	30DEC2013	PD	PD	No	No
311-0006/73/F/A2	WEEK 12	16JAN2014	PD	PD	No	No
311-0009/51/F/A2	WEEK 12	30SEP2014	PD	PD	No	No
311-0010/47/M/A2	WEEK 12	18NOV2014	PR	PR	Yes	Yes
	WEEK 24	12FEB2015	PR	PR	Yes	Yes
	WEEK 36	07MAY2015	PR	PR	Yes	Yes

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Best Overall Disease Control (BODC) is calculated using the non-missing Objective Response across all visits. BODC is 'Yes' if, at any visit, the Disease Control is 'Yes'. BOOR is 'No' if, for all visits, the Disease Control is 'No'.

Listing 16.2.6.5
Best Overall Tumor Response and Best Overall Disease Control
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Date	Overall Response	Best Overall Tumor Response	Disease Control	Best Overall Disease Control[3]
311-0011/46/M/A2	UNSCHEDULED	30DEC2014	PD	PD	No	No
311-0012/55/M/A2	WEEK 12	16APR2015	SD	SD	Yes	Yes
401-0001/70/M/A7		.		Missing		Missing
401-0002/55/M/A7		.		Missing		Missing
402-0001/35/M/A7	UNSCHEDULED	10JUN2013	PD	PD	No	No
402-0002/58/M/A7	WEEK 12	09JUL2013	PD	PD	No	No
402-0005/70/M/A7	WEEK 12	23JUL2013	PD	PD	No	No
402-0010/50/M/A7	UNSCHEDULED	02JUL2013	PD	PD	No	No
402-0022/60/F/A7	WEEK 12	11NOV2013	PD	PD	No	No
402-0023/57/M/A7	WEEK 12	19NOV2013	PD	PD	No	No
402-0029/49/M/A7	UNSCHEDULED	30DEC2013	PD	PD	No	No
402-0032/49/F/A7	WEEK 12	20FEB2014	PD	PD	No	No
402-0034/43/F/A7	WEEK 12	06MAR2014	SD	SD	Yes	Yes
	WEEK 24	29MAY2014	PD	SD	No	Yes
403-0004/37/M/A7	WEEK 12	25SEP2013	PD	PD	No	No
404-0003/53/M/A7	UNSCHEDULED	30SEP2013	PD	PD	No	No
404-0004/61/F/A7	UNSCHEDULED	02DEC2013	PD	PD	No	No

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Best Overall Disease Control (BODC) is calculated using the non-missing Objective Response across all visits. BODC is 'Yes' if, at any visit, the Disease Control is 'Yes'. BOOR is 'No' if, for all visits, the Disease Control is 'No'.

Listing 16.2.6.5
Best Overall Tumor Response and Best Overall Disease Control
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Date	Overall Response	Best Overall Tumor Response	Disease Control	Best Overall Disease Control[3]
405-0001/55/M/A7	WEEK 12	10JUL2013	PD	PD	No	No
405-0005/35/M/A6	WEEK 12	10JUL2013	SD	SD	Yes	Yes
	WEEK 24	02OCT2013	SD	SD	Yes	Yes
	WEEK 36	23DEC2013	PD	SD	No	Yes
405-0012/72/M/A7	WEEK 12	29JUL2013	SD	SD	Yes	Yes
	WEEK 24	21OCT2013	PD	SD	No	Yes
405-0019/61/M/A7		.		Missing		Missing
405-0024/69/M/A7		.		Missing		Missing
405-0026/67/M/A7	WEEK 12	25SEP2013	PD	PD	No	No
405-0036/70/M/A7	UNSCHEDULED	16OCT2013	SD	SD	Yes	Yes
	WEEK 12	12NOV2013	PD	SD	No	Yes
405-0041/57/M/A7	WEEK 12	25NOV2013	SD	SD	Yes	Yes
	WEEK 24	17FEB2014	SD	SD	Yes	Yes
	WEEK 36	02MAY2014	PD	SD	No	Yes
501-0003/22/M/A1	WEEK 12	25FEB2014	PD	PD	No	No
501-0004/26/M/A1	WEEK 12	05MAR2014	PD	PD	No	No
501-0011/61/M/A1	WEEK 12	12DEC2014	PD	PD	No	No

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Best Overall Disease Control (BODC) is calculated using the non-missing Objective Response across all visits. BODC is 'Yes' if, at any visit, the Disease Control is 'Yes'. BOOR is 'No' if, for all visits, the Disease Control is 'No'.

Listing 16.2.6.5
Best Overall Tumor Response and Best Overall Disease Control
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Date	Overall Response	Best Overall Tumor Response	Disease Control	Best Overall Disease Control[3]
502-0001/70/M/A1		.		Missing		Missing
502-0003/48/M/A1	WEEK 12	10APR2014	PD	PD	No	No
503-0002/71/F/A1	WEEK 12	13MAY2014	SD	SD	Yes	Yes
	WEEK 24	04AUG2014	SD	SD	Yes	Yes
	WEEK 36	28OCT2014	PD	SD	No	Yes
503-0003/47/F/A1		.		Missing		Missing
503-0005/72/M/A1	WEEK 12	17JUN2014	SD	SD	Yes	Yes
	WEEK 24	11SEP2014	SD	SD	Yes	Yes
	WEEK 36	25NOV2014	SD	SD	Yes	Yes
	WEEK 48	02MAR2015	PD	SD	No	Yes
504-0003/53/M/A1	UNSCHEDULED	11APR2014	PD	PD	No	No
504-0005/41/F/A1		.		Missing		Missing
504-0006/51/M/A1		.		Missing		Missing
506-0001/43/M/A1		.		Missing		Missing
506-0005/24/M/A1		.		Missing		Missing
507-0001/51/M/A1	WEEK 12	14OCT2014	PD	PD	No	No
507-0002/44/M/A1	UNSCHEDULED	17SEP2014	PD	PD	No	No

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Best Overall Disease Control (BODC) is calculated using the non-missing Objective Response across all visits. BODC is 'Yes' if, at any visit, the Disease Control is 'Yes'. BOOR is 'No' if, for all visits, the Disease Control is 'No'.

Listing 16.2.6.5
Best Overall Tumor Response and Best Overall Disease Control
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Date	Overall Response	Best Overall Tumor Response	Disease Control	Best Overall Disease Control[3]
508-0002/64/M/A1		.		Missing		Missing
508-0004/58/M/A1		.		Missing		Missing
509-0003/39/M/A1	WEEK 12	14OCT2014	PD	PD	No	No
510-0001/67/M/A1	WEEK 12	15MAY2014	PR	PR	Yes	Yes
	WEEK 24	06AUG2014	PR	PR	Yes	Yes
	WEEK 36	30OCT2014	PR	PR	Yes	Yes
	UNSCHEDULED	08DEC2014	PD	PR	No	Yes
510-0003/43/M/A1	UNSCHEDULED	14AUG2014	PD	PD	No	No
513-0003/46/M/A1		.		Missing		Missing
515-0005/45/M/A1	WEEK 12	09SEP2014	PD	PD	No	No
517-0003/45/M/A1	WEEK 12	01AUG2014	PD	PD	No	No
517-0010/67/M/A1	WEEK 12	02FEB2015	PD	PD	No	No

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Best Overall Disease Control (BODC) is calculated using the non-missing Objective Response across all visits. BODC is 'Yes' if, at any visit, the Disease Control is 'Yes'. BOOR is 'No' if, for all visits, the Disease Control is 'No'.

Listing 16.2.6.6
Time to Tumor Progression
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
101-0001/59/M/A2	26JUL2011	.	03JAN2012	03JAN2012	5.4+	Lost to follow-up
101-0005/77/M/W2	08AUG2011	17APR2013	25OCT2011	.	2.6	
101-0006/62/M/W2	12AUG2011	17APR2012	12OCT2011	.	2.1	
101-0007/77/M/A1	16AUG2011	11MAY2013	08NOV2011	.	2.8	
101-0008/83/M/BL	22AUG2011	11AUG2012	15NOV2011	.	2.8	
101-0009/82/M/A1	14SEP2011	05SEP2012	20DEC2011	.	3.3	
101-0011/75/F/W2	14NOV2011	16DEC2011	29NOV2011	.	0.5	
101-0012/68/M/W2	29NOV2011	02AUG2012	18JAN2012	.	1.7	
101-0013/66/F/A5	10JAN2012	14JUL2014	23MAR2012	.	2.5	
101-0016/61/M/A4	10JAN2012	.	11SEP2012	.	14	
101-0018/51/M/A1	21FEB2012	31MAR2012	.	16FEB2012	0+	No post-treatment radiological assessment
101-0019/68/M/W2	28FEB2012	20MAR2014	15MAY2012	.	2.6	
101-0021/74/M/W2	20MAR2012	10JUN2013	29MAY2012	.	2.4	
101-0022/55/M/BL	20MAR2012	31MAY2012	13APR2012	.	0.8	
101-0023/70/M/W2	30MAR2012	18DEC2012	.	14JUN2012	2.6+	No pression

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[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Time to Tumor Progression is calculated as (date of disease progression - date of randomization + 1) / 30. Censored records are indicated with +. For censoring rules, refer to Table 3 in the Statistical Analysis Plan.

Listing 16.2.6.6
Time to Tumor Progression
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
101-0024/35/F/A4	01MAY2012	05NOV2013	10JUL2012	.	2.4	
101-0025/57/F/W2	20APR2012	03AUG2012	15JUN2012	.	1.9	
101-0026/82/M/W2	15MAY2012	16MAY2013	11JAN2013	.	8.1	
101-0028/60/M/W2	15JUN2012	02APR2013	.	07SEP2012	2.8+	No pression
101-0029/70/M/A1	18JUN2012	02AUG2013	28AUG2012	.	2.4	
101-0030/51/M/W2	05JUL2012	20DEC2012	05SEP2012	.	2.1	
101-0032/84/M/W2	01AUG2012	06JUL2013	.	09OCT2012	2.3+	No pression
101-0033/66/F/W2	03AUG2012	.	04JAN2013	.	5.2	
101-0036/67/M/A4	23OCT2012	05FEB2013	12DEC2012	.	1.7	
101-0037/57/M/A1	07DEC2012	.	.	.	0+	Lost to follow-up and no post-treatment radio
101-0038/56/M/W2	05FEB2013	01FEB2014	.	30JAN2013	0+	No post-treatment radiological assessment
101-0039/77/F/W2	05APR2013	.	27NOV2013	.	7.9	
101-0040/60/M/W2	27JUN2013	03NOV2013	06AUG2013	.	1.4	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Time to Tumor Progression is calculated as (date of disease progression - date of randomization + 1) / 30. Censored records are indicated with +. For censoring rules, refer to Table 3 in the Statistical Analysis Plan.

Listing 16.2.6.6
Time to Tumor Progression
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
101-0041/54/M/W2	30JUL2013	24NOV2014	.	12JUL2013	0+	No post-treatment radiological assessment
101-0042/64/M/W2	05AUG2013	12OCT2014	.	15JUL2013	0+	No post-treatment radiological assessment
101-0044/78/M/W2	17OCT2013	24OCT2014	27DEC2013	.	2.4	
101-0045/74/F/W2	21OCT2013	26APR2014	16JAN2014	.	2.9	
101-0046/70/M/OTH	22OCT2013	28MAR2014	02JAN2014	.	2.4	
101-0047/52/M/W2	22OCT2013	26FEB2015	16DEC2013	.	1.9	
101-0048/66/F/W2	22OCT2013	.	30DEC2013	.	2.3	
101-0049/71/M/A8	28OCT2013	.	08JAN2014	.	2.4	
101-0050/59/M/W2	29OCT2013	15JAN2014	05DEC2013	.	1.3	
102-0001/53/M/BL	25APR2012	09NOV2012	07JUN2012	.	1.5	
102-0003/63/M/BL	12SEP2012	25JAN2013	23NOV2012	.	2.4	
102-0008/64/M/BL	08JAN2014	10FEB2014	.	02JAN2014	0+	No post-treatment radiological assessment

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Time to Tumor Progression is calculated as (date of disease progression - date of randomization + 1) / 30. Censored records are indicated with +. For censoring rules, refer to Table 3 in the Statistical Analysis Plan.

Listing 16.2.6.6
Time to Tumor Progression
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
102-0009/58/M/W2	29OCT2014	04FEB2015	09DEC2014	.	1.4	
103-0001/56/M/W2	11MAY2012	23OCT2012	26JUL2012	.	2.6	
103-0003/66/M/W2	15FEB2013	26OCT2013	23JUL2013	.	5.3	
103-0004/40/F/A1	17APR2014	01SEP2014	03JUN2014	.	1.6	
104-0003/56/F/W2	19JUL2012	19OCT2012	.	16JUL2012	0+	No post-treatment radiological assessment
104-0004/74/M/W2	23OCT2012	24MAY2013	.	01OCT2012	0+	No post-treatment radiological assessment
104-0008/55/M/PI	03SEP2013	11SEP2014	.	29NOV2013	2.9+	No pression
104-0010/71/F/A8	08JAN2014	.	17SEP2014	.	8.4	
104-0012/78/F/A2	02OCT2014	25MAR2015	29NOV2014	.	2	
106-0001/42/F/W2	28FEB2012	05OCT2012	29JUN2012	.	4.1	
107-0002/71/M/W2	23AUG2012	23DEC2013	07NOV2012	.	2.6	
107-0003/73/M/BL	22FEB2013	07MAY2013	.	07FEB2013	0+	No post-treatment radiological assessment

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Time to Tumor Progression is calculated as (date of disease progression - date of randomization + 1) / 30. Censored records are indicated with +. For censoring rules, refer to Table 3 in the Statistical Analysis Plan.

Listing 16.2.6.6
Time to Tumor Progression
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
107-0004/63/M/W2	01MAR2013	.	.	21MAY2013	2.7+	No pression
107-0006/60/M/W2	14MAY2013	04APR2014	29JUL2013	.	2.6	
108-0001/60/F/W2	20MAR2012	19JUN2012	18JUN2012	.	1.5	
108-0002/78/M/BL	31MAY2012	03APR2013	10JUL2012	.	1.2	
108-0004/61/M/W2	18APR2013	22JUL2014	.	.	1	
108-0005/68/M/W2	08MAY2013	19OCT2013	29JUL2013	.	2.8	
108-0008/77/M/W2	09OCT2014	.	17MAR2015	.	5.3	
109-0003/68/M/W2	03MAY2013	09AUG2013	01JUL2013	.	2	
109-0004/57/M/W2	19JUL2013	22FEB2014	07OCT2013	.	2.7	
109-0006/62/M/PI	22AUG2013	25AUG2014	06NOV2013	.	2.6	
109-0007/55/M/W2	05DEC2013	10AUG2014	23APR2014	.	4.7	
109-0008/70/F/W2	22MAY2014	.	18NOV2014	.	5.9	
109-0009/57/M/W2	09JUL2014	25MAY2015	22SEP2014	.	2.5	
109-0010/65/M/W2	09JUL2014	.	24SEP2014	.	2.6	
109-0011/64/M/A4	24SEP2014	.	09DEC2014	.	2.6	
109-0013/64/F/W2	05NOV2014	10MAY2015	13APR2015	.	5.3	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Time to Tumor Progression is calculated as (date of disease progression - date of randomization + 1) / 30. Censored records are indicated with +. For censoring rules, refer to Table 3 in the Statistical Analysis Plan.

Listing 16.2.6.6
Time to Tumor Progression
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
110-0003/63/M/OTH	09JUL2012	01DEC2013	.	17DEC2012	5.4+	No pression
110-0004/53/M/A4	25OCT2012	23NOV2013	.	08JAN2013	2.5+	No pression
110-0005/77/M/W2	15MAR2013	.	.	24MAY2013	2.4+	No pression
110-0007/62/M/A4	17MAY2013	26FEB2014	13JAN2014	.	8.1	
110-0008/63/F/BL	09JUL2013	10FEB2014	.	11JUN2013	0+	No post-treatment radiological assessment
110-0011/77/M/A1	22JAN2015	.	07APR2015	.	2.5	
111-0001/37/M/A4	12JUL2012	06JUL2014	27JUL2012	.	0.5	
111-0004/64/M/W2	23MAY2013	29AUG2013	.	31JUL2013	2.3+	No pression
111-0006/59/M/W2	03OCT2013	12MAY2014	.	26MAR2014	5.8+	No pression
111-0007/55/M/W2	06FEB2014	.	14APR2014	.	2.3	
112-0006/58/M/W2	26MAR2013	29AUG2013	03JUN2013	.	2.3	
112-0009/50/M/A8	19JUN2013	12DEC2013	04SEP2013	.	2.6	
112-0011/56/M/A4	10JAN2014	28JUN2014	28FEB2014	.	1.7	
112-0012/71/M/W2	23MAY2014	07FEB2015	08AUG2014	.	2.6	
112-0013/28/F/W2	23MAY2014	29OCT2014	.	12JUL2014	1.7+	No pression

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Time to Tumor Progression is calculated as (date of disease progression - date of randomization + 1) / 30. Censored records are indicated with +. For censoring rules, refer to Table 3 in the Statistical Analysis Plan.

Listing 16.2.6.6
Time to Tumor Progression
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
112-0014/79/M/A8	06JUN2014	24OCT2014	22AUG2014	.	2.6	
112-0015/66/M/A8	24OCT2014	02JAN2015	12DEC2014	.	1.7	
113-0001/60/M/W2	24AUG2012	20JAN2014	06FEB2013	.	5.6	
113-0002/64/F/W2	12OCT2012	11APR2014	10JUN2013	.	8.3	
113-0005/58/M/W2	22JAN2014	05APR2014	.	09JAN2014	0+	No post-treatment radiological assessment
113-0008/78/M/A8	13FEB2014	.	.	31JAN2014	0+	No post-treatment radiological assessment
113-0010/59/M/W2	28APR2014	22JUN2014	.	18APR2014	0+	No post-treatment radiological assessment
113-0013/56/M/W2	04NOV2014	.	13JAN2015	.	2.4	
113-0016/72/M/A8	03FEB2015	.	21APR2015	.	2.6	
114-0003/59/M/W2	29NOV2012	07OCT2013	.	10APR2013	4.4+	No pression
114-0005/73/M/W2	05DEC2013	.	.	06FEB2014	2.1+	Lost to follow-up
114-0007/60/F/W2	18NOV2014	.	.	01MAY2015	5.5+	No pression

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Time to Tumor Progression is calculated as (date of disease progression - date of randomization + 1) / 30. Censored records are indicated with +. For censoring rules, refer to Table 3 in the Statistical Analysis Plan.

Listing 16.2.6.6
Time to Tumor Progression
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
115-0001/59/F/A4	27NOV2012	.	11FEB2013	.	2.6	
115-0002/45/F/W2	27NOV2012	18FEB2013	10JAN2013	.	1.5	
115-0003/63/M/W2	17JAN2013	17AUG2013	.	24JUN2013	5.3+	No pression
115-0008/51/M/A8	19JUN2013	17JUL2013	.	13JUN2013	0+	No post-treatment radiological assessment
115-0009/85/M/W2	12DEC2013	01SEP2014	21MAY2014	.	5.4	
115-0011/56/M/W2	05JUN2014	27NOV2014	29AUG2014	.	2.9	
115-0014/72/M/W2	10FEB2015	10MAY2015	.	21JAN2015	0+	No post-treatment radiological assessment
116-0002/67/F/W2	18MAR2013	14DEC2013	18NOV2013	.	8.1	
116-0003/66/M/BL	28MAR2013	29MAY2013	21MAY2013	.	1.8	
117-0001/69/M/W2	02APR2013	08NOV2014	12JUN2013	.	2.4	
118-0001/67/F/A8	09AUG2013	29NOV2014	29OCT2013	.	2.7	
119-0001/80/M/A8	21JAN2014	01AUG2014	.	14JAN2014	0+	No post-treatment radiological assessment

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Time to Tumor Progression is calculated as (date of disease progression - date of randomization + 1) / 30. Censored records are indicated with +. For censoring rules, refer to Table 3 in the Statistical Analysis Plan.

Listing 16.2.6.6
Time to Tumor Progression
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
121-0001/62/M/W2	14FEB2014	.	.	06MAY2014	2.7+	Lost to follow-up
121-0004/64/F/W2	02JAN2015	06MAR2015	.	30DEC2014	0+	No post-treatment radiological assessment
201-0001/68/F/W2	25JAN2012	24SEP2012	24APR2012	.	3	
201-0005/73/M/W2	19JUL2012	14JAN2013	10OCT2012	.	2.8	
201-0008/79/M/W2	16MAY2013	15OCT2013	.	29JUL2013	2.5+	No pression
201-0011/73/M/W2	04JUL2013	.	20SEP2013	.	2.6	
201-0012/79/M/W2	24JUL2013	.	18SEP2014	.	14	
201-0013/67/F/W2	24JUL2013	19MAY2014	11OCT2013	.	2.7	
201-0016/72/M/W2	14NOV2013	30APR2015	18APR2014	.	5.2	
201-0017/82/M/W2	28NOV2013	05MAR2015	.	25NOV2013	0+	No post-treatment radiological assessment
201-0018/78/F/W2	06DEC2013	21JAN2014	.	14NOV2013	0+	No post-treatment radiological assessment
201-0019/68/M/W2	19DEC2013	.	12MAR2014	.	2.6	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Time to Tumor Progression is calculated as (date of disease progression - date of randomization + 1) / 30. Censored records are indicated with +. For censoring rules, refer to Table 3 in the Statistical Analysis Plan.

Listing 16.2.6.6
Time to Tumor Progression
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
201-0020/67/M/W2	23JAN2014	.	.	09JAN2014	0+	No post-treatment radiological assessment
201-0021/54/M/W2	13FEB2014	10JUN2014	05MAY2014	.	2.6	
201-0024/74/M/W2	29JAN2015	11APR2015	13MAR2015	.	1.5	
201-0025/75/M/W2	29JAN2015	.	.	12JAN2015	0+	No post-treatment radiological assessment
203-0001/61/F/W2	06MAR2012	06JUN2012	.	23FEB2012	0+	No post-treatment radiological assessment
203-0002/72/M/W2	06MAR2012	19APR2012	.	22FEB2012	0+	No post-treatment radiological assessment
203-0005/53/M/W2	05APR2012	26JUN2013	09JUL2012	.	3.2	
203-0013/68/M/W2	30DEC2013	17MAR2014	.	03DEC2013	0+	No post-treatment radiological assessment
203-0015/85/M/W2	30JAN2014	01JUN2014	10APR2014	.	2.4	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Time to Tumor Progression is calculated as (date of disease progression - date of randomization + 1) / 30. Censored records are indicated with +. For censoring rules, refer to Table 3 in the Statistical Analysis Plan.

Listing 16.2.6.6
Time to Tumor Progression
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
203-0017/58/M/W2	03MAR2014	29AUG2014	.	25FEB2014	0+	No post-treatment radiological assessment
203-0018/58/F/W2	04APR2014	24JUL2014	.	26MAR2014	0+	No post-treatment radiological assessment
205-0001/77/M/W2	24FEB2012	06NOV2014	01OCT2013	.	19.5	
205-0004/77/F/W2	20MAR2012	24JUN2012	05JUN2012	.	2.6	
205-0008/76/M/W2	27APR2012	30JUL2012	.	03APR2012	0+	No post-treatment radiological assessment
205-0012/73/F/W2	06DEC2012	08JAN2013	.	27NOV2012	0+	No post-treatment radiological assessment
205-0015/71/M/W2	19JUN2013	22JUN2014	.	11JUN2013	0+	No post-treatment radiological assessment
205-0016/70/M/W2	25JUN2013	.	.	21APR2015	22.2+	No pression
205-0017/71/M/W2	08AUG2013	18AUG2014	14JAN2014	.	5.3	
205-0020/82/M/W2	11OCT2013	18MAY2014	27DEC2013	.	2.6	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Time to Tumor Progression is calculated as (date of disease progression - date of randomization + 1) / 30. Censored records are indicated with +. For censoring rules, refer to Table 3 in the Statistical Analysis Plan.

Listing 16.2.6.6
Time to Tumor Progression
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
205-0022/67/M/W2	05NOV2013	22NOV2013	.	08OCT2013	0+	No post-treatment radiological assessment
205-0024/80/M/W2	03DEC2013	16AUG2014	25FEB2014	.	2.8	
205-0025/63/F/W2	29NOV2013	21MAR2014	27FEB2014	.	2.5	
207-0001/81/F/W2	19MAR2012	23OCT2012	.	06FEB2012	0+	No post-treatment radiological assessment
207-0005/74/M/W2	12JUN2012	.	.	.	0+	Lost to follow-up and no post-treatment radio
207-0006/73/M/W2	18JUN2012	03OCT2012	19SEP2012	.	3	
207-0008/66/M/W2	09JUL2012	28AUG2012	.	11JUN2012	0+	No post-treatment radiological assessment
207-0011/78/M/W2	21JAN2013	06MAR2013	.	11JAN2013	0+	No post-treatment radiological assessment
207-0015/77/M/W2	13AUG2013	02OCT2014	23OCT2013	.	2.4	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Time to Tumor Progression is calculated as (date of disease progression - date of randomization + 1) / 30. Censored records are indicated with +. For censoring rules, refer to Table 3 in the Statistical Analysis Plan.

Listing 16.2.6.6
Time to Tumor Progression
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
207-0020/77/M/W2	18JUN2014	17SEP2014	05SEP2014	.	2.6	
207-0021/74/M/W2	19JUN2014	30MAR2015	20FEB2015	.	8	
207-0022/74/M/W2	10JUL2014	.	.	23SEP2014	2.5+	No pression
208-0001/59/M/W2	20SEP2012	.	.	17JUN2015	33.4+	No pression
208-0002/82/F/W2	20SEP2012	08MAR2013	12DEC2012	.	2.8	
208-0006/69/F/W2	28AUG2013	20JUL2014	13NOV2013	.	2.6	
208-0007/53/M/W2	07JUL2014	.	08OCT2014	.	2.7	
209-0001/66/M/W2	15NOV2012	04MAY2013	31JAN2013	.	2.6	
209-0004/74/M/W2	09APR2013	26OCT2013	24JUN2013	.	2.6	
209-0008/66/M/W2	11JUL2013	01NOV2013	30SEP2013	.	2.7	
209-0012/63/M/W2	03DEC2013	04AUG2014	22MAY2014	.	5.7	
209-0013/52/M/W2	23DEC2013	.	.	.	2.6	
210-0001/67/M/W2	30AUG2013	30APR2014	06MAR2014	.	6	
210-0002/80/M/W2	09OCT2013	20MAY2015	04SEP2014	.	11	
210-0007/72/M/W2	07JUL2014	.	.	04JUN2015	11.1+	No pression
210-0009/49/F/W2	10NOV2014	.	29JAN2015	.	2.6	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Time to Tumor Progression is calculated as (date of disease progression - date of randomization + 1) / 30. Censored records are indicated with +. For censoring rules, refer to Table 3 in the Statistical Analysis Plan.

Listing 16.2.6.6
Time to Tumor Progression
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
210-0011/73/M/W2	17NOV2014	04MAR2015	05FEB2015	.	2.6	
210-0012/47/F/W2	16DEC2014	.	26MAR2015	.	3.1	
210-0014/71/F/W2	26JAN2015	.	07MAY2015	.	3.1	
251-0001/55/F/W2	24JUL2012	26DEC2012	.	16OCT2012	2.8+	No pression
252-0002/76/M/W2	28AUG2012	26MAY2013	.	31JUL2012	0+	No post-treatment radiological assessment
252-0003/68/M/W2	28DEC2012	24AUG2013	19MAR2013	.	2.7	
252-0007/77/M/W2	25FEB2014	03MAY2014	.	25MAR2014	0+	No post-treatment radiological assessment
252-0011/81/M/BL	24NOV2014	.	.	07MAY2015	5.5+	No pression
253-0002/63/M/W2	09MAR2012	09AUG2012	25MAY2012	.	2.6	
253-0010/76/M/W2	07JUN2013	30MAY2014	13NOV2013	.	5.3	
254-0001/69/M/W2	17MAY2012	04DEC2012	08AUG2012	.	2.8	
257-0001/47/M/A4	04APR2012	10SEP2012	.	19MAR2012	0+	No post-treatment radiological assessment

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Time to Tumor Progression is calculated as (date of disease progression - date of randomization + 1) / 30. Censored records are indicated with +. For censoring rules, refer to Table 3 in the Statistical Analysis Plan.

Listing 16.2.6.6
Time to Tumor Progression
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
257-0002/56/M/W2	18APR2012	22DEC2012	.	30MAR2012	0+	No post-treatment radiological assessment
257-0007/80/M/W2	21FEB2013	20JAN2014	09MAY2013	.	2.6	
257-0008/80/F/W2	26MAR2013	06JUN2014	13JUN2013	.	2.7	
257-0010/42/M/BL	23MAY2013	.	05AUG2013	.	2.5	
257-0012/75/M/W2	13MAY2013	25JUN2013	.	15APR2013	0+	No post-treatment radiological assessment
257-0015/69/F/BL	14APR2014	25MAY2014	.	07APR2014	0+	No post-treatment radiological assessment
257-0017/74/M/A8	02MAY2014	10JUL2015	21JUL2014	.	2.7	
257-0018/53/M/A6	28APR2014	31MAY2014	.	11APR2014	0+	No post-treatment radiological assessment
257-0022/60/M/W2	01DEC2014	29MAY2015	02FEB2015	.	2.1	
257-0024/75/M/W2	22DEC2014	31MAR2015	.	15DEC2014	0+	No post-treatment radiological assessment

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Time to Tumor Progression is calculated as (date of disease progression - date of randomization + 1) / 30. Censored records are indicated with +. For censoring rules, refer to Table 3 in the Statistical Analysis Plan.

Listing 16.2.6.6
Time to Tumor Progression
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
257-0025/69/M/BL	22DEC2014	30APR2015	09MAR2015	.	2.6	
257-0026/65/M/W2	19JAN2015	.	.	05JAN2015	0+	No post-treatment radiological assessment
257-0027/52/M/A6	19JAN2015	02MAR2015	.	29DEC2014	0+	No post-treatment radiological assessment
258-0005/64/M/OTH	09AUG2013	16MAY2014	.	09OCT2013	2.1+	No pression
258-0007/74/M/W2	09OCT2013	23NOV2013	.	02OCT2013	0+	No post-treatment radiological assessment
258-0008/70/M/W2	18NOV2013	26MAR2014	.	06NOV2013	0+	No post-treatment radiological assessment
258-0009/64/M/W2	19MAY2014	30APR2015	29OCT2014	.	5.5	
258-0010/53/M/W2	02JUN2014	.	12NOV2014	.	5.5	
258-0012/66/F/W2	15JUL2014	09APR2015	09OCT2014	.	2.6	
258-0015/65/M/W2	02DEC2014	.	.	02DEC2014	0+	No post-treatment radiological assessment

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Time to Tumor Progression is calculated as (date of disease progression - date of randomization + 1) / 30. Censored records are indicated with +. For censoring rules, refer to Table 3 in the Statistical Analysis Plan.

Listing 16.2.6.6
Time to Tumor Progression
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
259-0001/68/F/W2	03JUN2013	.	.	30APR2014	11.1+	No pression
259-0002/54/F/W2	09SEP2013	06JUL2014	27NOV2013	.	2.7	
260-0003/81/M/A7	05NOV2014	.	.	03JUL2015	8+	No pression
301-0005/61/M/A2	24MAY2012	24NOV2012	12AUG2012	.	2.6	
301-0007/55/F/A2	04JAN2013	26MAR2013	.	02JAN2013	0+	No post-treatment radiological assessment
301-0009/55/M/A2	11JAN2013	01MAY2013	28MAR2013	.	2.6	
302-0002/32/F/A2	07NOV2011	15DEC2011	.	03NOV2011	0+	No post-treatment radiological assessment
302-0004/57/M/A2	10JAN2012	21MAR2012	.	05JAN2012	0+	No post-treatment radiological assessment
302-0007/76/M/A2	14FEB2012	23MAR2013	03MAY2012	.	2.7	
302-0008/37/M/A2	28FEB2012	07SEP2012	14MAY2012	.	2.6	
302-0010/45/M/A2	17APR2012	08DEC2012	05JUL2012	.	2.7	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Time to Tumor Progression is calculated as (date of disease progression - date of randomization + 1) / 30. Censored records are indicated with +. For censoring rules, refer to Table 3 in the Statistical Analysis Plan.

Listing 16.2.6.6
Time to Tumor Progression
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
302-0011/52/M/A2	24APR2012	06JUN2012	.	02APR2012	0+	No post-treatment radiological assessment
302-0015/60/M/A2	16APR2013	10MAR2014	08JUL2013	.	2.8	
302-0016/60/M/A2	16APR2013	28JAN2014	09JUL2013	.	2.6	
302-0019/52/M/A2	14MAY2013	20MAY2014	05AUG2013	.	2.6	
302-0022/65/M/A2	09JUL2013	05OCT2013	23SEP2013	.	2.4	
302-0023/68/M/A2	10SEP2013	07SEP2014	.	09SEP2013	0+	No post-treatment radiological assessment
302-0024/66/F/A2	24SEP2013	09APR2015	10DEC2013	.	2.6	
302-0025/40/M/A2	22OCT2013	06JUL2014	.	17OCT2013	0+	No post-treatment radiological assessment
302-0026/49/M/A2	12NOV2013	.	15JUL2014	.	8.2	
303-0001/50/M/A2	03FEB2012	18FEB2013	25APR2012	.	2.5	
303-0003/47/M/A2	28NOV2012	20APR2013	20FEB2013	.	2.7	
303-0004/18/M/A2	10DEC2012	10MAY2013	27FEB2013	.	2.5	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Time to Tumor Progression is calculated as (date of disease progression - date of randomization + 1) / 30. Censored records are indicated with +. For censoring rules, refer to Table 3 in the Statistical Analysis Plan.

Listing 16.2.6.6
Time to Tumor Progression
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
303-0006/64/M/A2	10APR2013	25JUL2013	29MAY2013	.	1.4	
303-0007/50/M/A2	24JUL2013	25OCT2013	.	12JUL2013	0+	No post-treatment radiological assessment
304-0001/54/M/A2	05NOV2012	08FEB2013	14DEC2012	.	1.3	
304-0005/58/M/A2	05JUN2013	05JUL2013	29JUN2013	.	0.8	
305-0002/57/M/A2	14FEB2012	23DEC2013	24FEB2012	.	0.4	
305-0003/50/M/A2	15FEB2012	07AUG2013	03AUG2012	.	5.7	
305-0005/48/M/A2	21FEB2012	09MAY2012	.	16FEB2012	0+	No post-treatment radiological assessment
305-0006/65/M/A2	08MAR2012	22OCT2012	22AUG2012	.	5.6	
305-0009/45/F/A2	11APR2012	15JUL2014	26SEP2012	.	5.6	
305-0010/64/F/A2	18APR2012	30AUG2013	10JUL2012	.	2.8	
305-0011/68/M/A2	27APR2012	26NOV2012	10AUG2012	.	3.5	
305-0012/62/F/A2	04MAY2012	.	11JAN2013	.	8.4	
305-0014/61/F/A2	10JUL2012	09MAR2013	23SEP2012	.	2.5	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Time to Tumor Progression is calculated as (date of disease progression - date of randomization + 1) / 30. Censored records are indicated with +. For censoring rules, refer to Table 3 in the Statistical Analysis Plan.

Listing 16.2.6.6
Time to Tumor Progression
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
305-0019/35/M/A2	11SEP2012	13NOV2012	.	07SEP2012	0+	No post-treatment radiological assessment
305-0023/54/M/A2	02JAN2013	03SEP2013	.	.	2.8	
305-0025/77/F/A2	22JAN2013	02AUG2013	16APR2013	.	2.8	
305-0026/45/M/A2	26FEB2013	20DEC2013	.	13AUG2013	5.6+	No pression
305-0028/73/F/A2	15MAR2013	16JUN2013	05JUN2013	.	2.8	
305-0030/61/M/A2	02APR2013	26JUN2014	.	28MAR2013	0+	No post-treatment radiological assessment
305-0031/29/M/A2	02APR2013	13MAY2013	.	29MAR2013	0+	No post-treatment radiological assessment
305-0034/53/M/A2	03JUL2013	24AUG2013	05AUG2013	.	1.1	
305-0036/38/M/A2	05SEP2013	.	28NOV2013	22NOV2013	2.6+	Lost to follow-up
305-0037/50/M/A2	24OCT2013	24JUN2014	.	09JAN2014	2.6+	No pression
305-0039/35/M/A2	28NOV2013	26DEC2013	.	22NOV2013	0+	No post-treatment radiological assessment

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Time to Tumor Progression is calculated as (date of disease progression - date of randomization + 1) / 30. Censored records are indicated with +. For censoring rules, refer to Table 3 in the Statistical Analysis Plan.

Listing 16.2.6.6
Time to Tumor Progression
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
305-0040/61/M/A2	15NOV2013	26JUN2014	.	11NOV2013	0+	No post-treatment radiological assessment
305-0043/70/M/A2	01JUL2014	.	26SEP2014	.	2.6	
305-0044/67/M/A2	08JUL2014	.	07OCT2014	.	2.8	
305-0045/65/M/A2	17OCT2014	05DEC2014	.	06OCT2014	0+	No post-treatment radiological assessment
305-0047/58/M/A2	25DEC2014	28JAN2015	.	24DEC2014	0+	No post-treatment radiological assessment
305-0048/55/M/A2	24FEB2015	.	13MAY2015	.	2.6	
306-0001/56/M/A2	17FEB2012	04NOV2013	08MAY2012	.	2.6	
306-0002/73/M/A2	14FEB2012	21AUG2012	08MAY2012	.	2.6	
306-0005/69/F/A2	24FEB2012	29JUL2012	26APR2012	.	2.1	
306-0006/43/M/A2	20MAR2012	14MAY2012	12APR2012	.	0.8	
306-0007/56/M/A2	05MAR2012	28NOV2012	24APR2012	.	1.7	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Time to Tumor Progression is calculated as (date of disease progression - date of randomization + 1) / 30. Censored records are indicated with +. For censoring rules, refer to Table 3 in the Statistical Analysis Plan.

Listing 16.2.6.6
Time to Tumor Progression
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
306-0008/40/M/A2	12MAR2012	12JUN2012	.	07MAR2012	0+	No post-treatment radiological assessment
306-0011/47/M/A2	15MAR2012	02JUN2012	04JUN2012	.	2.6	
306-0012/61/M/A2	02APR2012	22NOV2012	.	11SEP2012	5.4+	No pression
306-0014/47/M/A2	19APR2012	20JUN2012	.	06APR2012	0+	No post-treatment radiological assessment
306-0017/49/M/A2	12JUL2012	16NOV2012	31AUG2012	.	1.4	
306-0019/78/M/A2	22AUG2012	04DEC2012	05NOV2012	.	2.5	
306-0020/63/M/A2	04OCT2012	07JUN2013	24DEC2012	.	2.6	
306-0023/68/M/A2	27NOV2012	28JUN2013	08JAN2013	.	1.3	
306-0026/58/M/A2	04FEB2013	.	17OCT2013	.	8.3	
306-0027/67/M/A2	19FEB2013	.	09JUL2014	.	16.6	
306-0030/63/M/A2	23APR2013	18JUL2013	.	18APR2013	0+	No post-treatment radiological assessment
306-0031/40/M/A2	15MAY2013	17MAY2014	24JUL2013	.	2.2	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Time to Tumor Progression is calculated as (date of disease progression - date of randomization + 1) / 30. Censored records are indicated with +. For censoring rules, refer to Table 3 in the Statistical Analysis Plan.

Listing 16.2.6.6
Time to Tumor Progression
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
306-0034/65/M/A2	01JUL2013	09AUG2013	01AUG2013	.	0.8	
306-0035/48/M/A2	08JUL2013	01DEC2013	26AUG2013	.	1.5	
306-0036/73/M/A2	09JUL2013	25NOV2013	24SEP2014	.	2.1	
306-0038/66/M/A2	21AUG2013	04MAY2014	06NOV2013	.	2.4	
306-0039/62/M/A2	20AUG2013	15DEC2013	05NOV2013	.	2.4	
306-0040/44/F/A2	24SEP2013	09JUL2014	11MAR2014	.	5.5	
306-0041/62/M/A2	29OCT2013	12MAR2014	24FEB2014	.	3.9	
306-0043/56/M/A2	19MAY2014	07OCT2014	11AUG2014	.	2.6	
307-0002/61/M/A2	03NOV2011	16APR2012	20JAN2012	.	2.6	
307-0003/68/M/A2	10NOV2011	09FEB2013	.	10JUL2012	8.1+	No pression
307-0004/60/M/A2	10NOV2011	18MAR2012	27JAN2012	.	2.4	
307-0008/58/M/A2	20DEC2011	01OCT2012	12MAR2012	.	2.7	
307-0011/75/M/A2	07FEB2012	02APR2012	.	03FEB2012	0+	No post-treatment radiological assessment
307-0014/61/M/A2	16FEB2012	21MAY2013	28JUL2012	.	5.4	
307-0018/70/M/A2	14JUN2012	14JAN2015	16MAY2013	.	11	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Time to Tumor Progression is calculated as (date of disease progression - date of randomization + 1) / 30. Censored records are indicated with +. For censoring rules, refer to Table 3 in the Statistical Analysis Plan.

Listing 16.2.6.6
Time to Tumor Progression
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
307-0020/68/F/A2	16AUG2012	23MAR2013	31OCT2012	.	2.5	
307-0022/59/M/A2	27NOV2012	18APR2013	18FEB2013	.	2.7	
307-0025/68/M/A2	18DEC2012	25SEP2013	03JUN2013	.	5.5	
307-0026/65/M/A2	27DEC2012	09DEC2013	05JUN2013	.	5.3	
307-0030/53/M/A2	06MAR2013	31MAY2013	14MAY2013	.	2.3	
307-0031/60/M/A2	15MAR2013	19DEC2013	18NOV2013	.	8.2	
307-0032/74/F/A2	11APR2013	11MAY2013	.	10APR2013	0+	No post-treatment radiological assessment
307-0037/61/M/A2	03OCT2013	19APR2014	.	30SEP2013	0+	No post-treatment radiological assessment
307-0039/51/M/A2	05NOV2013	16OCT2014	24JAN2014	.	2.6	
307-0040/65/M/A2	27MAY2014	04AUG2014	.	22MAY2014	0+	No post-treatment radiological assessment
307-0043/54/M/A2	25JUN2014	01NOV2014	.	09SEP2014	2.6+	No pression

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Time to Tumor Progression is calculated as (date of disease progression - date of randomization + 1) / 30. Censored records are indicated with +. For censoring rules, refer to Table 3 in the Statistical Analysis Plan.

Listing 16.2.6.6
Time to Tumor Progression
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
307-0044/53/M/A2	27JUN2014	11SEP2014	.	23JUN2014	0+	No post-treatment radiological assessment
307-0045/48/M/A2	07JUL2014	.	22SEP2014	.	2.6	
307-0046/46/M/A2	17JUL2014	13MAR2015	.	30JUN2014	0+	No post-treatment radiological assessment
308-0003/54/M/A2	29JAN2013	10DEC2013	15OCT2013	.	8.3	
308-0005/68/F/A2	30APR2013	10SEP2013	18JUL2013	.	2.7	
309-0001/46/M/A2	12JUN2012	04APR2013	27AUG2012	.	2.4	
309-0002/56/M/A2	13JUN2012	27OCT2012	27JUN2012	.	0.3	
309-0003/52/F/A2	20JUN2012	29JAN2013	05SEP2012	.	2.4	
309-0004/55/M/A2	25JUN2012	19JUL2012	.	19JUN2012	0+	No post-treatment radiological assessment
309-0008/38/M/A2	21FEB2013	31DEC2013	09MAY2013	.	2.4	
309-0010/47/M/A2	25MAR2013	.	27OCT2014	.	19.2	
309-0011/59/M/A2	08APR2013	02JUL2013	24JUN2013	.	2.4	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Time to Tumor Progression is calculated as (date of disease progression - date of randomization + 1) / 30. Censored records are indicated with +. For censoring rules, refer to Table 3 in the Statistical Analysis Plan.

Listing 16.2.6.6
Time to Tumor Progression
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
309-0012/82/M/A2	23MAY2013	31DEC2013	08AUG2013	.	2.4	
309-0015/62/M/A2	24JUN2013	20MAY2014	09SEP2013	.	2.4	
309-0016/72/F/A2	05SEP2013	14JAN2014	21NOV2013	.	2.4	
309-0017/73/F/A2	02DEC2013	26JUN2014	17FEB2014	.	2.4	
309-0018/82/M/A2	03JUN2014	28OCT2014	01SEP2014	.	2.8	
309-0021/54/F/A2	17JUL2014	28NOV2014	22SEP2014	.	2.1	
309-0025/49/M/A2	25AUG2014	04SEP2014	.	12AUG2014	0+	No post-treatment radiological assessment
309-0026/41/M/A2	22SEP2014	15FEB2015	29JAN2015	.	4.3	
309-0028/62/M/A2	03NOV2014	.	13APR2015	.	5.2	
309-0030/33/M/A2	15DEC2014	20FEB2015	09FEB2015	.	1.9	
309-0031/34/M/A2	25DEC2014	03APR2015	13MAR2015	.	2.6	
309-0032/63/M/A2	08JAN2015	30MAR2015	26MAR2015	.	2.4	
309-0033/78/F/A2	29JAN2015	.	08JUL2015	.	5.2	
310-0001/61/M/A2	19JUN2012	01JUN2013	22AUG2012	.	2.1	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
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[3] Time to Tumor Progression is calculated as (date of disease progression - date of randomization + 1) / 30. Censored records are indicated with +. For censoring rules, refer to Table 3 in the Statistical Analysis Plan.

Listing 16.2.6.6
Time to Tumor Progression
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
310-0002/55/M/A2	12JUL2012	13OCT2012	.	28JUN2012	0+	No post-treatment radiological assessment
310-0003/61/M/A2	06FEB2013	29APR2014	24APR2013	.	2.6	
310-0008/49/M/A2	19JUN2013	13AUG2013	.	30MAY2013	0+	No post-treatment radiological assessment
310-0012/73/M/A2	07NOV2013	.	14APR2014	.	5.2	
310-0013/54/M/A2	03SEP2014	29APR2015	17NOV2014	.	2.4	
311-0002/60/M/A2	14AUG2013	20NOV2013	16OCT2013	.	1.9	
311-0007/55/M/A2	18NOV2013	13NOV2014	27JAN2013	.	2.4	
311-0008/71/M/A2	21MAY2014	01DEC2014	09JUL2014	.	1.7	
401-0003/36/M/A7	24JUN2013	24NOV2013	03SEP2013	.	2.4	
401-0005/58/M/A7	16OCT2013	17MAY2014	18DEC2013	.	2.1	
402-0003/75/M/A7	30APR2013	08NOV2013	08OCT2013	.	5.4	
402-0006/71/M/A7	02MAY2013	20NOV2013	30JUL2013	.	2.7	
402-0008/43/M/A7	21MAY2013	22JUL2013	14JUN2013	.	0.5	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
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[3] Time to Tumor Progression is calculated as (date of disease progression - date of randomization + 1) / 30. Censored records are indicated with +. For censoring rules, refer to Table 3 in the Statistical Analysis Plan.

Listing 16.2.6.6
Time to Tumor Progression
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
402-0009/70/M/A7	16MAY2013	11AUG2013	11JUL2013	.	1.7	
402-0011/64/M/A7	23MAY2013	04OCT2013	11JUL2013	.	1.4	
402-0017/50/M/A7	11JUN2013	09AUG2013	.	27MAY2013	0+	No post-treatment radiological assessment
402-0018/48/M/A7	24JUN2013	08DEC2013	16SEP2013	.	2.6	
402-0019/54/M/A7	01JUL2013	06NOV2013	16SEP2013	.	2.6	
402-0021/64/M/A7	13AUG2013	.	07OCT2014	.	13.8	
402-0024/57/M/A7	27AUG2013	24DEC2013	05NOV2013	.	2.4	
402-0025/58/M/A7	25SEP2013	08JAN2015	19DEC2013	.	2.6	
402-0027/52/M/A7	04OCT2013	28NOV2013	21NOV2013	.	1.6	
402-0028/60/M/A7	04OCT2013	29JAN2014	.	26SEP2013	0+	No post-treatment radiological assessment
402-0031/65/M/A7	12NOV2013	.	29JAN2014	.	2.6	
402-0033/63/F/A7	06DEC2013	07APR2014	07FEB2014	.	1.8	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Time to Tumor Progression is calculated as (date of disease progression - date of randomization + 1) / 30. Censored records are indicated with +. For censoring rules, refer to Table 3 in the Statistical Analysis Plan.

Listing 16.2.6.6
Time to Tumor Progression
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
402-0035/44/M/A7	24DEC2013	02MAY2014	.	18DEC2013	0+	No post-treatment radiological assessment
403-0001/55/M/A7	22MAY2013	11SEP2013	03JUL2013	.	1.4	
403-0002/52/M/A7	11JUN2013	11OCT2013	22AUG2013	.	2.4	
403-0005/50/F/A7	16JUL2013	28OCT2013	02AUG2013	.	0.6	
403-0006/66/M/A7	29JUL2013	24MAR2014	23OCT2013	.	2.7	
403-0007/64/M/MIX	21AUG2013	05JAN2014	14NOV2013	.	2.6	
404-0001/71/M/A7	22JUL2013	11SEP2013	12AUG2013	.	0.7	
404-0002/56/F/A7	22AUG2013	01JUN2014	12SEP2013	.	0.7	
405-0002/46/M/A7	16APR2013	12MAY2013	.	03APR2013	0+	No post-treatment radiological assessment
405-0004/38/M/A7	24APR2013	21MAY2014	10JUL2013	.	2.6	
405-0006/62/M/A7	29APR2013	10JUN2013	.	23APR2013	0+	No post-treatment radiological assessment
405-0007/53/M/A7	07MAY2013	02AUG2014	.	23JUL2013	2.6+	No pression

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Time to Tumor Progression is calculated as (date of disease progression - date of randomization + 1) / 30. Censored records are indicated with +. For censoring rules, refer to Table 3 in the Statistical Analysis Plan.

Listing 16.2.6.6
Time to Tumor Progression
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
405-0009/50/M/A7	14MAY2013	19AUG2013	.	10JUN2013	0.9+	No pression
405-0010/39/M/A7	23MAY2013	.	07AUG2013	06AUG2013	2.5+	Lost to follow-up
405-0011/63/M/A7	13MAY2013	05JUN2014	21OCT2013	.	5.4	
405-0013/45/M/A7	20MAY2013	.	.	05AUG2013	2.6+	Lost to follow-up
405-0014/35/M/A7	31MAY2013	19JUL2013	03JUL2013	.	1	
405-0016/41/M/A7	27MAY2013	14JUL2013	25JUN2013	.	1	
405-0018/70/F/A7	12JUN2013	13JUL2013	03JUL2013	.	0.7	
405-0020/69/M/A7	19JUN2013	14OCT2014	14MAY2014	.	11	
405-0021/47/M/A7	19JUN2013	05OCT2014	07AUG2014	.	13.8	
405-0022/65/M/A7	04JUL2013	17MAR2014	18DEC2013	.	5.4	
405-0023/46/M/A7	17JUN2013	10DEC2013	09SEP2013	.	2.7	
405-0025/47/M/A7	26JUN2013	10DEC2013	24JUL2013	.	0.7	
405-0028/67/M/A7	24JUL2013	07DEC2013	07OCT2013	.	2.5	
405-0030/35/M/A7	31JUL2013	06NOV2013	25SEP2013	.	1.9	
405-0032/69/M/A7	23JUL2013	13FEB2015	15SEP2014	.	13.7	
405-0033/43/M/A7	08AUG2013	28APR2014	23OCT2013	.	2.6	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Time to Tumor Progression is calculated as (date of disease progression - date of randomization + 1) / 30. Censored records are indicated with +. For censoring rules, refer to Table 3 in the Statistical Analysis Plan.

Listing 16.2.6.6
Time to Tumor Progression
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
405-0034/61/M/A7	08AUG2013	07OCT2014	23OCT2013	.	2.6	
405-0035/66/M/A7	19AUG2013	.	16OCT2013	.	14	
405-0039/73/M/A7	13SEP2013	02JUN2014	03DEC2013	.	2.7	
405-0040/65/M/A7	23SEP2013	.	09DEC2013	.	2.6	
405-0042/53/M/A7	04OCT2013	26DEC2013	06DEC2013	.	1.8	
405-0043/49/M/A7	26SEP2013	20DEC2013	05DEC2013	.	2.4	
405-0044/56/M/A7	25SEP2013	05DEC2014	13NOV2013	.	1.7	
501-0001/59/M/A1	13NOV2013	26MAY2014	23JAN2014	.	2.4	
501-0002/36/F/A1	02DEC2013	16JAN2015	19FEB2014	.	2.7	
501-0005/80/M/A1	23JAN2014	.	03JUN2015	.	16.6	
501-0006/60/M/A1	13FEB2014	18NOV2014	28APR2014	.	2.5	
501-0007/43/M/A1	03MAR2014	27JUN2014	19MAY2014	.	2.6	
501-0008/76/F/A1	15APR2014	23MAY2015	02JUL2014	.	2.6	
501-0009/62/M/A1	18JUL2014	.	29SEP2014	.	2.5	
501-0010/65/M/A1	10SEP2014	26MAR2015	26NOV2014	.	2.6	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Time to Tumor Progression is calculated as (date of disease progression - date of randomization + 1) / 30. Censored records are indicated with +. For censoring rules, refer to Table 3 in the Statistical Analysis Plan.

Listing 16.2.6.6
Time to Tumor Progression
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
502-0002/65/M/A1	08JAN2014	19JAN2014	.	08JAN2014	0+	No post-treatment radiological assessment
503-0001/32/M/A1	09DEC2013	14FEB2014	03JAN2014	.	1	
503-0004/49/M/A1	11MAR2014	05APR2014	.	11MAR2014	0+	No post-treatment radiological assessment
503-0006/54/M/A1	06AUG2014	.	.	14JAN2015	5.4+	No pression
503-0007/57/M/A1	28OCT2014	.	12JAN2015	.	2.6	
503-0008/50/M/A1	30OCT2014	30APR2015	.	29OCT2014	0+	No post-treatment radiological assessment
503-0009/57/M/A1	19NOV2014	29NOV2014	.	18NOV2014	0+	No post-treatment radiological assessment
504-0001/47/M/A1	17FEB2014	27JUL2014	.	06MAY2014	2.6+	No pression
504-0007/32/M/A1	11OCT2014	31OCT2014	.	26SEP2014	0+	No post-treatment radiological assessment
505-0001/70/M/A1	12AUG2014	24JAN2015	28SEP2014	.	1.6	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Time to Tumor Progression is calculated as (date of disease progression - date of randomization + 1) / 30. Censored records are indicated with +. For censoring rules, refer to Table 3 in the Statistical Analysis Plan.

Listing 16.2.6.6
Time to Tumor Progression
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
506-0002/54/M/A1	12MAY2014	.	10APR2015	.	11.1	
506-0003/66/M/A1	10SEP2014	04APR2015	29OCT2014	.	1.6	
506-0004/49/M/A1	27OCT2014	15FEB2015	25DEC2014	.	2	
508-0001/36/M/A1	08JAN2014	.	11FEB2014	08FEB2014	1.1+	Lost to follow-up
508-0003/49/F/A1	17MAR2014	15APR2014	.	13MAR2014	0+	No post-treatment radiological assessment
509-0001/45/M/A1	30APR2014	06AUG2014	18JUL2014	.	2.7	
509-0002/51/M/A1	26MAY2014	.	.	.	0+	Lost to follow-up and no post-treatment radio
510-0002/50/M/A1	23MAY2014	13AUG2014	.	21MAY2014	0+	No post-treatment radiological assessment
510-0004/72/M/A1	01AUG2014	.	15OCT2014	.	2.5	
511-0001/35/M/A1	21JAN2014	25AUG2014	26FEB2014	.	1.2	
511-0002/49/M/A1	11MAR2014	.	20AUG2014	.	5.4	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Time to Tumor Progression is calculated as (date of disease progression - date of randomization + 1) / 30. Censored records are indicated with +. For censoring rules, refer to Table 3 in the Statistical Analysis Plan.

Listing 16.2.6.6
Time to Tumor Progression
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
512-0001/59/M/A1	04MAR2014	04SEP2014	.	24MAY2014	2.7+	No pression
513-0001/28/M/A1	09APR2014	21JUN2014	22MAY2014	26MAY2014	1.6+	New anticancer treatment started
513-0004/46/M/A1	18JUN2014	26JUL2014	16JUL2014	.	1	
513-0005/61/M/A1	31OCT2014	01MAR2015	20JAN2015	.	2.7	
515-0001/64/M/A1	20FEB2014	17JUL2014	07MAY2014	.	2.6	
515-0003/69/M/A1	13MAY2014	05APR2015	29JUL2014	.	2.6	
515-0004/52/M/A1	27MAY2014	19SEP2014	.	11AUG2014	2.6+	No pression
515-0006/47/M/A1	05AUG2014	.	20OCT2014	.	2.6	
515-0007/39/M/A1	17SEP2014	22NOV2014	.	12SEP2014	0+	No post-treatment radiological assessment
515-0008/60/M/A1	27NOV2014	12MAY2015	11FEB2015	.	2.6	
516-0001/45/M/A1	07AUG2014	.	16JAN2015	.	5.4	
517-0001/42/M/A1	23DEC2013	02MAR2014	20JAN2014	.	1.2	
517-0002/43/M/A1	26MAR2014	.	04SEP2014	.	5.4	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Time to Tumor Progression is calculated as (date of disease progression - date of randomization + 1) / 30. Censored records are indicated with +. For censoring rules, refer to Table 3 in the Statistical Analysis Plan.

Listing 16.2.6.6
Time to Tumor Progression
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
517-0005/46/M/MIX	04JUN2014	28JUL2014	.	23MAY2014	0+	No post-treatment radiological assessment
517-0006/67/F/A1	20AUG2014	.	23APR2015	.	8.2	
517-0007/66/M/A1	20AUG2014	15NOV2014	.	07AUG2014	0+	No post-treatment radiological assessment
517-0008/59/M/A1	22AUG2014	18JAN2015	.	18AUG2014	0+	No post-treatment radiological assessment
517-0009/23/M/A1	17SEP2014	31MAY2015	10DEC2014	.	2.8	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Time to Tumor Progression is calculated as (date of disease progression - date of randomization + 1) / 30. Censored records are indicated with +. For censoring rules, refer to Table 3 in the Statistical Analysis Plan.

Listing 16.2.6.6
Time to Tumor Progression
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
101-0002/70/M/OTH	29JUL2011	04JUN2012	18OCT2011	.	2.6	
101-0004/78/F/A2	05AUG2011	.	13JAN2012	.	13.8	
101-0010/43/M/BL	14SEP2011	27OCT2011	.	26AUG2011	0+	No post-treatment radiological assessment
101-0014/61/M/W2	06JAN2012	26OCT2012	.	16MAR2012	2.4+	No pression
101-0015/65/M/A4	06JAN2012	03JAN2013	22MAR2012	.	2.6	
101-0017/60/M/W2	21FEB2012	19JAN2013	01MAY2012	.	2.4	
101-0020/86/M/W2	12MAR2012	30DEC2012	21AUG2012	.	5.4	
101-0027/72/M/W2	22MAY2012	11AUG2012	.	30APR2012	0+	No post-treatment radiological assessment
101-0031/69/F/W2	17JUL2012	15NOV2012	29SEP2012	.	2.5	
101-0034/44/M/OTH	11SEP2012	04DEC2013	.	02NOV2012	1.8+	No pression
101-0035/37/M/A6	14SEP2012	25JAN2013	.	20AUG2012	0+	No post-treatment radiological assessment
101-0043/69/M/W1	22OCT2013	26MAY2014	.	02JAN2014	2.4+	No pression

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Time to Tumor Progression is calculated as (date of disease progression - date of randomization + 1) / 30. Censored records are indicated with +. For censoring rules, refer to Table 3 in the Statistical Analysis Plan.

Listing 16.2.6.6
Time to Tumor Progression
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
101-0051/70/F/W2	27JAN2014	23MAY2014	.	13JAN2014	0+	No post-treatment radiological assessment
102-0006/66/M/BL	11DEC2013	11OCT2014	23FEB2014	.	2.5	
102-0007/61/M/W2	02JAN2014	19MAY2014	.	19MAR2014	2.6+	No pression
103-0002/74/M/W2	12DEC2012	09FEB2015	20MAY2013	.	5.3	
103-0006/57/M/W2	19NOV2014	.	04FEB2015	.	2.6	
104-0002/80/M/W2	07MAY2012	27JUL2013	.	12JAN2013	8.4+	No pression
104-0007/89/M/A1	07AUG2013	.	.	05JUN2015	22.3+	No pression
105-0003/57/M/W2	05NOV2013	.	.	03OCT2014	11.1+	No pression
105-0006/60/F/BL	29DEC2014	.	18JUN2015	.	5.5	
108-0003/85/M/W2	19NOV2012	30NOV2013	31DEC2012	.	1.4	
109-0002/63/M/W2	22MAR2013	.	30AUG2013	.	5.4	
109-0005/64/F/W2	30JUL2013	08OCT2013	.	24JUL2013	0+	No post-treatment radiological assessment
109-0012/21/F/W2	25SEP2014	.	.	18NOV2014	1.8+	No pression

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Time to Tumor Progression is calculated as (date of disease progression - date of randomization + 1) / 30. Censored records are indicated with +. For censoring rules, refer to Table 3 in the Statistical Analysis Plan.

Listing 16.2.6.6
Time to Tumor Progression
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
109-0014/50/F/W2	26JAN2015	11APR2015	13MAR2015	.	1.6	
111-0003/37/M/A1	08JAN2013	19MAR2013	13MAR2013	.	2.2	
112-0010/56/F/W2	06DEC2013	26APR2014	21FEB2014	.	2.6	
113-0007/74/M/W2	30JAN2014	27JUL2014	.	02JUL2014	5.1+	No pression
113-0015/58/F/BL	26NOV2014	.	.	24OCT2014	0+	No post-treatment radiological assessment
114-0001/25/F/OTH	02AUG2012	05DEC2012	27SEP2014	.	1.9	
114-0004/54/F/A1	06FEB2013	09JUN2014	.	27MAR2013	1.7+	No pression
115-0005/60/M/W2	15MAR2013	16MAY2013	.	06MAR2013	0+	No post-treatment radiological assessment
115-0006/62/M/W2	11APR2013	31JUL2013	.	25JUN2013	2.5+	No pression
115-0007/57/M/W2	19APR2013	23JUN2013	16MAY2013	.	0.9	
115-0010/54/M/A4	14APR2014	21OCT2014	20JUN2014	.	2.3	
121-0003/65/M/BL	01JUL2014	12JAN2015	.	27AUG2014	1.9+	No pression
201-0002/76/M/W2	15MAR2012	02OCT2013	11FEB2013	.	11.1	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Time to Tumor Progression is calculated as (date of disease progression - date of randomization + 1) / 30. Censored records are indicated with +. For censoring rules, refer to Table 3 in the Statistical Analysis Plan.

Listing 16.2.6.6
Time to Tumor Progression
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
201-0006/71/M/W2	12JUL2012	10NOV2013	21DEC2012	.	5.4	
201-0007/71/M/W2	26JUL2012	14JUL2014	02APR2013	.	8.2	
201-0009/64/M/W2	20JUN2013	.	.	20APR2015	22.3+	No pression
201-0010/81/F/W2	27JUN2013	26JAN2014	13SEP2013	.	2.6	
201-0014/73/M/W2	17JUL2013	18MAR2014	04OCT2013	.	2.7	
201-0015/49/M/W2	08AUG2013	28OCT2014	17MAR2014	.	7.3	
201-0022/80/F/W2	09MAY2014	.	28OCT2014	.	5.7	
203-0004/81/M/W2	30MAR2012	09MAY2013	13DEC2012	.	8.6	
203-0006/76/M/W2	11APR2012	07JUL2012	.	30MAR2012	0+	No post-treatment radiological assessment
203-0007/59/M/W2	04JUN2012	02OCT2012	.	08MAY2012	0+	No post-treatment radiological assessment
203-0009/73/M/W2	13SEP2012	07JAN2015	31OCT2013	.	13.8	
203-0010/74/M/W2	26SEP2012	.	.	02OCT2014	24.6+	No pression

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Time to Tumor Progression is calculated as (date of disease progression - date of randomization + 1) / 30. Censored records are indicated with +. For censoring rules, refer to Table 3 in the Statistical Analysis Plan.

Listing 16.2.6.6
Time to Tumor Progression
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
203-0014/73/M/W2	23JAN2014	13OCT2014	.	10JAN2014	0+	No post-treatment radiological assessment
203-0016/57/M/W2	04FEB2014	22SEP2014	31JUL2014	.	5.9	
203-0019/68/M/W2	22MAY2014	18AUG2014	04JUL2014	.	1.5	
204-0003/64/M/W2	08JUL2013	08JAN2014	26SEP2013	.	2.8	
204-0004/76/F/W2	15SEP2013	25JUN2014	17DEC2013	.	3.1	
205-0002/71/M/W2	24FEB2012	14JUN2012	08MAY2012	.	2.5	
205-0003/79/M/W2	27MAR2012	18DEC2013	04DEC2012	.	8.4	
205-0005/71/M/W2	20MAR2012	09NOV2012	11JUN2012	.	2.6	
205-0014/70/M/W2	18JUN2013	02NOV2013	.	11JUN2013	0+	No post-treatment radiological assessment
205-0023/72/M/W2	08NOV2013	10JUN2014	30JAN2014	.	2.5	
205-0026/61/F/W2	09FEB2015	.	05MAY2015	.	2.6	
205-0028/73/F/W2	27JAN2015	15FEB2015	.	20JAN2015	0+	No post-treatment radiological assessment

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Time to Tumor Progression is calculated as (date of disease progression - date of randomization + 1) / 30. Censored records are indicated with +. For censoring rules, refer to Table 3 in the Statistical Analysis Plan.

Listing 16.2.6.6
Time to Tumor Progression
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
207-0002/71/M/W2	21MAR2012	02OCT2012	20JUN2012	.	2.6	
207-0007/71/M/W2	02JUL2012	04JAN2013	18SEP2012	.	2.6	
207-0012/66/M/W2	21MAR2013	12APR2014	19FEB2014	.	11.2	
207-0016/82/F/W2	10OCT2013	04OCT2014	.	03JAN2014	2.9+	No pression
207-0017/81/F/W2	22NOV2013	07MAR2014	19FEB2014	.	3	
207-0019/55/M/W2	03JUN2014	25JUL2014	.	09MAY2014	0+	No post-treatment radiological assessment
209-0006/68/M/W2	02MAY2013	16JUL2014	08JAN2014	.	8.4	
209-0011/69/M/W2	03DEC2013	.	17FEB2014	.	2.6	
209-0014/79/M/W2	17MAR2014	.	01SEP2014	.	5.4	
210-0003/74/M/W2	04NOV2013	18JUL2014	.	21OCT2013	0+	No post-treatment radiological assessment
210-0004/71/M/W2	08JAN2014	22AUG2014	28MAR2014	.	2.6	
210-0005/53/M/W2	20FEB2014	23DEC2014	07MAY2014	.	2.6	
210-0006/45/M/W2	23JUN2014	26NOV2014	29SEP2014	.	2.9	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Time to Tumor Progression is calculated as (date of disease progression - date of randomization + 1) / 30. Censored records are indicated with +. For censoring rules, refer to Table 3 in the Statistical Analysis Plan.

Listing 16.2.6.6
Time to Tumor Progression
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
251-0002/69/M/W2	07AUG2013	20NOV2013	16OCT2013	.	2.4	
251-0003/68/M/W2	05NOV2013	26NOV2014	15APR2014	.	5.4	
252-0001/65/M/A3	08MAY2012	23DEC2012	.	01MAY2012	0+	No post-treatment radiological assessment
252-0004/50/M/A1	28MAY2013	06SEP2013	25JUL2013	.	2	
252-0006/64/M/W2	01OCT2013	23APR2015	.	11MAR2014	5.4+	No pression
252-0008/76/M/W2	27MAY2014	07MAR2015	12AUG2014	.	2.6	
252-0010/56/F/W2	04NOV2014	31MAR2015	20JAN2015	.	2.6	
253-0003/75/M/W2	15JUN2012	30SEP2013	13FEB2013	.	8.1	
253-0004/79/M/W2	07SEP2012	16MAR2013	19NOV2012	.	2.5	
253-0005/74/F/W2	02NOV2012	08MAR2013	.	15OCT2012	0+	No post-treatment radiological assessment
253-0006/63/M/A3	28DEC2012	09SEP2014	17MAY2013	.	4.7	
253-0011/67/M/W2	06OCT2014	.	.	08JUN2015	8.2+	No pression

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Time to Tumor Progression is calculated as (date of disease progression - date of randomization + 1) / 30. Censored records are indicated with +. For censoring rules, refer to Table 3 in the Statistical Analysis Plan.

Listing 16.2.6.6
Time to Tumor Progression
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
253-0012/67/M/W2	08DEC2014	20JAN2015	.	12NOV2014	0+	No post-treatment radiological assessment
257-0005/66/M/W2	03JAN2013	19MAY2013	21MAR2013	.	2.5	
257-0013/63/M/W2	30MAY2013	07AUG2013	.	02MAY2013	0+	No post-treatment radiological assessment
257-0020/72/M/A1	27OCT2014	21JAN2015	22NOV2014	.	0.8	
258-0002/69/F/W2	11APR2013	21JUL2014	11DEC2013	.	8.2	
258-0003/67/F/W2	15MAY2013	.	28OCT2013	.	5.4	
258-0004/65/M/W2	21MAY2013	23JUN2013	.	09MAY2013	0+	No post-treatment radiological assessment
258-0006/69/M/W2	15OCT2013	07DEC2013	.	02OCT2013	0+	No post-treatment radiological assessment
258-0013/59/M/W2	11NOV2014	21MAR2015	28JAN2015	.	2.6	
259-0003/73/M/W2	11JUN2014	10JUL2015	.	29APR2015	10.8+	No pression

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Time to Tumor Progression is calculated as (date of disease progression - date of randomization + 1) / 30. Censored records are indicated with +. For censoring rules, refer to Table 3 in the Statistical Analysis Plan.

Listing 16.2.6.6
Time to Tumor Progression
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
259-0004/52/M/W2	21JUL2014	31DEC2014	.	16JUL2014	0+	No post-treatment radiological assessment
260-0002/66/M/W2	02OCT2013	24JUL2014	20NOV2013	.	1.5	
301-0001/47/F/A2	01NOV2011	18APR2013	19JAN2012	.	2.6	
301-0003/61/F/A2	01MAR2012	28AUG2012	24MAY2012	.	2.6	
301-0008/53/M/A2	04JAN2013	22MAY2013	23MAR2013	.	2.6	
302-0006/49/M/A2	10JAN2012	24MAR2012	.	04JAN2012	0+	No post-treatment radiological assessment
302-0009/73/M/A2	17APR2012	04JUL2012	.	03APR2012	0+	No post-treatment radiological assessment
302-0012/62/M/A2	24APR2012	11OCT2012	19JUL2012	.	2.7	
302-0013/62/M/A2	26MAR2013	14DEC2013	.	21MAR2013	0+	No post-treatment radiological assessment
302-0020/52/M/A2	21MAY2013	26NOV2013	.	16MAY2013	0+	No post-treatment radiological assessment

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Time to Tumor Progression is calculated as (date of disease progression - date of randomization + 1) / 30. Censored records are indicated with +. For censoring rules, refer to Table 3 in the Statistical Analysis Plan.

Listing 16.2.6.6
Time to Tumor Progression
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
302-0021/75/F/A2	11JUN2013	14FEB2014	25NOV2013	.	5.4	
304-0003/56/F/A2	14MAR2013	.	05JUN2013	.	2.7	
304-0004/69/M/A2	03JUN2013	25SEP2013	.	30MAY2013	0+	No post-treatment radiological assessment
304-0007/72/M/A2	13NOV2013	28SEP2014	29JAN2014	.	2.6	
305-0001/79/M/A2	14FEB2012	03JUL2012	.	03FEB2012	0+	No post-treatment radiological assessment
305-0004/79/M/A2	24FEB2012	03JUL2012	.	07MAY2012	2.5+	No pression
305-0007/67/M/A2	09MAR2012	08NOV2013	24AUG2012	.	5.6	
305-0015/84/M/A2	06JUL2012	28NOV2012	20SEP2012	.	2.5	
305-0016/78/M/A2	10JUL2012	12NOV2012	25SEP2012	.	2.6	
305-0021/83/F/A2	22NOV2012	23MAR2013	15FEB2013	.	2.6	
305-0024/68/M/A2	15JAN2013	08AUG2013	12APR2013	.	2.9	
305-0033/37/F/A2	02JUL2013	19JUL2014	24SEP2013	.	2.8	
305-0035/60/M/A2	28AUG2013	29SEP2014	12FEB2014	.	5.6	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Time to Tumor Progression is calculated as (date of disease progression - date of randomization + 1) / 30. Censored records are indicated with +. For censoring rules, refer to Table 3 in the Statistical Analysis Plan.

Listing 16.2.6.6
Time to Tumor Progression
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
305-0046/60/M/A2	07NOV2014	.	23APR2015	.	5.3	
306-0004/46/M/A2	21FEB2012	07APR2012	06APR2012	.	1.4	
306-0010/69/M/A2	21MAR2012	30MAR2013	12JUN2012	.	2.6	
306-0013/42/M/A2	16APR2012	18JUN2012	.	13APR2012	0+	No post-treatment radiological assessment
306-0015/73/M/A2	17MAY2012	14MAY2013	02JUL2012	.	1.4	
306-0016/58/M/A2	25JUN2012	21SEP2013	17SEP2012	.	2.6	
306-0022/56/M/A2	13NOV2012	03FEB2014	30APR2013	.	5.5	
306-0028/53/M/A2	28MAR2013	23DEC2013	19JUN2013	13JUN2013	2.6+	No pression
306-0045/60/F/A1	20JUN2014	12JUN2015	09SEP2014	.	2.5	
307-0006/72/M/A2	29NOV2011	23DEC2011	.	08NOV2011	0+	No post-treatment radiological assessment
307-0009/53/M/A2	03JAN2012	29MAR2012	.	28DEC2011	0+	No post-treatment radiological assessment

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Time to Tumor Progression is calculated as (date of disease progression - date of randomization + 1) / 30. Censored records are indicated with +. For censoring rules, refer to Table 3 in the Statistical Analysis Plan.

Listing 16.2.6.6
Time to Tumor Progression
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
307-0012/42/M/A2	07FEB2012	10APR2012	.	03FEB2012	0+	No post-treatment radiological assessment
307-0015/75/M/A2	25APR2012	05MAR2013	05OCT2012	.	5.4	
307-0021/68/M/A2	21AUG2012	10FEB2013	.	08NOV2012	2.7+	No pression
307-0028/69/F/A2	14JAN2013	15JUN2013	08APR2013	.	2.6	
307-0034/48/M/A2	13AUG2013	04FEB2014	31OCT2013	.	2.6	
307-0036/76/M/A2	02OCT2013	30JUN2014	19DEC2013	.	2.6	
307-0042/55/M/A2	19JUN2014	.	27NOV2014	.	5.4	
308-0002/36/F/A2	31DEC2012	16FEB2014	26MAR2013	.	2.7	
308-0004/52/M/A2	05FEB2013	07APR2015	25APR2013	.	2.7	
308-0006/64/M/A2	14MAY2013	14NOV2014	27JUN2013	.	1.5	
308-0008/47/M/A2	23JUL2013	26DEC2013	08OCT2013	.	2.5	
308-0009/61/M/A2	19JUL2013	12SEP2013	.	27JUN2013	0+	No post-treatment radiological assessment
309-0006/56/M/A2	26NOV2012	24MAY2015	29JUL2013	.	8	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Time to Tumor Progression is calculated as (date of disease progression - date of randomization + 1) / 30. Censored records are indicated with +. For censoring rules, refer to Table 3 in the Statistical Analysis Plan.

Listing 16.2.6.6
Time to Tumor Progression
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
309-0007/58/M/A2	17DEC2012	12JUN2013	04MAR2013	.	2.4	
309-0013/45/M/A2	20JUN2013	17NOV2014	05SEP2013	.	2.4	
309-0014/39/M/A2	20JUN2013	18JAN2014	05SEP2013	.	2.4	
309-0019/68/M/A2	24JUN2014	.	.	12MAY2015	10.8+	No pression
309-0027/49/M/A2	03NOV2014	12JUN2015	19JAN2015	.	2.4	
309-0029/50/M/A2	01DEC2014	09APR2015	10FEB2015	.	2.4	
310-0004/50/F/A2	06FEB2013	01AUG2013	24APR2013	.	2.4	
310-0005/58/M/A2	27MAR2013	07DEC2013	10JUN2013	.	2.4	
310-0006/50/F/A2	01MAY2013	05OCT2014	27DEC2013	.	7.9	
310-0007/74/M/A2	13JUN2013	.	06MAY2014	.	10.8	
310-0009/46/M/A2	07AUG2013	10JAN2014	27SEP2013	.	1.7	
310-0010/34/F/A2	26AUG2013	11DEC2013	26SEP2013	.	1	
310-0011/52/M/A2	24OCT2013	.	08JAN2014	.	2.4	
310-0014/64/M/A2	24SEP2014	16JUN2015	03DEC2014	.	2.4	
311-0003/44/M/A2	25SEP2013	22NOV2014	11DEC2013	.	2.6	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Time to Tumor Progression is calculated as (date of disease progression - date of randomization + 1) / 30. Censored records are indicated with +. For censoring rules, refer to Table 3 in the Statistical Analysis Plan.

Listing 16.2.6.6
Time to Tumor Progression
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
311-0004/68/M/A2	30SEP2013	16NOV2013	.	26SEP2013	0+	No post-treatment radiological assessment
311-0005/58/M/A2	21OCT2013	03AUG2014	30DEC2013	.	2.4	
311-0006/73/F/A2	07NOV2013	16MAR2014	16JAN2014	.	2.4	
311-0009/51/F/A2	15JUL2014	.	30SEP2014	.	2.6	
311-0010/47/M/A2	02SEP2014	.	.	07MAY2015	8.3+	No pression
311-0011/46/M/A2	30OCT2014	.	31DEC2014	.	2.1	
311-0012/55/M/A2	29JAN2015	.	.	16APR2015	2.6+	No pression
401-0001/70/M/A7	04JUN2013	18AUG2013	.	03JUN2013	0+	No post-treatment radiological assessment
401-0002/55/M/A7	19JUN2013	21FEB2014	.	12JUN2013	0+	No post-treatment radiological assessment
402-0001/35/M/A7	22APR2013	03AUG2013	24JUN2013	.	1.7	
402-0002/58/M/A7	23APR2013	08MAY2014	09JUL2013	.	2.6	
402-0005/70/M/A7	09MAY2013	02OCT2013	01AUG2013	.	2.5	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Time to Tumor Progression is calculated as (date of disease progression - date of randomization + 1) / 30. Censored records are indicated with +. For censoring rules, refer to Table 3 in the Statistical Analysis Plan.

Listing 16.2.6.6
Time to Tumor Progression
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
402-0010/50/M/A7	20MAY2013	13JUL2013	08JUL2013	.	1.5	
402-0022/60/F/A7	19AUG2013	03MAR2014	18NOV2013	.	2.8	
402-0023/57/M/A7	02SEP2013	29DEC2013	26NOV2013	.	2.6	
402-0029/49/M/A7	11NOV2013	04JAN2014	06JAN2014	.	1.7	
402-0032/49/F/A7	06DEC2013	19JUN2014	27FEB2014	.	2.6	
402-0034/43/F/A7	19DEC2013	.	05JUN2014	.	5.4	
403-0004/37/M/A7	11JUL2013	01MAY2015	01OCT2013	.	2.6	
404-0003/53/M/A7	10SEP2013	20OCT2013	30SEP2013	.	0.7	
404-0004/61/F/A7	15OCT2013	25DEC2013	02DEC2013	.	1.6	
405-0001/55/M/A7	22APR2013	15MAR2014	10JUL2013	.	2.7	
405-0005/35/M/A6	24APR2013	01MAY2015	23DEC2013	.	8.1	
405-0012/72/M/A7	15MAY2013	02DEC2013	21OCT2013	.	5.3	
405-0019/61/M/A7	26JUN2013	11AUG2013	.	18JUN2013	0+	No post-treatment radiological assessment

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Time to Tumor Progression is calculated as (date of disease progression - date of randomization + 1) / 30. Censored records are indicated with +. For censoring rules, refer to Table 3 in the Statistical Analysis Plan.

Listing 16.2.6.6
Time to Tumor Progression
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
405-0024/69/M/A7	03JUL2013	05AUG2013	.	21JUN2013	0+	No post-treatment radiological assessment
405-0026/67/M/A7	08JUL2013	13FEB2014	25SEP2013	.	2.7	
405-0036/70/M/A7	19AUG2013	15JAN2014	12NOV2013	.	2.9	
405-0041/57/M/A7	13SEP2013	.	02MAY2014	.	7.7	
501-0003/22/M/A1	11DEC2013	01JUL2014	25FEB2014	.	2.6	
501-0004/26/M/A1	18DEC2013	31JUL2014	05MAR2014	.	2.6	
501-0011/61/M/A1	25SEP2014	07JAN2015	12DEC2014	.	2.6	
502-0001/70/M/A1	13DEC2013	14JAN2014	.	13DEC2013	0+	No post-treatment radiological assessment
502-0003/48/M/A1	14JAN2014	10JUL2014	10APR2014	.	2.9	
503-0002/71/F/A1	20FEB2014	20APR2015	22OCT2014	.	8.4	
503-0003/47/F/A1	07MAR2014	01JUN2014	.	07MAR2014	0+	No post-treatment radiological assessment
503-0005/72/M/A1	25MAR2014	.	02MAR2015	.	11.4	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Time to Tumor Progression is calculated as (date of disease progression - date of randomization + 1) / 30. Censored records are indicated with +. For censoring rules, refer to Table 3 in the Statistical Analysis Plan.

Listing 16.2.6.6
Time to Tumor Progression
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
504-0003/53/M/A1	13MAR2014	16MAY2014	14APR2014	.	1	
504-0005/41/F/A1	03SEP2014	08NOV2014	.	02SEP2014	0+	No post-treatment radiological assessment
504-0006/51/M/A1	04SEP2014	13MAR2015	.	04SEP2014	0+	No post-treatment radiological assessment
506-0001/43/M/A1	15APR2014	29JUL2014	.	01APR2014	0+	No post-treatment radiological assessment
506-0005/24/M/A1	22DEC2014	20JAN2015	.	16DEC2014	0+	No post-treatment radiological assessment
507-0001/51/M/A1	24JUL2014	.	14OCT2014	.	2.8	
507-0002/44/M/A1	29JUL2014	10NOV2014	17SEP2014	.	1.7	
508-0002/64/M/A1	19FEB2014	15APR2014	.	14FEB2014	0+	No post-treatment radiological assessment

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Time to Tumor Progression is calculated as (date of disease progression - date of randomization + 1) / 30. Censored records are indicated with +. For censoring rules, refer to Table 3 in the Statistical Analysis Plan.

Listing 16.2.6.6
Time to Tumor Progression
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Date of Randomization	Date of Death	Date of Disease Progression	Date of last radiological assessment of measured lesions	Duration[3] (Months)	If Censored, Reason
508-0004/58/M/A1	27AUG2014	.	.	.	0+	Lost to follow-up and no post-treatment radio
509-0003/39/M/A1	24JUL2014	01JAN2015	09OCT2014	.	2.8	
510-0001/67/M/A1	26FEB2014	.	08DEC2014	.	9.5	
510-0003/43/M/A1	05JUN2014	20NOV2014	14AUG2014	.	2.4	
513-0003/46/M/A1	30APR2014	12JUN2014	.	24APR2014	0+	No post-treatment radiological assessment
515-0005/45/M/A1	23JUN2014	04OCT2014	09SEP2014	.	2.6	
517-0003/45/M/A1	14MAY2014	.	01AUG2014	01AUG2014	2.7+	Lost to follow-up
517-0010/67/M/A1	12NOV2014	24MAR2015	02FEB2015	.	2.8	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Time to Tumor Progression is calculated as (date of disease progression - date of randomization + 1) / 30. Censored records are indicated with +. For censoring rules, refer to Table 3 in the Statistical Analysis Plan.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
101-0001/59/M/A2	SCREENING	15JUL2011	16:48	1.3	ng/ml	.	Stable
	WEEK 2	02AUG2011	09:24	1.3	ng/ml	0	
	WEEK 4	16AUG2011	14:39	1.2	ng/ml	7.69	
	WEEK 8	16SEP2011	10:34	1.5	ng/ml	-15.38	
	WEEK 12	14OCT2011	12:43	1.5	ng/ml	-15.38	
	WEEK 16	11NOV2011	15:24	1.3	ng/ml	0	
	WEEK 24	06JAN2012	15:36	1.3	ng/ml	0	
	END OF TREATMENT	30JAN2012	10:30	1.4	ng/ml	-7.69	
	Minimum Post-baseline	16AUG2011	14:39	1.2	ng/ml	7.69	
101-0005/77/M/W2	SCREENING	02AUG2011	09:45	87.9	ng/ml	.	Rise

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
101-0005/77/M/W2	WEEK 8	27SEP2011	12:23	101.1	ng/ml	-15.02	
	WEEK 12	25OCT2011	14:11	119.5	ng/ml	-35.95	
	END OF TREATMENT	11NOV2011	13:22	152.3	ng/ml	-73.27	
	Minimum Post-baseline	27SEP2011	12:23	101.1	ng/ml	-15.02	
101-0006/62/M/W2	SCREENING	05AUG2011	08:24	19.2	ng/ml	.	Decline
	WEEK 8	30SEP2011	08:17	11.2	ng/ml	41.67	
	END OF TREATMENT	01NOV2011	08:40	7.3	ng/ml	61.98	
	Minimum Post-baseline	01NOV2011	08:40	7.3	ng/ml	61.98	
101-0007/77/M/A1	SCREENING	19AUG2011	13:06	38.5	ng/ml	.	Stable
	WEEK 4	13SEP2011	10:32	23.3	ng/ml	39.48	

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[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
101-0007/77/M/A1	WEEK 8	11OCT2011	11:13	26.1	ng/ml	32.21	
	WEEK 12	08NOV2011	15:27	44.4	ng/ml	-15.32	
	END OF TREATMENT	09DEC2011	11:31	44.1	ng/ml	-14.55	
	Minimum Post-baseline	13SEP2011	10:32	23.3	ng/ml	39.48	
101-0008/83/M/BL	SCREENING	12AUG2011	16:21	85.6	ng/ml	.	Stable
	WEEK 4	20SEP2011	08:38	52.6	ng/ml	38.55	
	WEEK 8	18OCT2011	15:23	65.1	ng/ml	23.95	
	WEEK 12	15NOV2011	14:52	64.8	ng/ml	24.3	
	END OF TREATMENT	16DEC2011	15:23	67.2	ng/ml	21.5	
	Minimum Post-baseline	20SEP2011	08:38	52.6	ng/ml	38.55	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
101-0009/82/M/A1	SCREENING	30SEP2011	13:15	50615.3	ng/ml	.	Rise
	WEEK 4	25OCT2011	15:51	150714.6	ng/ml	-197.76	
	WEEK 8	22NOV2011	14:13	307548.5	ng/ml	-507.62	
	WEEK 12	20DEC2011	14:49	537400	ng/ml	-961.73	
	Minimum Post-baseline	25OCT2011	15:51	150714.6	ng/ml	-197.76	
101-0011/75/F/W2	SCREENING	11NOV2011	10:53	757.1	ng/ml	.	Stable
101-0012/68/M/W2	SCREENING	22NOV2011	11:08	5.8	ng/ml	.	Stable
	WEEK 4	20DEC2011	11:17	5.5	ng/ml	5.17	
	WEEK 8	17JAN2012	09:33	7.2	ng/ml	-24.14	
	END OF TREATMENT	28FEB2012	10:27	4.8	ng/ml	17.24	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
101-0012/68/M/W2	Minimum Post-baseline	28FEB2012	10:27	4.8	ng/ml	17.24	
101-0013/66/F/A5	SCREENING	03JAN2012	10:38	1060.8	ng/ml	.	Rise
	WEEK 4	31JAN2012	09:57	1313.3	ng/ml	-23.8	
	WEEK 8	28FEB2012	11:08	4237.5	ng/ml	-299.46	
	WEEK 12	27MAR2012	10:17	6588.5	ng/ml	-521.09	
	WEEK 16	24APR2012	14:57	10418.3	ng/ml	-882.12	
	END OF TREATMENT	08JUN2012	10:15	12562	ng/ml	-1084.2	
	Minimum Post-baseline	31JAN2012	09:57	1313.3	ng/ml	-23.8	
101-0016/61/M/A4	SCREENING	10JAN2012	12:09	2.4	ng/ml	.	Stable
	WEEK 4	07FEB2012	10:22	2.4	ng/ml	0	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
101-0016/61/M/A4	WEEK 8	06MAR2012	15:55	2.6	ng/ml	-8.33	
	WEEK 12	06APR2012	15:45	2.4	ng/ml	0	
	WEEK 16	04MAY2012	07:38	2.1	ng/ml	12.5	
	WEEK 20	29MAY2012	12:58	2.2	ng/ml	8.33	
	WEEK 24	26JUN2012	09:42	2.1	ng/ml	12.5	
	WEEK 28	24JUL2012	12:02	1.9	ng/ml	20.83	
	WEEK 32	21AUG2012	07:56	2.1	ng/ml	12.5	
	Minimum Post-baseline	24JUL2012	12:02	1.9	ng/ml	20.83	
101-0018/51/M/A1	SCREENING	16FEB2012	14:14	6307.5	ng/ml	.	Stable
101-0019/68/M/W2	SCREENING	21FEB2012	11:52	43715.7	NG/ML	.	Decline

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
101-0019/68/M/W2	WEEK 4	20MAR2012	10:43	36161	NG/ML	17.28	
	WEEK 8	17APR2012	11:38	56993.2	ng/ml	-30.37	
	WEEK 12	15MAY2012	15:26	100855.5	ng/ml	-130.71	
	END OF TREATMENT	05JUL2012	09:30	10579.7	ng/ml	75.8	
	Minimum Post-baseline	05JUL2012	09:30	10579.7	ng/ml	75.8	
101-0021/74/M/W2	SCREENING	20MAR2012	07:54	3.9	ng/ml	.	Stable
	WEEK 4	10APR2012	14:24	4.9	ng/ml	-25.64	
	WEEK 8	08MAY2012	10:43	4	ng/ml	-2.56	
	WEEK 12	05JUN2012	08:58	2.8	ng/ml	28.21	
	Minimum Post-baseline	05JUN2012	08:58	2.8	ng/ml	28.21	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
101-0022/55/M/BL	SCREENING	20MAR2012	12:15	9269.3	ng/ml	.	Rise
	WEEK 4	10APR2012	18:18	11719	ng/ml	-26.43	
	END OF TREATMENT	04MAY2012	17:28	24617	ng/ml	-165.58	
	Minimum Post-baseline	10APR2012	18:18	11719	ng/ml	-26.43	
101-0023/70/M/W2	SCREENING	30MAR2012	10:38	879.3	ng/ml	.	Rise
	WEEK 4	20APR2012	07:51	1144.9	ng/ml	-30.21	
	WEEK 8	18MAY2012	08:21	2123.9	ng/ml	-141.54	
	WEEK 12	15JUN2012	08:13	4310.7	ng/dl	-390.24	
	END OF TREATMENT	07SEP2012	09:13	11722.9	ng/ml	-1233.21	
	Minimum Post-baseline	20APR2012	07:51	1144.9	ng/ml	-30.21	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
101-0024/35/F/A4	SCREENING	01MAY2012	16:02	3349.1	ng/ml	.	Rise
	WEEK 4	22MAY2012	11:42	5596.2	NG/ML	-67.1	
	WEEK 8	19JUN2012	15:21	9541.6	ng/ml	-184.9	
	WEEK 12	17JUL2012	14:59	18615.8	ng/ml	-455.84	
	Minimum Post-baseline	22MAY2012	11:42	5596.2	NG/ML	-67.1	
101-0025/57/F/W2	SCREENING	20APR2012	12:01	7798.3	ng/ml	.	Rise
	WEEK 4	11MAY2012	08:36	8428.6	ng/ml	-8.08	
	WEEK 8	08JUN2012	13:09	15341.4	ng/ml	-96.73	
	Minimum Post-baseline	11MAY2012	08:36	8428.6	ng/ml	-8.08	
101-0026/82/M/W2	SCREENING	15MAY2012	09:31	19.4	ng/ml	.	Rise

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
101-0026/82/M/W2	WEEK 4	05JUN2012	15:40	20	ng/ml	-3.09	
	WEEK 8	05JUL2012	11:10	21.2	ng/ml	-9.28	
	WEEK 12	03AUG2012	14:55	27.5	ng/ml	-41.75	
	WEEK 16	31AUG2012	14:20	30	ng/ml	-54.64	
	WEEK 20	28SEP2012	15:55	38.5	NG/ML	-98.45	
	WEEK 24	23OCT2012	11:23	64.3	NG/ML	-231.44	
	WEEK 28	23NOV2012	10:32	244.2	NG/ML	-1158.76	
	WEEK 32	18DEC2012	09:41	908.9	NG/ML	-4585.05	
	Minimum Post-baseline	05JUN2012	15:40	20	ng/ml	-3.09	
101-0028/60/M/W2	SCREENING	15JUN2012	09:37	4375.3	ng/ml	.	Stable

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
101-0028/60/M/W2	WEEK 4	03JUL2012	07:59	4253.4	ng/ml	2.79	
	WEEK 8	31JUL2012	07:38	5878.7	ng/ml	-34.36	
	WEEK 12	28AUG2012	07:42	4667.1	ng/ml	-6.67	
	Minimum Post-baseline	03JUL2012	07:59	4253.4	ng/ml	2.79	
101-0029/70/M/A1	SCREENING	15JUN2012	10:31	257.4	ng/ml	.	Rise
	WEEK 4	10JUL2012	10:23	164.4	ng/ml	36.13	
	WEEK 8	07AUG2012	10:34	284.7	ng/ml	-10.61	
	UNSCHEDULED	04SEP2012	15:36	397	NG/ML	-54.23	
	END OF TREATMENT	04OCT2012	07:56	594.4	ng/mL	-130.92	
	Minimum Post-baseline	10JUL2012	10:23	164.4	ng/ml	36.13	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
101-0030/51/M/W2	SCREENING	05JUL2012	09:38	2594.9	ng/ml	.	Rise
	WEEK 4	24JUL2012	08:39	3276.4	ng/ml	-26.26	
	END OF TREATMENT	07SEP2012	09:35	6154.2	ng/ml	-137.17	
	Minimum Post-baseline	24JUL2012	08:39	3276.4	ng/ml	-26.26	
101-0032/84/M/W2	SCREENING	17JUL2012	10:50	1.4	ng/ml	.	Rise
	WEEK 4	21AUG2012	11:49	1.2	ng/ml	14.29	
	WEEK 7	14SEP2012	10:51	2.3	ng/dl	-64.29	
	WEEK 8	21SEP2012	09:29	1.7	NG/ML	-21.43	
	Minimum Post-baseline	21AUG2012	11:49	1.2	ng/ml	14.29	
101-0033/66/F/W2	SCREENING	03AUG2012	11:57	1175.2	NG/ML	.	Stable

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
101-0033/66/F/W2	WEEK 4	24AUG2012	10:21	1317.8	ng/ml	-12.13	
	WEEK 8	21SEP2012	10:22	1426.4	ng/ml	-21.38	
	WEEK 12	16OCT2012	11:03	1188	ng/ml	-1.09	
	WEEK 16	16NOV2012	10:55	1645.8	NG/ML	-40.04	
	WEEK 20	14DEC2012	07:48	1647.2	NG/ML	-40.16	
	Minimum Post-baseline	16OCT2012	11:03	1188	ng/ml	-1.09	
101-0036/67/M/A4	SCREENING	Unknown		.		.	
	WEEK 4	27NOV2012	13:51	170863.8	ng/mL	.	
	WEEK 6	11DEC2012	14:04	175743.8	NG/ML	.	
	END OF TREATMENT	04JAN2013	08:47	199693.9	NG/ML	.	

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
101-0036/67/M/A4	Minimum Post-baseline	27NOV2012	13:51	170863.8	ng/mL	.	
101-0037/57/M/A1	SCREENING	04DEC2012	10:17	156.2	NG/ML	.	Stable
	WEEK 4	28DEC2012	09:26	231.5	NG/ML	-48.21	
	Minimum Post-baseline	28DEC2012	09:26	231.5	NG/ML	-48.21	
101-0038/56/M/W2	SCREENING	05FEB2013	07:56	22.5	ng/ml	.	Decline
	WEEK 4	01MAR2013	11:12	3.9	ng/ml	82.67	
	END OF TREATMENT	14MAY2013	14:21	2.7	ng/ml	88	
	Minimum Post-baseline	14MAY2013	14:21	2.7	ng/ml	88	
101-0039/77/F/W2	SCREENING	05APR2013	12:07	46.1	ng/ml	.	Rise
	WEEK 4	26APR2013	08:38	58.7	ng/ml	-27.33	

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
101-0039/77/F/W2	WEEK 8	24MAY2013	11:21	65.9	ng/ml	-42.95	
	WEEK 12	21JUN2013	08:44	66.6	ng/ml	-44.47	
	WEEK 16	16JUL2013	08:41	49	ng/ml	-6.29	
	WEEK 20	13AUG2013	10:51	61.4	ng/ml	-33.19	
	WEEK 24	10SEP2013	07:36	110.6	ng/ml	-139.91	
	WEEK 28	08OCT2013	07:16	74.4	ng/ml	-61.39	
	WEEK 32	04NOV2013	07:43	90.6	ng/ml	-96.53	
	WEEK 36	02DEC2013	07:31	133.6	ng/ml	-189.8	
	END OF TREATMENT	30DEC2013	07:34	102	ng/ml	-121.26	
	Minimum Post-baseline	16JUL2013	08:41	49	ng/ml	-6.29	

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[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
101-0040/60/M/W2	SCREENING	18JUN2013	09:26	53.7	ng/ml	.	Rise
	WEEK 4	22JUL2013	08:40	218.3	ng/ml	-306.52	
	END OF TREATMENT	09SEP2013	11:22	654.5	ng/ml	-1118.81	
	Minimum Post-baseline	22JUL2013	08:40	218.3	ng/ml	-306.52	
101-0041/54/M/W2	SCREENING	30JUL2013	07:27	61.7	ng/ml	.	Stable
	END OF TREATMENT	10SEP2013	11:31	64.5	ng/ml	-4.54	
	Minimum Post-baseline	10SEP2013	11:31	64.5	ng/ml	-4.54	
101-0042/64/M/W2	SCREENING	05AUG2013	14:23	55	ng/ml	.	Stable
	WEEK 4	27AUG2013	16:02	60	ng/ml	-9.09	
	WEEK 8	23SEP2013	14:50	42	ng/ml	23.64	

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[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
101-0042/64/M/W2	Minimum Post-baseline	23SEP2013	14:50	42	ng/ml	23.64	
101-0044/78/M/W2	SCREENING	11OCT2013	08:20	816.8	ng/ml	.	Decline
	WEEK 4	08NOV2013	07:15	1247.4	ng/ml	-52.72	
	WEEK 8	06DEC2013	07:30	1265.8	ng/ml	-54.97	
	WEEK 12	03JAN2014	08:58	1780.2	ng/ml	-117.95	
	END OF TREATMENT	31JAN2014	11:46	217.6	ng/ml	73.36	
	Minimum Post-baseline	31JAN2014	11:46	217.6	ng/ml	73.36	
101-0045/74/F/W2	SCREENING	21OCT2013	07:33	2078.1	ng/ml	.	Rise
	WEEK 4	26NOV2013	07:41	2818	ng/ml	-35.6	
	WEEK 8	23DEC2013	07:48	4710	ng/ml	-126.65	

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
101-0045/74/F/W2	WEEK 12	21JAN2014	10:49	7803.9	ng/ml	-275.53	
	Minimum Post-baseline	26NOV2013	07:41	2818	ng/ml	-35.6	
101-0046/70/M/OTH	SCREENING	21OCT2013	10:20	14.4	ng/ml	.	Rise
	WEEK 4	12NOV2013	08:04	18.4	ng/ml	-27.78	
	WEEK 8	10DEC2013	07:31	17.5	ng/ml	-21.53	
	WEEK 12	07JAN2014	07:28	28	ng/ml	-94.44	
	END OF TREATMENT	04FEB2014	07:25	35.4	ng/ml	-145.83	
	Minimum Post-baseline	10DEC2013	07:31	17.5	ng/ml	-21.53	
101-0047/52/M/W2	SCREENING	21OCT2013	12:21	176.2	ng/ml	.	Rise
	WEEK 4	11NOV2013	08:02	537.8	ng/ml	-205.22	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
101-0047/52/M/W2	WEEK 8	09DEC2013	07:45	1327.1	ng/ml	-653.18	
	UNSCHEDULED	06JAN2014	09:13	1559.8	ng/ml	-785.24	
	END OF TREATMENT	20JAN2014	10:12	1672.6	ng/ml	-849.26	
	Minimum Post-baseline	11NOV2013	08:02	537.8	ng/ml	-205.22	
101-0048/66/F/W2	SCREENING	21OCT2013	14:24	16.3	ng/ml	.	Stable
	WEEK 5	19NOV2013	09:19	15.3	ng/ml	6.13	
	WEEK 12	06JAN2014	10:16	17.5	ng/ml	-7.36	
	END OF TREATMENT	04FEB2014	10:20	14.2	ng/ml	12.88	
	Minimum Post-baseline	04FEB2014	10:20	14.2	ng/ml	12.88	
101-0049/71/M/A8	SCREENING	22OCT2013	08:59	5.6	ng/ml	.	Stable

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
101-0049/71/M/A8	WEEK 4	18NOV2013	10:02	5.7	ng/ml	-1.79	
	WEEK 8	16DEC2013	12:07	4.6	ng/ml	17.86	
	WEEK 12	13JAN2014	08:37	5.6	ng/ml	0	
	END OF TREATMENT	10FEB2014	13:07	5.1	ng/ml	8.93	
	Minimum Post-baseline	16DEC2013	12:07	4.6	ng/ml	17.86	
101-0050/59/M/W2	SCREENING	29OCT2013	14:17	29.5	ng/ml	.	Stable
	WEEK 4	18NOV2013	08:44	26.2	ng/ml	11.19	
	Minimum Post-baseline	18NOV2013	08:44	26.2	ng/ml	11.19	
102-0001/53/M/BL	SCREENING	19APR2012	09:09	19167.4	ng/mL	.	Rise
	WEEK 4	15MAY2012	08:45	54479	ng/mL	-184.23	

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
102-0001/53/M/BL	WEEK 8	12JUN2012	08:57	67102.1	ng/mL	-250.08	
	TERMINATION	03JUL2012	09:00	69681.3	ng/mL	-263.54	
	Minimum Post-baseline	15MAY2012	08:45	54479	ng/mL	-184.23	
102-0003/63/M/BL	SCREENING	29AUG2012	09:28	3640.8	ng/mL	.	Rise
	WEEK 4	03OCT2012	08:18	5950.6	ng/mL	-63.44	
	WEEK 8	31OCT2012	07:22	9991.6	ng/mL	-174.43	
	WEEK 12	28NOV2012	08:36	17275.2	ng/mL	-374.49	
	Minimum Post-baseline	03OCT2012	08:18	5950.6	ng/mL	-63.44	
102-0008/64/M/BL	SCREENING	02JAN2014	13:23	11.5	ng/mL	.	Stable
	WEEK 4	28JAN2014	08:16	15.6	ng/mL	-35.65	

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
102-0008/64/M/BL	Minimum Post-baseline	28JAN2014	08:16	15.6	ng/mL	-35.65	
102-0009/58/M/W2	SCREENING	23OCT2014	09:35	104466.8	ng/mL	.	Stable
	WEEK 4	19NOV2014	11:25	132284.2	ng/mL	-26.63	
	WEEK 8	17DEC2014	10:01	140427.5	ng/mL	-34.42	
	Minimum Post-baseline	19NOV2014	11:25	132284.2	ng/mL	-26.63	
103-0001/56/M/W2	SCREENING	07MAY2012	11:15	572.6	ng/mL	.	Rise
	WEEK 4	01JUN2012	10:10	1538	ng/mL	-168.6	
	WEEK 8	29JUN2012	10:30	4434	ng/mL	-674.36	
	END OF TREATMENT	20AUG2012	11:05	56177.8	ng/mL	-9711	
	Minimum Post-baseline	01JUN2012	10:10	1538	ng/mL	-168.6	

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
103-0003/66/M/W2	SCREENING	04FEB2013	12:30	8.8	ng/mL	.	Stable
	WEEK 4	06MAR2013	11:00	10.4	ng/mL	-18.18	
	WEEK 8	03APR2013	11:45	8.2	ng/mL	6.82	
	WEEK 12	01MAY2013	14:45	11.2	ng/mL	-27.27	
	WEEK 16	29MAY2013	14:45	10.2	ng/mL	-15.91	
	WEEK 20	24JUN2013	10:40	11.2	ng/mL	-27.27	
	Minimum Post-baseline	03APR2013	11:45	8.2	ng/mL	6.82	
103-0004/40/F/A1	SCREENING	14APR2014	10:00	293.4	ng/mL	.	Rise
	WEEK 4	13MAY2014	13:00	399.6	ng/mL	-36.2	
	END OF TREATMENT	09JUN2014	10:00	519.3	ng/mL	-76.99	

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
103-0004/40/F/A1	Minimum Post-baseline	13MAY2014	13:00	399.6	ng/mL	-36.2	
104-0003/56/F/W2	SCREENING	11JUL2012	09:55	21649.2	ng/mL	.	Rise
	WEEK 4	08AUG2012	09:50	85024.5	ng/mL	-292.74	
	WEEK 8	06SEP2012	08:20	300000	ng/mL	-1285.73	
	Minimum Post-baseline	08AUG2012	09:50	85024.5	ng/mL	-292.74	
104-0004/74/M/W2	SCREENING	22OCT2012	09:20	3.6	ng/mL	.	Stable
	WEEK 4	13NOV2012	10:35	2.6	ng/mL	27.78	
	TERMINATION	11DEC2012	10:29	3	ng/mL	16.67	
	Minimum Post-baseline	13NOV2012	10:35	2.6	ng/mL	27.78	
104-0008/55/M/PI	SCREENING	29AUG2013	13:32	4.7	ng/mL	.	Rise

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
104-0008/55/M/PI	WEEK 4	26SEP2013	07:41	6.4	ng/mL	-36.17	
	WEEK 8	24OCT2013	07:52	6.6	ng/mL	-40.43	
	WEEK 12	21NOV2013	08:00	8.3	ng/mL	-76.6	
	TERMINATION	26DEC2013	08:25	13.1	ng/mL	-178.72	
	Minimum Post-baseline	26SEP2013	07:41	6.4	ng/mL	-36.17	
104-0010/71/F/A8	SCREENING	02JAN2014	10:20	394.8	ng/mL	.	Rise
	WEEK 4	29JAN2014	10:15	453	ng/mL	-14.74	
	WEEK 8	26FEB2014	10:21	339.8	ng/mL	13.93	
	WEEK 12	27MAR2014	09:20	455.5	ng/mL	-15.37	
	WEEK 16	23APR2014	09:25	434.9	ng/mL	-10.16	

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
104-0010/71/F/A8	WEEK 20	21MAY2014	09:24	522.8	ng/mL	-32.42	
	WEEK 24	18JUN2014	09:00	526.6	ng/mL	-33.38	
	WEEK 28	16JUL2014	09:05	375.2	ng/mL	4.96	
	WEEK 32	13AUG2014	09:06	616.2	ng/mL	-56.08	
	WEEK 36	10SEP2014	08:56	825.4	ng/mL	-109.07	
	END OF TREATMENT	01OCT2014	11:47	939.6	ng/mL	-137.99	
	Minimum Post-baseline	26FEB2014	10:21	339.8	ng/mL	13.93	
104-0012/78/F/A2	SCREENING	23SEP2014	11:15	646.2	ng/mL	.	Rise
	WEEK 4	22OCT2014	11:04	1010.9	ng/mL	-56.44	
	WEEK 8	18NOV2014	11:00	1203.3	ng/mL	-86.21	

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
104-0012/78/F/A2	END OF TREATMENT	23DEC2014	10:19	1606.2	ng/mL	-148.56	
	Minimum Post-baseline	22OCT2014	11:04	1010.9	ng/mL	-56.44	
106-0001/42/F/W2	SCREENING	20FEB2012	16:00	2.1	ng/mL	.	Rise
	WEEK 4	26MAR2012	09:30	2.5	ng/mL	-19.05	
	WEEK 8	23APR2012	10:20	3	ng/mL	-42.86	
	WEEK 12	21MAY2012	10:35	3.4	ng/mL	-61.9	
	WEEK 16	18JUN2012	11:40	4.7	ng/mL	-123.81	
	Minimum Post-baseline	26MAR2012	09:30	2.5	ng/mL	-19.05	
107-0002/71/M/W2	SCREENING	15AUG2012	10:25	87.3	ng/mL	.	Rise
	WEEK 4	21SEP2012	13:10	137.8	ng/mL	-57.85	

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
107-0002/71/M/W2	WEEK 8	15OCT2012	12:15	200.1	ng/mL	-129.21	
	WEEK 12	12NOV2012	10:00	262.4	ng/mL	-200.57	
	END OF TREATMENT	05DEC2012	13:25	375.9	ng/mL	-330.58	
	Minimum Post-baseline	21SEP2012	13:10	137.8	ng/mL	-57.85	
107-0003/73/M/BL	SCREENING	18FEB2013	12:05	46720.2	ng/mL	.	Rise
	WEEK 4	18MAR2013	09:49	82465.2	ng/mL	-76.51	
	WEEK 8	16APR2013	13:45	179977.9	ng/mL	-285.23	
	Minimum Post-baseline	18MAR2013	09:49	82465.2	ng/mL	-76.51	
107-0004/63/M/W2	SCREENING	26FEB2013	13:16	731.5	ng/mL	.	Stable
	WEEK 4	26MAR2013	10:20	551.2	ng/mL	24.65	

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
107-0004/63/M/W2	WEEK 8	23APR2013	07:45	492.8	ng/mL	32.63	
	WEEK 12	21MAY2013	10:30	551	ng/mL	24.68	
	END OF TREATMENT	18JUN2013	13:00	699.3	ng/mL	4.4	
	Minimum Post-baseline	23APR2013	07:45	492.8	ng/mL	32.63	
107-0006/60/M/W2	SCREENING	06MAY2013	09:15	6.2	ng/mL	.	Stable
	WEEK 4	04JUN2013	13:05	3.9	ng/mL	37.1	
	WEEK 8	01JUL2013	10:00	3.9	ng/mL	37.1	
	WEEK 12	29JUL2013	09:00	4.3	ng/mL	30.65	
	Minimum Post-baseline	01JUL2013	10:00	3.9	ng/mL	37.1	
108-0001/60/F/W2	SCREENING	07MAR2012	15:00	3131	ng/mL	.	Stable

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Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
108-0001/60/F/W2	WEEK 4	11APR2012	10:45	4673.4	ng/mL	-49.26	
	Minimum Post-baseline	11APR2012	10:45	4673.4	ng/mL	-49.26	
108-0002/78/M/BL	SCREENING	25MAY2012	09:55	230.5	ng/mL	.	Rise
	WEEK 4	21JUN2012	10:00	349.6	ng/mL	-51.67	
	TERMINATION	10JUL2012	11:20	448.7	ng/mL	-94.66	
	Minimum Post-baseline	21JUN2012	10:00	349.6	ng/mL	-51.67	
108-0004/61/M/W2	SCREENING	04APR2013	10:31	2065	ng/mL	.	Rise
	WEEK 4	09MAY2013	07:35	3898.4	ng/mL	-88.78	
	TERMINATION	30MAY2013	07:36	4662.9	ng/mL	-125.81	
	Minimum Post-baseline	09MAY2013	07:35	3898.4	ng/mL	-88.78	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
108-0005/68/M/W2	SCREENING	26APR2013	08:40	46.6	ng/mL	.	Rise
	WEEK 4	29MAY2013	13:30	32.6	ng/mL	30.04	
	WEEK 8	26JUN2013	09:30	66.5	ng/mL	-42.7	
	WEEK 12	24JUL2013	09:20	68.9	ng/mL	-47.85	
	TERMINATION	30JUL2013	09:35	85.2	ng/mL	-82.83	
	Minimum Post-baseline	29MAY2013	13:30	32.6	ng/mL	30.04	
108-0008/77/M/W2	SCREENING	01OCT2014	08:05	4.5	ng/mL	.	Decline
	WEEK 4	30OCT2014	09:20	4.3	ng/mL	4.44	
	WEEK 8	26NOV2014	12:06	4.6	ng/mL	-2.22	
	WEEK 12	23DEC2014	08:54	3.7	ng/mL	17.78	

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
108-0008/77/M/W2	WEEK 16	22JAN2015	09:15	2.4	ng/mL	46.67	
	WEEK 20	19FEB2015	08:15	3.4	ng/mL	24.44	
	WEEK 24	17MAR2015	08:25	1.8	ng/mL	60	
	END OF TREATMENT	16APR2015	13:47	1.5	ug/L	66.67	
	Minimum Post-baseline	16APR2015	13:47	1.5	ug/L	66.67	
109-0003/68/M/W2	SCREENING	30APR2013	11:33	94761.2	ng/mL	.	Rise
	WEEK 4	28MAY2013	16:00	162233	ng/mL	-71.2	
	Minimum Post-baseline	28MAY2013	16:00	162233	ng/mL	-71.2	
109-0004/57/M/W2	SCREENING	12JUL2013	11:15	7198.8	ng/mL	.	Decline
	WEEK 4	12AUG2013	13:45	3130.2	ng/mL	56.52	

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
109-0004/57/M/W2	WEEK 8	11SEP2013	13:55	1699.1	ng/mL	76.4	
	WEEK 12	09OCT2013	09:10	1274.3	ng/mL	82.3	
	Minimum Post-baseline	09OCT2013	09:10	1274.3	ng/mL	82.3	
109-0006/62/M/PI	SCREENING	14AUG2013	12:25	2703.9	ng/mL	.	Rise
	WEEK 4	12SEP2013	11:40	5116.1	ng/mL	-89.21	
	WEEK 8	09OCT2013	13:15	6261.9	ng/mL	-131.59	
	WEEK 12	06NOV2013	11:45	10778.5	ng/mL	-298.63	
	END OF TREATMENT	09DEC2013	13:10	29813.6	ng/mL	-1002.61	
	Minimum Post-baseline	12SEP2013	11:40	5116.1	ng/mL	-89.21	
109-0007/55/M/W2	SCREENING	05DEC2013	11:00	8.6	ng/mL	.	Decline

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
109-0007/55/M/W2	WEEK 4	03JAN2014	12:40	9.3	ng/mL	-8.14	
	WEEK 8	31JAN2014	13:20	7.2	ng/mL	16.28	
	WEEK 12	26FEB2014	12:40	4.2	ng/mL	51.16	
	WEEK 16	25MAR2014	13:52	4.3	ng/mL	50	
	WEEK 20	23APR2014	11:25	4.5	ng/mL	47.67	
	TERMINATION	21MAY2014	11:00	3.1	ng/mL	63.95	
	Minimum Post-baseline	21MAY2014	11:00	3.1	ng/mL	63.95	
109-0008/70/F/W2	SCREENING	21MAY2014	11:35	18446.8	ng/mL	.	Rise
	WEEK 4	25JUN2014	12:20	25098.4	ng/mL	-36.06	
	WEEK 8	23JUL2014	12:40	29525.1	ng/mL	-60.06	

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
109-0008/70/F/W2	WEEK 12	20AUG2014	13:10	18636.7	ng/mL	-1.03	
	WEEK 16	17SEP2014	12:45	30580.8	ng/mL	-65.78	
	WEEK 20	14OCT2014	08:39	26302.5	ng/mL	-42.59	
	WEEK 24	13NOV2014	09:20	36623.7	ng/mL	-98.54	
	END OF TREATMENT	17DEC2014	13:00	44257.9	ng/mL	-139.92	
	Minimum Post-baseline	20AUG2014	13:10	18636.7	ng/mL	-1.03	
109-0009/57/M/W2	SCREENING	25JUN2014	11:45	69.4	ng/mL	.	Rise
	WEEK 4	30JUL2014	12:15	63.6	ng/mL	8.36	
	WEEK 8	26AUG2014	11:19	156.7	ng/mL	-125.79	
	WEEK 12	23SEP2014	13:30	394.8	ng/mL	-468.88	

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
109-0009/57/M/W2	END OF TREATMENT	14OCT2014	12:30	761.4	ng/mL	-997.12	
	Minimum Post-baseline	30JUL2014	12:15	63.6	ng/mL	8.36	
109-0010/65/M/W2	SCREENING	25JUN2014	14:45	10037.3	ng/mL	.	Stable
	WEEK 4	30JUL2014	14:10	10741.5	ng/mL	-7.02	
	WEEK 6	13AUG2014	12:05	10359.4	ng/mL	-3.21	
	WEEK 8	27AUG2014	12:25	10373.7	ng/mL	-3.35	
	WEEK 12	24SEP2014	11:30	11183.5	ng/mL	-11.42	
	END OF TREATMENT	22OCT2014	15:20	11586.4	ng/mL	-15.43	
	Minimum Post-baseline	13AUG2014	12:05	10359.4	ng/mL	-3.21	
109-0011/64/M/A4	SCREENING	17SEP2014	16:25	2063.3	ng/mL	.	Rise

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
109-0011/64/M/A4	WEEK 4	15OCT2014	15:05	6440.9	ng/mL	-212.16	
	WEEK 8	11NOV2014	15:20	4798.5	ng/mL	-132.56	
	WEEK 12	10DEC2014	14:50	2910	ng/mL	-41.04	
	END OF TREATMENT	07JAN2015	16:20	2962.9	ng/mL	-43.6	
	Minimum Post-baseline	10DEC2014	14:50	2910	ng/mL	-41.04	
109-0013/64/F/W2	SCREENING	30OCT2014	14:30	1417.9	ng/mL	.	Decline
	WEEK 4	01DEC2014	15:45	1647.8	ng/mL	-16.21	
	WEEK 8	22DEC2014	14:55	1391.5	ng/mL	1.86	
	WEEK 12	20JAN2015	11:45	1028.9	ng/mL	27.43	
	UNSCHEDULED	24FEB2015	11:15	193	ng/mL	86.39	

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
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Serum Alpha Fetoprotein Response
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Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
109-0013/64/F/W2	WEEK 24	13APR2015	12:30	520.2	ng/mL	63.31	
	Minimum Post-baseline	24FEB2015	11:15	193	ng/mL	86.39	
110-0003/63/M/OTH	SCREENING	25JUN2012	16:00	10538.6	ng/mL	.	Rise
	WEEK 4	30JUL2012	12:15	6559.7	ng/mL	37.76	
	WEEK 8	27AUG2012	11:30	8453.6	ng/mL	19.78	
	WEEK 12	25SEP2012	12:30	10725	ng/mL	-1.77	
	WEEK 16	22OCT2012	11:55	13874.9	ng/mL	-31.66	
	WEEK 20	19NOV2012	11:35	19949.8	ng/mL	-89.3	
	WEEK 24	17DEC2012	15:30	18428.3	ng/mL	-74.86	
	Minimum Post-baseline	30JUL2012	12:15	6559.7	ng/mL	37.76	

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Serum Alpha Fetoprotein Response
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Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
110-0004/53/M/A4	SCREENING	11OCT2012	13:05	728.5	ng/mL	.	Rise
	WEEK 8	13DEC2012	11:15	1583.3	ng/mL	-117.34	
	WEEK 12	10JAN2013	11:45	2258.1	ng/mL	-209.97	
	Minimum Post-baseline	13DEC2012	11:15	1583.3	ng/mL	-117.34	
110-0005/77/M/W2	SCREENING	05MAR2013	11:45	104.8	ng/mL	.	Stable
	WEEK 4	02APR2013	14:30	55.5	ng/mL	47.04	
	WEEK 8	30APR2013	13:58	84.6	ng/mL	19.27	
	WEEK 12	28MAY2013	12:30	130.7	ng/mL	-24.71	
	TERMINATION	05JUN2013	15:00	143.4	ng/mL	-36.83	
	Minimum Post-baseline	02APR2013	14:30	55.5	ng/mL	47.04	

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
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Serum Alpha Fetoprotein Response
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Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
110-0007/62/M/A4	SCREENING	03MAY2013	11:58	123.3	ng/mL	.	Rise
	WEEK 4	07JUN2013	13:05	160.1	ng/mL	-29.85	
	WEEK 12	02AUG2013	12:00	177.1	ng/mL	-43.63	
	WEEK 16	30AUG2013	11:15	107.3	ng/mL	12.98	
	WEEK 24	25OCT2013	12:05	172.7	ng/mL	-40.06	
	WEEK 28	22NOV2013	11:35	355	ng/mL	-187.92	
	Minimum Post-baseline	30AUG2013	11:15	107.3	ng/mL	12.98	
110-0008/63/F/BL	SCREENING	26JUN2013	12:18	65.6	ng/mL	.	Rise
	WEEK 4	29JUL2013	12:05	160.4	ng/mL	-144.51	
	Minimum Post-baseline	29JUL2013	12:05	160.4	ng/mL	-144.51	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
110-0011/77/M/A1	SCREENING	12JAN2015	12:10	5.1	ng/mL	.	Rise
	WEEK 4	12FEB2015	11:55	6	ng/mL	-17.65	
	WEEK 8	12MAR2015	11:31	6.7	ng/mL	-31.37	
	WEEK 12	10APR2015	15:35	15.5	ng/mL	-203.92	
	Minimum Post-baseline	12FEB2015	11:55	6	ng/mL	-17.65	
111-0001/37/M/A4	SCREENING	02JUL2012	11:05	255.8	ng/mL	.	Stable
	WEEK 4	02AUG2012	13:00	313.4	ng/mL	-22.52	
	END OF TREATMENT	29AUG2012	12:48	195.8	ng/mL	23.46	
	Minimum Post-baseline	29AUG2012	12:48	195.8	ng/mL	23.46	
111-0004/64/M/W2	SCREENING	10MAY2013	11:25	394.6	ng/mL	.	Rise

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
111-0004/64/M/W2	WEEK 4	13JUN2013	09:52	681.3	ng/mL	-72.66	
	WEEK 8	11JUL2013	09:25	2826.9	ng/mL	-616.4	
	Minimum Post-baseline	13JUN2013	09:52	681.3	ng/mL	-72.66	
111-0006/59/M/W2	SCREENING	03OCT2013	08:25	28	ng/mL	.	Stable
	WEEK 4	30OCT2013	07:15	25.7	ng/mL	8.21	
	WEEK 8	26NOV2013	08:24	23.4	ng/mL	16.43	
	WEEK 12	02JAN2014	09:15	24.9	ng/mL	11.07	
	WEEK 16	29JAN2014	11:20	22.6	ng/mL	19.29	
	WEEK 20	26FEB2014	10:40	16.8	ng/mL	40	
	WEEK 24	26MAR2014	07:25	24.4	ng/mL	12.86	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
111-0006/59/M/W2	WEEK 28	23APR2014	07:55	20.2	ng/mL	27.86	
	Minimum Post-baseline	26FEB2014	10:40	16.8	ng/mL	40	
111-0007/55/M/W2	SCREENING	23JAN2014	15:46	7.3	ng/mL	.	Stable
	WEEK 4	27FEB2014	11:12	6.9	ng/mL	5.48	
	WEEK 8	27MAR2014	11:35	8.3	ng/mL	-13.7	
	WEEK 12	25APR2014	07:50	7.5	ng/mL	-2.74	
	END OF TREATMENT	22MAY2014	12:08	10.2	ng/mL	-39.73	
	Minimum Post-baseline	27FEB2014	11:12	6.9	ng/mL	5.48	
112-0006/58/M/W2	SCREENING	15MAR2013	10:23	14.5	ng/mL	.	Stable
	WEEK 4	15APR2013	11:53	21.5	ng/mL	-48.28	

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
112-0006/58/M/W2	WEEK 8	13MAY2013	12:09	21.4	ng/mL	-47.59	
	END OF TREATMENT	28JUN2013	11:22	15.9	ng/mL	-9.66	
	Minimum Post-baseline	28JUN2013	11:22	15.9	ng/mL	-9.66	
112-0009/50/M/A8	SCREENING	12JUN2013	09:40	173.7	ng/mL	.	Rise
	WEEK 8	07AUG2013	09:27	424.3	ng/mL	-144.27	
	WEEK 12	04SEP2013	07:53	497.8	ng/mL	-186.59	
	END OF TREATMENT	13SEP2013	08:52	649.4	ng/mL	-273.86	
	Minimum Post-baseline	07AUG2013	09:27	424.3	ng/mL	-144.27	
112-0011/56/M/A4	SCREENING	03JAN2014	10:10	33.5	ng/mL	.	Decline
	WEEK 4	31JAN2014	08:44	29.9	ng/mL	10.75	

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
112-0011/56/M/A4	WEEK 8	28FEB2014	09:02	13.2	ng/mL	60.6	
	END OF TREATMENT	28MAR2014	09:51	34.3	ng/mL	-2.39	
	Minimum Post-baseline	28FEB2014	09:02	13.2	ng/mL	60.6	
112-0012/71/M/W2	SCREENING	16MAY2014	08:05	800.9	ng/mL	.	Stable
	WEEK 4	13JUN2014	07:42	717.1	ng/mL	10.46	
	WEEK 12	08AUG2014	07:24	1124.7	ng/mL	-40.43	
	END OF TREATMENT	12SEP2014	13:30	1190.5	ng/mL	-48.65	
	Minimum Post-baseline	13JUN2014	07:42	717.1	ng/mL	10.46	
112-0013/28/F/W2	SCREENING	16MAY2014	11:25	1.1	ng/mL	.	Rise
	WEEK 4	13JUN2014	08:00	1.1	ng/mL	0	

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
112-0013/28/F/W2	WEEK 8	11JUL2014	08:21	1.7	ng/mL	-54.55	
	END OF TREATMENT	29AUG2014	12:00	0.9	ng/mL	18.18	
	Minimum Post-baseline	29AUG2014	12:00	0.9	ng/mL	18.18	
112-0014/79/M/A8	SCREENING	30MAY2014	13:10	29942.4	ng/mL	.	Rise
	WEEK 4	27JUN2014	11:38	68517.1	ng/mL	-128.83	
	WEEK 8	25JUL2014	09:20	91003.5	ng/mL	-203.93	
	WEEK 12	22AUG2014	07:56	164930.6	ng/mL	-450.83	
	END OF TREATMENT	19SEP2014	10:43	106340	ng/mL	-255.15	
	Minimum Post-baseline	27JUN2014	11:38	68517.1	ng/mL	-128.83	
112-0015/66/M/A8	SCREENING	17OCT2014	09:31	2344.5	ng/mL	.	Rise

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
112-0015/66/M/A8	WEEK 4	14NOV2014	08:41	5143.1	ng/mL	-119.37	
	WEEK 8	12DEC2014	10:20	10288.8	ng/mL	-338.85	
	Minimum Post-baseline	14NOV2014	08:41	5143.1	ng/mL	-119.37	
113-0001/60/M/W2	SCREENING	09AUG2012	15:45	6.3	ng/mL	.	Rise
	WEEK 4	17SEP2012	14:10	10.1	ng/mL	-60.32	
	WEEK 8	15OCT2012	12:30	10.2	ng/mL	-61.9	
	WEEK 12	15NOV2012	14:35	10.6	ng/mL	-68.25	
	WEEK 16	10DEC2012	11:49	10.7	ng/mL	-69.84	
	WEEK 20	07JAN2013	13:10	11.7	ng/mL	-85.71	
	WEEK 24	06FEB2013	13:00	17.1	ng/mL	-171.43	

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
113-0001/60/M/W2	Minimum Post-baseline	17SEP2012	14:10	10.1	ng/mL	-60.32	
113-0002/64/F/W2	SCREENING	08OCT2012	15:27	68	ng/mL	.	Rise
	WEEK 4	05NOV2012	11:00	72.9	ng/mL	-7.21	
	WEEK 8	26NOV2012	11:45	88.1	ng/mL	-29.56	
	WEEK 20	20FEB2013	09:05	125.8	ng/mL	-85	
	WEEK 24	25MAR2013	09:50	130.2	ng/mL	-91.47	
	WEEK 28	22APR2013	08:45	170.4	ng/mL	-150.59	
	WEEK 32	20MAY2013	08:04	234.7	ng/mL	-245.15	
	END OF TREATMENT	24JUN2013	08:53	297.9	ng/mL	-338.09	
	Minimum Post-baseline	05NOV2012	11:00	72.9	ng/mL	-7.21	

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
113-0005/58/M/W2	SCREENING	08JAN2014	09:50	860.5	ng/mL	.	Rise
	WEEK 4	13FEB2014	09:27	5858.4	ng/mL	-580.81	
	WEEK 8	12MAR2014	14:26	15471	ng/mL	-1697.91	
	Minimum Post-baseline	13FEB2014	09:27	5858.4	ng/mL	-580.81	
113-0008/78/M/A8	SCREENING	07FEB2014	13:25	7.5	ng/mL	.	Stable
113-0010/59/M/W2	SCREENING	16APR2014	14:17	4748.7	ng/mL	.	Stable
	WEEK 4	23MAY2014	08:40	6879.4	ng/mL	-44.87	
	Minimum Post-baseline	23MAY2014	08:40	6879.4	ng/mL	-44.87	
113-0013/56/M/W2	SCREENING	29OCT2014	10:14	5.6	ng/mL	.	Stable
	WEEK 4	24NOV2014	08:24	6.6	ng/mL	-17.86	

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
113-0013/56/M/W2	WEEK 8	22DEC2014	08:35	6.7	ng/mL	-19.64	
	END OF TREATMENT	26JAN2015	08:45	5.2	ng/mL	7.14	
	Minimum Post-baseline	26JAN2015	08:45	5.2	ng/mL	7.14	
113-0016/72/M/A8	SCREENING	22JAN2015	14:27	6.8	ng/mL	.	Stable
	WEEK 4	25FEB2015	13:34	5.5	ng/mL	19.12	
	WEEK 8	23MAR2015	08:37	5.8	ng/mL	14.71	
	Minimum Post-baseline	25FEB2015	13:34	5.5	ng/mL	19.12	
114-0003/59/M/W2	SCREENING	19NOV2012	11:15	34	ng/mL	.	Rise
	WEEK 4	19DEC2012	11:40	152.3	ng/mL	-347.94	
	WEEK 8	16JAN2013	11:45	73.2	ng/mL	-115.29	

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
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Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
114-0003/59/M/W2	WEEK 12	13FEB2013	11:34	97.9	ng/mL	-187.94	
	WEEK 16	13MAR2013	11:32	208.9	ng/mL	-514.41	
	WEEK 20	10APR2013	12:12	282.6	ng/mL	-731.18	
	END OF TREATMENT	16APR2013	13:25	317.6	ng/mL	-834.12	
	Minimum Post-baseline	16JAN2013	11:45	73.2	ng/mL	-115.29	
114-0005/73/M/W2	SCREENING	04DEC2013	12:22	1.9	ng/mL	.	Stable
	WEEK 4	31DEC2013	08:53	2.1	ng/mL	-10.53	
	WEEK 8	29JAN2014	08:08	2	ng/mL	-5.26	
	Minimum Post-baseline	29JAN2014	08:08	2	ng/mL	-5.26	
114-0007/60/F/W2	SCREENING	14NOV2014	11:46	1.6	ng/mL	.	Stable

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
114-0007/60/F/W2	WEEK 4	09DEC2014	11:49	2	ng/mL	-25	
	WEEK 6	23DEC2014	10:19	2	ng/mL	-25	
	WEEK 8	06JAN2015	10:11	1.6	ng/mL	0	
	WEEK 12	04FEB2015	10:20	1.8	ng/mL	-12.5	
	WEEK 20	31MAR2015	10:27	1.3	ng/mL	18.75	
	WEEK 24	28APR2015	10:38	1.8	ng/mL	-12.5	
	WEEK 28	26MAY2015	10:51	1.6	ng/mL	0	
	WEEK 32	23JUN2015	10:32	1.5	ng/mL	6.25	
	Minimum Post-baseline	31MAR2015	10:27	1.3	ng/mL	18.75	
115-0001/59/F/A4	SCREENING	26NOV2012	09:07	5.1	ng/mL	.	Stable

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
115-0001/59/F/A4	WEEK 4	18DEC2012	09:30	4	ng/mL	21.57	
	WEEK 8	15JAN2013	08:45	5.4	ng/mL	-5.88	
	WEEK 12	14FEB2013	07:25	6.5	ng/mL	-27.45	
	END OF TREATMENT	22MAR2013	08:36	5.9	ng/mL	-15.69	
	Minimum Post-baseline	18DEC2012	09:30	4	ng/mL	21.57	
115-0002/45/F/W2	SCREENING	26NOV2012	12:44	2.9	ng/mL	.	Rise
	WEEK 4	18DEC2012	13:26	2.8	ng/mL	3.45	
	TERMINATION	07FEB2013	10:11	4.4	ng/mL	-51.72	
	Minimum Post-baseline	18DEC2012	13:26	2.8	ng/mL	3.45	
115-0003/63/M/W2	SCREENING	15JAN2013	15:05	41.7	ng/mL	.	Rise

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
115-0003/63/M/W2	WEEK 4	07FEB2013	08:12	34.9	ng/mL	16.31	
	WEEK 8	07MAR2013	08:14	44.6	ng/mL	-6.95	
	WEEK 12	04APR2013	07:16	69.6	ng/mL	-66.91	
	WEEK 16	02MAY2013	07:50	59.3	ng/mL	-42.21	
	WEEK 20	30MAY2013	07:25	80.3	ng/mL	-92.57	
	WEEK 24	24JUN2013	08:05	63.4	ng/mL	-52.04	
	Minimum Post-baseline	07FEB2013	08:12	34.9	ng/mL	16.31	
115-0008/51/M/A8	SCREENING	13JUN2013	13:50	22709.2	ng/mL	.	Stable
115-0009/85/M/W2	SCREENING	03DEC2013	15:25	8.1	ng/mL	.	Rise
	WEEK 4	02JAN2014	08:25	9.7	ng/mL	-19.75	

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[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
115-0009/85/M/W2	WEEK 8	28JAN2014	09:55	9.2	ng/mL	-13.58	
	WEEK 12	24FEB2014	10:37	13.5	ng/mL	-66.67	
	WEEK 16	27MAR2014	09:17	13.5	ng/mL	-66.67	
	WEEK 20	22APR2014	13:07	13.1	ng/mL	-61.73	
	WEEK 24	21MAY2014	08:54	15.1	ng/mL	-86.42	
	Minimum Post-baseline	28JAN2014	09:55	9.2	ng/mL	-13.58	
115-0011/56/M/W2	SCREENING	30MAY2014	07:08	47058.2	ng/mL	.	Rise
	WEEK 4	26JUN2014	08:45	56062.7	ng/mL	-19.13	
	WEEK 12	22AUG2014	07:34	87428.5	ng/mL	-85.79	
	Minimum Post-baseline	26JUN2014	08:45	56062.7	ng/mL	-19.13	

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
115-0014/72/M/W2	SCREENING	30JAN2015	14:05	2.6	ng/mL	.	Stable
	WEEK 4	03MAR2015	08:45	2.7	ng/mL	-3.85	
	WEEK 8	31MAR2015	12:30	2.3	ng/mL	11.54	
	Minimum Post-baseline	31MAR2015	12:30	2.3	ng/mL	11.54	
116-0002/67/F/W2	SCREENING	11MAR2013	16:44	21.8	ng/mL	.	Rise
	WEEK 4	08APR2013	14:02	18.5	ng/mL	15.14	
	WEEK 8	06MAY2013	13:54	25.6	ng/mL	-17.43	
	WEEK 12	03JUN2013	14:00	30.9	ng/mL	-41.74	
	WEEK 16	01JUL2013	13:35	53.8	ng/mL	-146.79	
	WEEK 20	29JUL2013	13:52	50.1	ng/mL	-129.82	

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
116-0002/67/F/W2	WEEK 24	26AUG2013	14:09	86.5	ng/mL	-296.79	
	WEEK 28	23SEP2013	13:52	114.6	ng/mL	-425.69	
	WEEK 32	21OCT2013	13:41	130.9	ng/mL	-500.46	
	WEEK 36	18NOV2013	14:00	223.5	ng/mL	-925.23	
	END OF TREATMENT	02DEC2013	14:03	294	ng/mL	-1248.62	
	Minimum Post-baseline	08APR2013	14:02	18.5	ng/mL	15.14	
116-0003/66/M/BL	SCREENING	18MAR2013	16:20	563.7	ng/mL	.	Rise
	WEEK 4	18APR2013	10:34	972.7	ng/mL	-72.56	
	TERMINATION	23MAY2013	08:43	1394.4	ng/mL	-147.37	
	Minimum Post-baseline	18APR2013	10:34	972.7	ng/mL	-72.56	

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
117-0001/69/M/W2	SCREENING	19MAR2013	13:35	1.5	ng/mL	.	Stable
	WEEK 4	23APR2013	13:45	1.9	ng/mL	-26.67	
	WEEK 8	21MAY2013	13:00	1.6	ng/mL	-6.67	
	END OF TREATMENT	18JUN2013	13:05	1.5	ng/mL	0	
	Minimum Post-baseline	18JUN2013	13:05	1.5	ng/mL	0	
118-0001/67/F/A8	SCREENING	06AUG2013	13:20	25.5	ng/mL	.	Rise
	WEEK 4	03SEP2013	13:00	33.1	ng/mL	-29.8	
	WEEK 8	03OCT2013	13:15	56.2	ng/mL	-120.39	
	WEEK 12	29OCT2013	09:35	120.1	ng/mL	-370.98	
	END OF TREATMENT	21NOV2013	13:05	20.8	ng/mL	18.43	

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
118-0001/67/F/A8	Minimum Post-baseline	21NOV2013	13:05	20.8	ng/mL	18.43	
119-0001/80/M/A8	SCREENING	07JAN2014	15:58	2.2	ng/mL	.	Stable
121-0001/62/M/W2	SCREENING	11FEB2014	07:55	4.4	ng/mL	.	Stable
	WEEK 4	11MAR2014	09:00	4.7	ng/mL	-6.82	
	WEEK 8	08APR2014	09:40	5.9	ng/mL	-34.09	
	WEEK 12	06MAY2014	09:05	5.5	ng/mL	-25	
	Minimum Post-baseline	11MAR2014	09:00	4.7	ng/mL	-6.82	
121-0004/64/F/W2	SCREENING	05JAN2015	10:10	12193.4	ng/mL	.	Stable
201-0001/68/F/W2	SCREENING	20JAN2012	08:00	9.9	ng/mL	.	Rise
	WEEK 4	16FEB2012	08:00	12.9	ng/mL	-30.3	

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[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
201-0001/68/F/W2	WEEK 8	15MAR2012	09:20	30.6	ng/mL	-209.09	
	WEEK 12	11APR2012	08:10	51.6	ng/mL	-421.21	
	END OF TREATMENT	23MAY2012	08:00	137.3	ng/mL	-1286.87	
	Minimum Post-baseline	16FEB2012	08:00	12.9	ng/mL	-30.3	
201-0005/73/M/W2	SCREENING	05JUL2012	08:00	12463.8	ng/mL	.	Rise
	WEEK 4	09AUG2012	07:50	59456.3	ng/mL	-377.03	
	WEEK 8	06SEP2012	08:00	188087.9	ng/mL	-1409.07	
	WEEK 12	04OCT2012	08:00	203745.5	ng/mL	-1534.7	
	END OF TREATMENT	21NOV2012	08:00	300000	ng/mL	-2306.97	
	Minimum Post-baseline	09AUG2012	07:50	59456.3	ng/mL	-377.03	

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
201-0008/79/M/W2	SCREENING	10MAY2013	08:30	9.2	ng/mL	.	Stable
	WEEK 4	06JUN2013	08:00	12.5	ng/mL	-35.87	
	WEEK 8	04JUL2013	08:15	12.9	ng/mL	-40.22	
	Minimum Post-baseline	06JUN2013	08:00	12.5	ng/mL	-35.87	
201-0011/73/M/W2	SCREENING	27JUN2013	08:40	6.4	ng/mL	.	Stable
	WEEK 4	24JUL2013	08:40	5.6	ng/mL	12.5	
	WEEK 8	22AUG2013	08:10	6.1	ng/mL	4.69	
	WEEK 12	18SEP2013	07:50	5.8	ng/mL	9.38	
	END OF TREATMENT	21OCT2013	08:00	4.9	ng/mL	23.44	
	Minimum Post-baseline	21OCT2013	08:00	4.9	ng/mL	23.44	

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
201-0012/79/M/W2	SCREENING	17JUL2013	08:50	41.4	ng/mL	.	Rise
	WEEK 8	12SEP2013	08:05	31.7	ng/mL	23.43	
	WEEK 12	10OCT2013	08:00	40.3	ng/mL	2.66	
	WEEK 16	07NOV2013	08:40	45.6	ng/mL	-10.14	
	WEEK 20	06DEC2013	07:50	46.5	ng/mL	-12.32	
	WEEK 24	03JAN2014	07:50	56.3	ng/mL	-35.99	
	WEEK 28	30JAN2014	08:30	67.7	ng/mL	-63.53	
	WEEK 32	27FEB2014	08:20	62.9	ng/mL	-51.93	
	WEEK 36	27MAR2014	08:30	61.8	ng/mL	-49.28	
	WEEK 40	24APR2014	08:00	57.4	ng/mL	-38.65	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
201-0012/79/M/W2	WEEK 44	21MAY2014	08:25	66.5	ng/mL	-60.63	
	WEEK 48	19JUN2014	08:15	57.3	ng/mL	-38.41	
	WEEK 52	16JUL2014	08:00	54.2	ng/mL	-30.92	
	WEEK 60	11SEP2014	08:30	56.3	ng/mL	-35.99	
	END OF TREATMENT	15OCT2014	08:00	96.9	ng/mL	-134.06	
	Minimum Post-baseline	12SEP2013	08:05	31.7	ng/mL	23.43	
201-0013/67/F/W2	SCREENING	18JUL2013	08:00	9.1	ng/mL	.	Stable
	WEEK 8	12SEP2013	08:20	7.6	ng/mL	16.48	
	WEEK 12	10OCT2013	08:30	8	ng/mL	12.09	
	END OF TREATMENT	11NOV2013	08:30	7.9	ng/mL	13.19	

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
201-0013/67/F/W2	Minimum Post-baseline	12SEP2013	08:20	7.6	ng/mL	16.48	
201-0016/72/M/W2	SCREENING	31OCT2013	08:30	77.8	ng/mL	.	Rise
	UNSCHEDULED	07NOV2013	08:00	63.2	ng/mL	18.77	
	WEEK 4	06DEC2013	08:20	85	ng/mL	-9.25	
	WEEK 8	03JAN2014	08:10	108.9	ng/mL	-39.97	
	WEEK 12	30JAN2014	08:10	115.7	ng/mL	-48.71	
	WEEK 16	27FEB2014	08:00	160.5	ng/mL	-106.3	
	WEEK 20	27MAR2014	08:15	182	ng/mL	-133.93	
	END OF TREATMENT	21MAY2014	08:10	273.6	ng/mL	-251.67	
	Minimum Post-baseline	07NOV2013	08:00	63.2	ng/mL	18.77	

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
201-0017/82/M/W2	SCREENING	18NOV2013	08:00	2975.6	ng/mL	.	Stable
	END OF TREATMENT	30JAN2014	07:45	1577.9	ng/mL	46.97	
	Minimum Post-baseline	30JAN2014	07:45	1577.9	ng/mL	46.97	
201-0018/78/F/W2	SCREENING	28NOV2013	08:20	157832.2	ng/mL	.	Stable
201-0019/68/M/W2	SCREENING	12DEC2013	09:00	8.9	ng/mL	.	Rise
	WEEK 4	09JAN2014	08:15	8.2	ng/mL	7.87	
	WEEK 8	06FEB2014	08:20	10.9	ng/mL	-22.47	
	WEEK 12	06MAR2014	08:10	15.7	ng/mL	-76.4	
	Minimum Post-baseline	09JAN2014	08:15	8.2	ng/mL	7.87	
201-0020/67/M/W2	SCREENING	17JAN2014	09:30	12179.2	ng/mL	.	Rise

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
201-0020/67/M/W2	END OF TREATMENT	24MAR2014	08:30	40876.3	ng/mL	-235.62	
	Minimum Post-baseline	24MAR2014	08:30	40876.3	ng/mL	-235.62	
201-0021/54/M/W2	SCREENING	04FEB2014	08:00	66.6	ng/mL	.	Decline
	WEEK 4	06MAR2014	07:50	57.6	ng/mL	13.51	
	WEEK 8	03APR2014	08:00	25.4	ng/mL	61.86	
	WEEK 12	30APR2014	08:00	14.3	ng/mL	78.53	
	END OF TREATMENT	04JUN2014	08:30	4.6	ng/mL	93.09	
	Minimum Post-baseline	04JUN2014	08:30	4.6	ng/mL	93.09	
201-0024/74/M/W2	SCREENING	16JAN2015	09:30	44373.5	ng/mL	.	Stable
	WEEK 4	19FEB2015	07:50	62048	ng/mL	-39.83	

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
201-0024/74/M/W2	Minimum Post-baseline	19FEB2015	07:50	62048	ng/mL	-39.83	
201-0025/75/M/W2	SCREENING	21JAN2015	08:00	54.7	ng/mL	.	Rise
	END OF TREATMENT	19MAR2015	08:10	257	ng/mL	-369.84	
	Minimum Post-baseline	19MAR2015	08:10	257	ng/mL	-369.84	
203-0001/61/F/W2	SCREENING	29FEB2012	08:00	39.7	ng/mL	.	Decline
	WEEK 4	29MAR2012	08:00	15.7	ng/mL	60.45	
	END OF TREATMENT	30APR2012	08:00	9.8	ng/mL	75.31	
	Minimum Post-baseline	30APR2012	08:00	9.8	ng/mL	75.31	
203-0002/72/M/W2	SCREENING	02MAR2012	08:00	13.9	ng/mL	.	Stable
	WEEK 4	27MAR2012	08:00	12.4	ng/mL	10.79	

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
203-0002/72/M/W2	Minimum Post-baseline	27MAR2012	08:00	12.4	ng/mL	10.79	
203-0005/53/M/W2	SCREENING	29MAR2012	08:00	1187.7	ng/mL	.	Rise
	WEEK 4	27APR2012	08:00	2187.5	ng/mL	-84.18	
	WEEK 8	31MAY2012	09:00	1799.8	ng/mL	-51.54	
	END OF TREATMENT	21SEP2012	08:00	1727.1	ng/mL	-45.42	
	Minimum Post-baseline	21SEP2012	08:00	1727.1	ng/mL	-45.42	
203-0013/68/M/W2	SCREENING	23DEC2013	09:00	9938.1	ng/mL	.	Stable
	WEEK 4	22JAN2014	08:00	12218.4	ng/mL	-22.95	
	END OF TREATMENT	31JAN2014	08:00	14143.1	ng/mL	-42.31	
	Minimum Post-baseline	22JAN2014	08:00	12218.4	ng/mL	-22.95	

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
203-0015/85/M/W2	SCREENING	17JAN2014	09:00	669.4	ng/mL	.	Rise
	WEEK 4	24FEB2014	09:00	1095.6	ng/mL	-63.67	
	WEEK 8	28MAR2014	09:00	1296.2	ng/mL	-93.64	
	Minimum Post-baseline	24FEB2014	09:00	1095.6	ng/mL	-63.67	
203-0017/58/M/W2	SCREENING	18FEB2014	09:00	2533.9	ng/mL	.	Stable
203-0018/58/F/W2	SCREENING	26MAR2014	08:00	16.6	ng/mL	.	Rise
	WEEK 4	05MAY2014	09:00	24.4	ng/mL	-46.99	
	WEEK 8	04JUN2014	09:00	37.2	ng/mL	-124.1	
	Minimum Post-baseline	05MAY2014	09:00	24.4	ng/mL	-46.99	
205-0001/77/M/W2	SCREENING	14FEB2012	09:00	4.4	ng/mL	.	Rise

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
205-0001/77/M/W2	WEEK 4	14MAR2012	09:00	3.4	ng/mL	22.73	
	WEEK 8	13APR2012	09:00	4.1	ng/mL	6.82	
	WEEK 12	08MAY2012	09:00	3.9	ng/mL	11.36	
	WEEK 16	08JUN2012	09:00	2.9	ng/mL	34.09	
	WEEK 20	06JUL2012	09:00	2.6	ng/mL	40.91	
	WEEK 24	06AUG2012	09:00	2.7	ng/mL	38.64	
	WEEK 28	31AUG2012	09:00	3.1	ng/mL	29.55	
	WEEK 32	28SEP2012	09:00	2.7	ng/mL	38.64	
	WEEK 36	23OCT2012	09:00	2.7	ng/mL	38.64	
	WEEK 40	20NOV2012	09:00	4	ng/mL	9.09	

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[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

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Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
205-0001/77/M/W2	WEEK 44	20DEC2012	09:00	4	ng/mL	9.09	
	WEEK 48	17JAN2013	09:00	5.1	ng/mL	-15.91	
	WEEK 52	13FEB2013	09:00	6.6	ng/mL	-50	
	WEEK 54	28FEB2013	09:00	5.9	ng/mL	-34.09	
	WEEK 56	13MAR2013	09:00	7.7	ng/mL	-75	
	WEEK 60	16APR2013	09:00	9	ng/mL	-104.55	
	WEEK 62	30APR2013	09:30	6.8	ng/mL	-54.55	
	WEEK 64	14MAY2013	09:30	9.1	ng/mL	-106.82	
	WEEK 66	28MAY2013	09:00	6.7	ng/mL	-52.27	
	WEEK 68	13JUN2013	09:00	7.1	ng/mL	-61.36	

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
205-0001/77/M/W2	WEEK 70	25JUN2013	09:30	6.2	ng/mL	-40.91	
	WEEK 72	09JUL2013	08:30	6.1	ng/mL	-38.64	
	WEEK 74	19JUL2013	09:30	7.1	ng/mL	-61.36	
	WEEK 78	26AUG2013	09:40	9	ng/mL	-104.55	
	WEEK 80	10SEP2013	09:00	9.2	ng/mL	-109.09	
	WEEK 82	24SEP2013	09:30	10.2	ng/mL	-131.82	
	END OF TREATMENT	12NOV2013	14:00	14.1	ng/mL	-220.45	
	Minimum Post-baseline	06JUL2012	09:00	2.6	ng/mL	40.91	
205-0004/77/F/W2	SCREENING	12MAR2012	09:00	697.6	ng/mL	.	Rise
	WEEK 4	12APR2012	09:00	3697.6	ng/mL	-430.05	

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
205-0004/77/F/W2	WEEK 8	10MAY2012	09:00	8717.7	ng/mL	-1149.67	
	WEEK 12	05JUN2012	09:00	20055.7	ng/mL	-2774.96	
	Minimum Post-baseline	12APR2012	09:00	3697.6	ng/mL	-430.05	
205-0008/76/M/W2	SCREENING	20APR2012	09:00	113787.4	ng/mL	.	Rise
	WEEK 4	17MAY2012	09:00	172722.2	ng/mL	-51.79	
	UNSCHEDULED	28MAY2012	09:00	246192.5	ng/mL	-116.36	
	END OF TREATMENT	12JUN2012	09:00	300000	ng/mL	-163.65	
	Minimum Post-baseline	17MAY2012	09:00	172722.2	ng/mL	-51.79	
205-0012/73/F/W2	SCREENING	27NOV2012	09:00	2649.5	ng/mL	.	Rise
	WEEK 4	27DEC2012	09:00	6062.4	ng/mL	-128.81	

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
205-0012/73/F/W2	Minimum Post-baseline	27DEC2012	09:00	6062.4	ng/mL	-128.81	
205-0015/71/M/W2	SCREENING	07JUN2013	07:30	26.2	ng/mL	.	Stable
	WEEK 4	12JUL2013	08:30	39	ng/mL	-48.85	
	WEEK 8	09AUG2013	10:30	35.9	ng/mL	-37.02	
	END OF TREATMENT	03SEP2013	08:30	35	ng/mL	-33.59	
	Minimum Post-baseline	03SEP2013	08:30	35	ng/mL	-33.59	
205-0016/70/M/W2	SCREENING	11JUN2013	08:30	13.1	ng/mL	.	Decline
	WEEK 4	19JUL2013	09:30	11.2	ng/mL	14.5	
	WEEK 12	20SEP2013	10:00	11.5	ng/mL	12.21	
	WEEK 16	17OCT2013	11:00	7.7	ng/mL	41.22	

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
205-0016/70/M/W2	WEEK 20	14NOV2013	14:00	8.5	ng/mL	35.11	
	WEEK 24	10DEC2013	10:45	8.3	ng/mL	36.64	
	WEEK 28	10JAN2014	11:00	7.2	ng/mL	45.04	
	WEEK 32	07FEB2014	11:15	7.3	ng/mL	44.27	
	WEEK 36	07MAR2014	10:30	6	ng/mL	54.2	
	WEEK 38	21MAR2014	10:30	6.6	ng/mL	49.62	
	WEEK 40	03APR2014	10:00	6.5	ng/mL	50.38	
	WEEK 44	29APR2014	09:30	6.4	ng/mL	51.15	
	WEEK 48	27MAY2014	10:15	6.7	ng/mL	48.85	
	WEEK 50	10JUN2014	10:30	6.6	ng/mL	49.62	

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
205-0016/70/M/W2	WEEK 52	24JUN2014	10:00	5.8	ng/mL	55.73	
	WEEK 56	22JUL2014	11:30	6.8	ng/mL	48.09	
	WEEK 60	11AUG2014	10:15	5.5	ng/mL	58.02	
	WEEK 64	11SEP2014	10:00	6.2	ng/mL	52.67	
	WEEK 68	09OCT2014	10:30	6.5	ng/mL	50.38	
	WEEK 72	06NOV2014	11:00	7.6	ng/mL	41.98	
	WEEK 76	04DEC2014	11:00	7.8	ng/mL	40.46	
	WEEK 78	18DEC2014	10:00	8	ng/mL	38.93	
	WEEK 80	30DEC2014	10:00	9.1	ng/mL	30.53	
	WEEK 84	29JAN2015	10:20	6.2	ng/mL	52.67	

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
205-0016/70/M/W2	WEEK 88	26FEB2015	10:50	5.7	ng/mL	56.49	
	WEEK 92	26MAR2015	11:00	8.2	ng/mL	37.4	
	WEEK 96	21APR2015	11:00	5.9	ng/mL	54.96	
	WEEK 100	21MAY2015	11:00	5.1	ng/mL	61.07	
	WEEK 104	18JUN2015	10:00	4.6	ng/mL	64.89	
	Minimum Post-baseline	18JUN2015	10:00	4.6	ng/mL	64.89	
205-0017/71/M/W2	SCREENING	02AUG2013	10:00	2596.4	ng/mL	.	Rise
	WEEK 4	26AUG2013	10:00	2509.3	ng/mL	3.35	
	WEEK 8	24SEP2013	09:00	2346	ng/mL	9.64	
	WEEK 12	25OCT2013	12:30	2598.9	ng/mL	-0.1	

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
205-0017/71/M/W2	WEEK 16	22NOV2013	09:30	3415.5	ng/mL	-31.55	
	WEEK 20	20DEC2013	09:15	4219.7	ng/mL	-62.52	
	WEEK 24	14JAN2014	08:45	5638.5	ng/mL	-117.17	
	END OF TREATMENT	18FEB2014	11:30	9672.6	ng/mL	-272.54	
	Minimum Post-baseline	24SEP2013	09:00	2346	ng/mL	9.64	
205-0020/82/M/W2	SCREENING	01OCT2013	09:30	19973.3	ng/mL	.	Rise
	WEEK 4	31OCT2013	11:30	23456.1	ng/mL	-17.44	
	WEEK 8	29NOV2013	09:30	27200	ng/mL	-36.18	
	WEEK 12	23DEC2013	09:00	33228.9	ng/mL	-66.37	
	Minimum Post-baseline	31OCT2013	11:30	23456.1	ng/mL	-17.44	

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
205-0022/67/M/W2	SCREENING	25OCT2013	10:00	23875.7	ng/mL	.	Stable
205-0024/80/M/W2	SCREENING	19NOV2013	09:45	2021.8	ng/mL	.	Rise
	WEEK 4	23DEC2013	11:00	4554.8	ng/mL	-125.28	
	WEEK 8	23JAN2014	12:30	4832.2	ng/mL	-139	
	WEEK 12	25FEB2014	12:00	8514.7	ng/mL	-321.14	
	END OF TREATMENT	18APR2014	09:00	14211.6	ng/mL	-602.92	
	Minimum Post-baseline	23DEC2013	11:00	4554.8	ng/mL	-125.28	
205-0025/63/F/W2	SCREENING	21NOV2013	12:30	5707.9	ng/mL	.	Rise
	WEEK 4	19DEC2013	10:00	5005.1	ng/mL	12.31	
	WEEK 8	14JAN2014	11:15	10210.3	ng/mL	-78.88	

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
205-0025/63/F/W2	WEEK 12	14FEB2014	10:30	11443.6	ng/mL	-100.49	
	Minimum Post-baseline	19DEC2013	10:00	5005.1	ng/mL	12.31	
207-0001/81/F/W2	SCREENING	08MAR2012	11:30	104.5	ng/mL	.	Rise
	TERMINATION	23APR2012	10:45	249.5	ng/mL	-138.76	
	Minimum Post-baseline	23APR2012	10:45	249.5	ng/mL	-138.76	
207-0005/74/M/W2	SCREENING	21MAY2012	13:30	66.5	ng/mL	.	Stable
	UNSCHEDULED	11JUN2012	13:15	65.1	ng/mL	2.11	
	Minimum Post-baseline	11JUN2012	13:15	65.1	ng/mL	2.11	
207-0006/73/M/W2	SCREENING	08JUN2012	11:30	25522.4	ng/mL	.	Rise
	WEEK 4	09JUL2012	09:30	45073.6	ng/mL	-76.6	

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
207-0006/73/M/W2	WEEK 8	13AUG2012	09:40	74886.9	ng/mL	-193.42	
	END OF TREATMENT	19SEP2012	11:30	142974.1	ng/mL	-460.19	
	Minimum Post-baseline	09JUL2012	09:30	45073.6	ng/mL	-76.6	
207-0008/66/M/W2	SCREENING	25JUN2012	12:00	2.7	ng/mL	.	Stable
	WEEK 4	13AUG2012	09:25	3.2	ng/mL	-18.52	
	Minimum Post-baseline	13AUG2012	09:25	3.2	ng/mL	-18.52	
207-0011/78/M/W2	SCREENING	09JAN2013	12:45	185.9	ng/mL	.	Stable
207-0015/77/M/W2	SCREENING	08AUG2013	11:20	31.1	ng/mL	.	Rise
	WEEK 4	03SEP2013	11:45	30.8	ng/mL	0.96	
	WEEK 8	01OCT2013	09:50	33.1	ng/mL	-6.43	

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
207-0015/77/M/W2	END OF TREATMENT	28NOV2013	10:00	47.1	ng/mL	-51.45	
	Minimum Post-baseline	03SEP2013	11:45	30.8	ng/mL	0.96	
207-0020/77/M/W2	SCREENING	11JUN2014	10:20	12331.1	ng/mL	.	Rise
	WEEK 4	09JUL2014	09:50	25804.5	ng/mL	-109.26	
	WEEK 8	06AUG2014	09:45	69982	ng/mL	-467.52	
	Minimum Post-baseline	09JUL2014	09:50	25804.5	ng/mL	-109.26	
207-0021/74/M/W2	SCREENING	11JUN2014	11:15	98.7	ng/mL	.	Rise
	WEEK 4	10JUL2014	11:30	145.6	ng/mL	-47.52	
	WEEK 8	07AUG2014	11:15	241.1	ng/mL	-144.28	
	WEEK 12	04SEP2014	11:00	246.7	ng/mL	-149.95	

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
207-0021/74/M/W2	WEEK 16	02OCT2014	11:30	380.1	ng/mL	-285.11	
	WEEK 20	30OCT2014	09:40	710.6	ng/mL	-619.96	
	WEEK 24	28NOV2014	13:00	950.4	ng/mL	-862.92	
	WEEK 28	29DEC2014	10:30	1629.3	ng/mL	-1550.76	
	WEEK 32	23JAN2015	09:30	2080.6	ng/mL	-2008	
	Minimum Post-baseline	10JUL2014	11:30	145.6	ng/mL	-47.52	
207-0022/74/M/W2	SCREENING	30JUN2014	10:45	649.3	ng/mL	.	Rise
	WEEK 8	28AUG2014	10:30	737.9	ng/mL	-13.65	
	TERMINATION	21OCT2014	10:00	1274.5	ng/mL	-96.29	
	Minimum Post-baseline	28AUG2014	10:30	737.9	ng/mL	-13.65	

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
208-0001/59/M/W2	SCREENING	14SEP2012	09:15	2.2	ng/mL	.	Stable
	WEEK 4	11OCT2012	08:30	2.7	ng/mL	-22.73	
	WEEK 8	07NOV2012	08:30	2.4	ng/mL	-9.09	
	WEEK 12	05DEC2012	08:50	2	ng/mL	9.09	
	WEEK 16	02JAN2013	08:20	1.9	ng/mL	13.64	
	WEEK 20	30JAN2013	08:40	2.3	ng/mL	-4.55	
	WEEK 24	01MAR2013	09:00	1.9	ng/mL	13.64	
	WEEK 28	27MAR2013	08:45	2.2	ng/mL	0	
	WEEK 32	24APR2013	09:00	1.9	ng/mL	13.64	
	WEEK 36	22MAY2013	08:30	2.1	ng/mL	4.55	

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
208-0001/59/M/W2	WEEK 40	19JUN2013	08:30	2.3	ng/mL	-4.55	
	WEEK 44	17JUL2013	08:30	2.3	ng/mL	-4.55	
	WEEK 48	19AUG2013	08:15	2.1	ng/mL	4.55	
	WEEK 52	11SEP2013	08:30	2.1	ng/mL	4.55	
	WEEK 56	09OCT2013	08:15	2	ng/mL	9.09	
	WEEK 60	06NOV2013	08:30	2.1	ng/mL	4.55	
	WEEK 64	04DEC2013	09:00	2.1	ng/mL	4.55	
	WEEK 68	02JAN2014	08:50	2.2	ng/mL	0	
	WEEK 72	29JAN2014	08:30	2.2	ng/mL	0	
	WEEK 76	26FEB2014	08:30	1.9	ng/mL	13.64	

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
208-0001/59/M/W2	WEEK 80	26MAR2014	08:40	2.1	ng/mL	4.55	
	WEEK 84	23APR2014	09:00	2.1	ng/mL	4.55	
	WEEK 86	07MAY2014	08:10	1.8	ng/mL	18.18	
	WEEK 88	21MAY2014	08:30	1.8	ng/mL	18.18	
	WEEK 90	04JUN2014	08:20	1.6	ng/mL	27.27	
	WEEK 92	18JUN2014	08:15	1.9	ng/mL	13.64	
	WEEK 94	02JUL2014	08:45	2.2	ng/mL	0	
	WEEK 96	16JUL2014	08:20	2.1	ng/mL	4.55	
	WEEK 100	13AUG2014	09:15	1.7	ng/mL	22.73	
	WEEK 104	10SEP2014	09:00	2.1	ng/mL	4.55	

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
208-0001/59/M/W2	WEEK 108	08OCT2014	08:20	2	ng/mL	9.09	
	WEEK 110	22OCT2014	08:15	2	ng/mL	9.09	
	WEEK 112	05NOV2014	08:30	1.8	ng/mL	18.18	
	WEEK 116	03DEC2014	09:40	1.8	ng/mL	18.18	
	WEEK 120	02JAN2015	08:30	2.2	ng/mL	0	
	WEEK 124	28JAN2015	08:15	2.2	ng/mL	0	
	WEEK 128	25FEB2015	08:30	2.3	ng/mL	-4.55	
	WEEK 132	25MAR2015	08:15	2	ng/mL	9.09	
	UNS CENTRAL LABS	17JUN2015	08:50	2.2	ng/mL	0	
	Minimum Post-baseline	04JUN2014	08:20	1.6	ng/mL	27.27	

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
208-0002/82/F/W2	SCREENING	14SEP2012	10:00	16255.9	ng/mL	.	Rise
	WEEK 4	11OCT2012	09:00	38079.7	ng/mL	-134.25	
	WEEK 8	07NOV2012	08:45	50737.6	ng/mL	-212.12	
	TERMINATION	12DEC2012	08:45	30641.1	ng/mL	-88.49	
	Minimum Post-baseline	12DEC2012	08:45	30641.1	ng/mL	-88.49	
208-0006/69/F/W2	SCREENING	19AUG2013	09:45	51.9	ng/mL	.	Rise
	WEEK 4	18SEP2013	09:00	58.8	ng/mL	-13.29	
	WEEK 8	16OCT2013	09:15	73.5	ng/mL	-41.62	
	WEEK 12	13NOV2013	08:45	97.7	ng/mL	-88.25	
	END OF TREATMENT	27DEC2013	08:45	162.2	ng/mL	-212.52	

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
208-0006/69/F/W2	Minimum Post-baseline	18SEP2013	09:00	58.8	ng/mL	-13.29	
208-0007/53/M/W2	SCREENING	23JUN2014	10:00	10.1	ng/mL	.	Stable
	WEEK 4	30JUL2014	08:30	6.4	ng/mL	36.63	
	WEEK 8	27AUG2014	08:20	7.1	ng/mL	29.7	
	WEEK 12	25SEP2014	08:30	10.1	ng/mL	0	
	END OF TREATMENT	08OCT2014	08:50	9.6	ng/mL	4.95	
	Minimum Post-baseline	30JUL2014	08:30	6.4	ng/mL	36.63	
209-0001/66/M/W2	SCREENING	08NOV2012	10:30	143825.2	ng/mL	.	Rise
	WEEK 4	06DEC2012	10:10	195219.1	ng/mL	-35.73	
	WEEK 8	03JAN2013	09:50	145672.4	ng/mL	-1.28	

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
209-0001/66/M/W2	WEEK 12	31JAN2013	10:15	254891	ng/mL	-77.22	
	TERMINATION	28FEB2013	10:30	240725.1	ng/mL	-67.37	
	Minimum Post-baseline	03JAN2013	09:50	145672.4	ng/mL	-1.28	
209-0004/74/M/W2	SCREENING	28MAR2013	10:15	41.3	ng/mL	.	Rise
	WEEK 4	30APR2013	09:15	42.9	ng/mL	-3.87	
	WEEK 8	30MAY2013	09:30	56.2	ng/mL	-36.08	
	WEEK 12	25JUN2013	10:45	73.7	ng/mL	-78.45	
	TERMINATION	02AUG2013	08:50	92.1	ng/mL	-123	
	Minimum Post-baseline	30APR2013	09:15	42.9	ng/mL	-3.87	
209-0008/66/M/W2	SCREENING	26JUN2013	07:45	420.4	ng/mL	.	Rise

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
209-0008/66/M/W2	WEEK 4	31JUL2013	09:30	1013.4	ng/mL	-141.06	
	WEEK 12	24SEP2013	09:00	5009.4	ng/mL	-1091.58	
	Minimum Post-baseline	31JUL2013	09:30	1013.4	ng/mL	-141.06	
209-0012/63/M/W2	SCREENING	26NOV2013	10:10	85.6	ng/mL	.	Rise
	WEEK 4	23DEC2013	09:00	193.5	ng/mL	-126.05	
	WEEK 8	22JAN2014	09:30	407	ng/mL	-375.47	
	WEEK 12	19FEB2014	09:00	1754	ng/mL	-1949.07	
	WEEK 16	19MAR2014	10:00	7786.8	ng/mL	-8996.73	
	WEEK 20	16APR2014	09:00	18326.5	ng/mL	-21309.46	
	WEEK 24	15MAY2014	10:00	24320.2	ng/mL	-28311.45	

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
209-0012/63/M/W2	TERMINATION	17JUN2014	11:15	57000.5	ng/mL	-66489.37	
	Minimum Post-baseline	23DEC2013	09:00	193.5	ng/mL	-126.05	
209-0013/52/M/W2	SCREENING	10DEC2013	09:00	4806.6	ng/mL	.	Rise
	WEEK 4	14JAN2014	09:30	6773.3	ng/mL	-40.92	
	WEEK 8	12FEB2014	09:35	6419.3	ng/mL	-33.55	
	WEEK 12	11MAR2014	11:05	9358.8	ng/mL	-94.71	
	WEEK 16	08APR2014	10:40	7736.4	ng/mL	-60.95	
	WEEK 20	07MAY2014	09:30	8114.4	ng/mL	-68.82	
	WEEK 24	04JUN2014	10:15	8267.7	ng/mL	-72.01	
	WEEK 28	02JUL2014	09:15	7490.5	ng/mL	-55.84	

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Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
209-0013/52/M/W2	WEEK 32	29JUL2014	10:15	8416.1	ng/mL	-75.09	
	WEEK 36	26AUG2014	09:40	8025.4	ng/mL	-66.97	
	TERMINATION	23SEP2014	09:00	7546.1	ng/mL	-56.99	
	Minimum Post-baseline	12FEB2014	09:35	6419.3	ng/mL	-33.55	
210-0001/67/M/W2	SCREENING	28AUG2013	09:30	30489.8	ng/mL	.	Decline
	WEEK 4	19SEP2013	09:30	1467.7	ng/mL	95.19	
	WEEK 8	17OCT2013	10:00	94.1	ng/mL	99.69	
	WEEK 12	14NOV2013	10:15	13.2	ng/mL	99.96	
	WEEK 16	12DEC2013	09:45	6.9	ng/mL	99.98	
	WEEK 20	09JAN2014	09:30	6.5	ng/mL	99.98	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
210-0001/67/M/W2	TERMINATION	13MAR2014	11:30	2.3	ng/mL	99.99	
	Minimum Post-baseline	13MAR2014	11:30	2.3	ng/mL	99.99	
210-0002/80/M/W2	SCREENING	02OCT2013	10:15	14	ng/mL	.	Decline
	WEEK 4	31OCT2013	10:10	10.5	ng/mL	25	
	WEEK 8	29NOV2013	10:10	11	ng/mL	21.43	
	WEEK 12	23DEC2013	09:30	9.5	ng/mL	32.14	
	WEEK 16	22JAN2014	09:15	8.1	ng/mL	42.14	
	WEEK 20	19FEB2014	09:30	8.3	ng/mL	40.71	
	WEEK 24	19MAR2014	09:15	7.6	ng/mL	45.71	
	WEEK 32	14MAY2014	09:30	8.8	ng/mL	37.14	

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
210-0002/80/M/W2	WEEK 36	12JUN2014	09:30	8.7	ng/mL	37.86	
	WEEK 38	25JUN2014	09:30	8.1	ng/mL	42.14	
	WEEK 40	07JUL2014	09:30	6.9	ng/mL	50.71	
	WEEK 44	06AUG2014	09:20	10.1	ng/mL	27.86	
	WEEK 46	20AUG2014	09:15	9.2	ng/mL	34.29	
	Minimum Post-baseline	07JUL2014	09:30	6.9	ng/mL	50.71	
210-0007/72/M/W2	SCREENING	03JUL2014	09:30	31.8	ng/mL	.	Decline
	WEEK 4	31JUL2014	09:15	41.9	ng/mL	-31.76	
	WEEK 8	28AUG2014	09:10	38.4	ng/mL	-20.75	
	WEEK 12	24SEP2014	09:30	38.6	ng/mL	-21.38	

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
210-0007/72/M/W2	WEEK 20	27NOV2014	09:45	27.7	ng/mL	12.89	
	WEEK 24	22DEC2014	10:10	16.2	ng/mL	49.06	
	WEEK 28	22JAN2015	09:45	13.9	ng/mL	56.29	
	WEEK 32	19FEB2015	10:40	13.2	ng/mL	58.49	
	WEEK 36	19MAR2015	09:45	11.7	ng/mL	63.21	
	WEEK 42	29APR2015	10:00	11.7	ng/mL	63.21	
	Minimum Post-baseline	29APR2015	10:00	11.7	ng/mL	63.21	
210-0009/49/F/W2	SCREENING	05NOV2014	09:30	1.6	ng/mL	.	Stable
	WEEK 4	03DEC2014	10:00	1.5	ng/mL	6.25	
	WEEK 8	29DEC2014	09:40	1.6	ng/mL	0	

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
210-0009/49/F/W2	WEEK 12	28JAN2015	10:00	1.1	ng/mL	31.25	
	Minimum Post-baseline	28JAN2015	10:00	1.1	ng/mL	31.25	
210-0011/73/M/W2	SCREENING	12NOV2014	09:30	2724.8	ng/mL	.	Rise
	WEEK 4	10DEC2014	10:00	3832.1	ng/mL	-40.64	
	WEEK 8	08JAN2015	10:15	4195.7	ng/mL	-53.98	
	Minimum Post-baseline	10DEC2014	10:00	3832.1	ng/mL	-40.64	
210-0012/47/F/W2	SCREENING	11DEC2014	09:30	27238.8	ng/mL	.	Rise
	WEEK 4	08JAN2015	09:35	62628.5	ng/mL	-129.92	
	WEEK 8	05FEB2015	09:55	65025	ng/mL	-138.72	
	WEEK 12	05MAR2015	09:40	126691	ng/mL	-365.11	

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
210-0012/47/F/W2	Minimum Post-baseline	08JAN2015	09:35	62628.5	ng/mL	-129.92	
210-0014/71/F/W2	SCREENING	15JAN2015	10:15	57.2	ng/mL	.	Rise
	WEEK 4	19FEB2015	10:35	98.5	ng/mL	-72.2	
	WEEK 8	19MAR2015	09:40	141.1	ng/mL	-146.68	
	WEEK 12	16APR2015	10:10	141	ng/mL	-146.5	
	Minimum Post-baseline	19FEB2015	10:35	98.5	ng/mL	-72.2	
251-0001/55/F/W2	SCREENING	23JUL2012	14:50	194	ng/mL	.	Rise
	WEEK 4	21AUG2012	12:00	329.5	ng/mL	-69.85	
	WEEK 8	18SEP2012	11:30	435	ng/mL	-124.23	
	WEEK 12	16OCT2012	12:00	349.8	ng/mL	-80.31	

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
251-0001/55/F/W2	Minimum Post-baseline	21AUG2012	12:00	329.5	ng/mL	-69.85	
252-0002/76/M/W2	SCREENING	21AUG2012	11:45	145.4	ng/mL	.	Stable
	WEEK 4	18SEP2012	11:55	85.3	ng/mL	41.33	
	UNSCHEDULED	06NOV2012	11:20	211.9	ng/mL	-45.74	
	Minimum Post-baseline	18SEP2012	11:55	85.3	ng/mL	41.33	
252-0003/68/M/W2	SCREENING	11DEC2012	14:00	7193.6	ng/mL	.	Rise
	WEEK 4	22JAN2013	10:10	12903.1	ng/mL	-79.37	
	WEEK 7	12FEB2013	10:20	12394.9	ng/mL	-72.3	
	WEEK 8	19FEB2013	10:15	13324.5	ng/mL	-85.23	
	WEEK 12	19MAR2013	09:30	29007.6	ng/mL	-303.24	

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[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
252-0003/68/M/W2	END OF TREATMENT	23APR2013	10:40	59757.2	ng/mL	-730.7	
	Minimum Post-baseline	12FEB2013	10:20	12394.9	ng/mL	-72.3	
252-0007/77/M/W2	SCREENING	11FEB2014	08:25	33088.3	ng/mL	.	Stable
252-0011/81/M/BL	SCREENING	18NOV2014	11:20	4.5	ng/mL	.	Rise
	WEEK 8	13JAN2015	08:15	5.7	ng/mL	-26.67	
	WEEK 12	10FEB2015	08:25	5.2	ng/mL	-15.56	
	WEEK 16	10MAR2015	12:00	5.3	ng/mL	-17.78	
	WEEK 20	07APR2015	09:00	6.3	ng/mL	-40	
	WEEK 24	05MAY2015	08:50	7.5	ng/mL	-66.67	
	WEEK 28	02JUN2015	08:10	8.2	ng/mL	-82.22	

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[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
252-0011/81/M/BL	WEEK 32	30JUN2015	08:10	9.5	ng/mL	-111.11	
	Minimum Post-baseline	10FEB2015	08:25	5.2	ng/mL	-15.56	
253-0002/63/M/W2	SCREENING	02MAR2012	13:45	226.1	ng/mL	.	Rise
	WEEK 4	30MAR2012	10:10	354.6	ng/mL	-56.83	
	WEEK 8	27APR2012	11:15	684.2	ng/mL	-202.61	
	TERMINATION	08JUN2012	11:30	3518.9	ng/mL	-1456.35	
	Minimum Post-baseline	30MAR2012	10:10	354.6	ng/mL	-56.83	
253-0010/76/M/W2	SCREENING	31MAY2013	10:30	22.3	ng/mL	.	Stable
	WEEK 4	28JUN2013	11:00	24.6	ng/mL	-10.31	
	WEEK 8	26JUL2013	11:30	26	ng/mL	-16.59	

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
253-0010/76/M/W2	WEEK 12	23AUG2013	11:00	25.1	ng/mL	-12.56	
	WEEK 16	20SEP2013	10:40	24.1	ng/mL	-8.07	
	WEEK 20	18OCT2013	10:30	26.7	ng/mL	-19.73	
	WEEK 24	18NOV2013	10:30	29.5	ng/mL	-32.29	
	TERMINATION	06DEC2013	11:30	29.3	ng/mL	-31.39	
	Minimum Post-baseline	20SEP2013	10:40	24.1	ng/mL	-8.07	
254-0001/69/M/W2	SCREENING	04MAY2012	12:15	1403.2	ng/mL	.	Decline
	WEEK 4	13JUN2012	12:30	1062.4	ng/mL	24.29	
	WEEK 8	10JUL2012	13:05	512.3	ng/mL	63.49	
	WEEK 12	06AUG2012	13:00	1938.6	ng/mL	-38.16	

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
254-0001/69/M/W2	END OF TREATMENT	24SEP2012	13:00	684.4	ng/mL	51.23	
	Minimum Post-baseline	10JUL2012	13:05	512.3	ng/mL	63.49	
257-0001/47/M/A4	SCREENING	29MAR2012	12:45	816.3	ng/mL	.	Decline
	WEEK 4	26APR2012	14:25	278.4	ng/mL	65.89	
	WEEK 8	24MAY2012	10:55	544.8	ng/mL	33.26	
	TERMINATION	28JUN2012	11:20	3209.5	ng/mL	-293.18	
	Minimum Post-baseline	26APR2012	14:25	278.4	ng/mL	65.89	
257-0002/56/M/W2	SCREENING	12APR2012	10:35	162637.8	ng/mL	.	Stable
257-0007/80/M/W2	SCREENING	13FEB2013	09:13	4.6	ng/mL	.	Stable
	UNSCHEDULED	21FEB2013	13:20	4.9	ng/mL	-6.52	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
257-0007/80/M/W2	WEEK 2	28FEB2013	12:00	5.5	ng/mL	-19.57	
	WEEK 4	14MAR2013	11:05	4.7	ng/mL	-2.17	
	WEEK 8	11APR2013	10:50	5.2	ng/mL	-13.04	
	WEEK 12	09MAY2013	11:20	5.4	ng/mL	-17.39	
	Minimum Post-baseline	14MAR2013	11:05	4.7	ng/mL	-2.17	
257-0008/80/F/W2	SCREENING	21MAR2013	13:15	3480.5	ng/mL	.	Decline
	WEEK 4	18APR2013	10:05	5157.5	ng/mL	-48.18	
	WEEK 8	16MAY2013	12:05	1275.6	ng/mL	63.35	
	WEEK 12	13JUN2013	12:50	103.3	ng/mL	97.03	
	Minimum Post-baseline	13JUN2013	12:50	103.3	ng/mL	97.03	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
257-0010/42/M/BL	SCREENING	16MAY2013	14:35	14.3	ng/mL	.	Stable
	WEEK 4	13JUN2013	12:40	13.3	ng/mL	6.99	
	WEEK 8	08JUL2013	14:13	12	ng/mL	16.08	
	WEEK 12	05AUG2013	14:12	14.4	ng/mL	-0.7	
	Minimum Post-baseline	08JUL2013	14:13	12	ng/mL	16.08	
257-0012/75/M/W2	SCREENING	09MAY2013	11:08	153.7	ng/mL	.	Rise
	WEEK 4	07JUN2013	11:24	331.4	ng/mL	-115.61	
	Minimum Post-baseline	07JUN2013	11:24	331.4	ng/mL	-115.61	
257-0015/69/F/BL	SCREENING	31MAR2014	13:57	89.5	ng/mL	.	Stable
257-0017/74/M/A8	SCREENING	28APR2014	14:20	1292.9	ng/mL	.	Rise

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
257-0017/74/M/A8	WEEK 4	27MAY2014	15:30	1620.7	ng/mL	-25.35	
	WEEK 8	23JUN2014	15:05	2110.8	ng/mL	-63.26	
	WEEK 12	21JUL2014	14:00	2548.8	ng/mL	-97.14	
	Minimum Post-baseline	27MAY2014	15:30	1620.7	ng/mL	-25.35	
257-0018/53/M/A6	SCREENING	17APR2014	11:00	38337.7	ng/mL	.	Rise
	WEEK 4	19MAY2014	14:20	60660	ng/mL	-58.23	
	Minimum Post-baseline	19MAY2014	14:20	60660	ng/mL	-58.23	
257-0022/60/M/W2	SCREENING	26NOV2014	11:35	38.6	ng/mL	.	Rise
	WEEK 4	22DEC2014	14:00	43.1	ng/mL	-11.66	
	WEEK 8	19JAN2015	15:20	54.4	ng/mL	-40.93	

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
257-0022/60/M/W2	UNSCHEDULED	26JAN2015	10:15	56.2	ng/mL	-45.6	
	TERMINATION	09FEB2015	16:00	60	ng/mL	-55.44	
	Minimum Post-baseline	22DEC2014	14:00	43.1	ng/mL	-11.66	
257-0024/75/M/W2	SCREENING	15DEC2014	13:20	300000	ng/mL	.	Stable
	WEEK 4	12JAN2015	13:30	300000	ng/mL	0	
	WEEK 8	09FEB2015	15:34	300000	ng/mL	0	
	Minimum Post-baseline	09FEB2015	15:34	300000	ng/mL	0	
257-0025/69/M/BL	SCREENING	15DEC2014	14:15	1712.3	ng/mL	.	Rise
	WEEK 4	12JAN2015	13:20	2302.1	ng/mL	-34.44	
	WEEK 8	09FEB2015	15:05	2667.5	ng/mL	-55.78	

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
257-0025/69/M/BL	UNSCHEDULED	16FEB2015	10:00	3846.2	ng/mL	-124.62	
	WEEK 12	09MAR2015	14:00	4668.9	ng/mL	-172.67	
	Minimum Post-baseline	12JAN2015	13:20	2302.1	ng/mL	-34.44	
257-0026/65/M/W2	SCREENING	12JAN2015	15:10	1351	ng/mL	.	Rise
	WEEK 4	09FEB2015	14:45	804.1	ng/mL	40.48	
	WEEK 12	09APR2015	09:45	3238.7	ng/mL	-139.73	
	Minimum Post-baseline	09FEB2015	14:45	804.1	ng/mL	40.48	
257-0027/52/M/A6	SCREENING	16JAN2015	10:45	35320	ng/mL	.	Stable
	WEEK 4	09FEB2015	15:00	31720	ng/mL	10.19	
	Minimum Post-baseline	09FEB2015	15:00	31720	ng/mL	10.19	

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
258-0005/64/M/OTH	SCREENING	31JUL2013	10:50	2.3	ng/mL	.	Rise
	WEEK 4	04SEP2013	11:15	2.7	ng/mL	-17.39	
	UNSCHEDULED	25SEP2013	11:15	4.2	ng/mL	-82.61	
	WEEK 8	02OCT2013	11:25	4.2	ng/mL	-82.61	
	TERMINATION	18OCT2013	12:15	3.5	ng/mL	-52.17	
	Minimum Post-baseline	04SEP2013	11:15	2.7	ng/mL	-17.39	
258-0007/74/M/W2	SCREENING	02OCT2013	12:28	247.4	ng/mL	.	Stable
	WEEK 4	01NOV2013	11:32	248	ng/mL	-0.24	
	Minimum Post-baseline	01NOV2013	11:32	248	ng/mL	-0.24	
258-0008/70/M/W2	SCREENING	06NOV2013	10:14	64595.2	ng/mL	.	Stable

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
258-0009/64/M/W2	SCREENING	16MAY2014	12:09	4	ng/mL	.	Rise
	WEEK 4	11JUN2014	10:05	4.4	ng/mL	-10	
	WEEK 8	09JUL2014	10:38	5.6	ng/mL	-40	
	WEEK 12	06AUG2014	10:40	3.7	ng/mL	7.5	
	WEEK 16	03SEP2014	10:45	3.6	ng/mL	10	
	WEEK 20	01OCT2014	10:25	3.8	ng/mL	5	
	WEEK 24	29OCT2014	11:43	5	ng/mL	-25	
	END OF TREATMENT	26NOV2014	11:25	9.5	ng/mL	-137.5	
	Minimum Post-baseline	03SEP2014	10:45	3.6	ng/mL	10	
258-0010/53/M/W2	SCREENING	30MAY2014	11:12	2.8	ng/mL	.	Stable

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
258-0010/53/M/W2	WEEK 4	25JUN2014	10:10	2.4	ng/mL	14.29	
	WEEK 8	21JUL2014	10:20	2.1	ng/mL	25	
	WEEK 12	20AUG2014	09:12	2.1	ng/mL	25	
	WEEK 16	17SEP2014	10:20	2	ng/mL	28.57	
	WEEK 20	16OCT2014	09:30	2	ng/mL	28.57	
	WEEK 24	12NOV2014	10:05	1.9	ng/mL	32.14	
	END OF TREATMENT	10DEC2014	11:32	2.2	ng/mL	21.43	
	Minimum Post-baseline	12NOV2014	10:05	1.9	ng/mL	32.14	
258-0012/66/F/W2	SCREENING	09JUL2014	10:30	10607.9	ng/mL	.	Stable
	WEEK 4	06AUG2014	12:15	11740.3	ng/mL	-10.68	

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
258-0012/66/F/W2	WEEK 8	03SEP2014	12:05	14559.3	ng/mL	-37.25	
	WEEK 12	01OCT2014	11:20	9776.9	ng/mL	7.83	
	END OF TREATMENT	12NOV2014	11:35	14706.2	ng/mL	-38.63	
	Minimum Post-baseline	01OCT2014	11:20	9776.9	ng/mL	7.83	
258-0015/65/M/W2	SCREENING	28NOV2014	09:33	2.2	ng/mL	.	Stable
	END OF TREATMENT	04FEB2015	10:20	2	ng/mL	9.09	
	Minimum Post-baseline	04FEB2015	10:20	2	ng/mL	9.09	
259-0001/68/F/W2	SCREENING	24MAY2013	09:15	23.8	ng/mL	.	Rise
	WEEK 4	26JUN2013	14:00	23.7	ng/mL	0.42	
	WEEK 8	24JUL2013	13:20	25.7	ng/mL	-7.98	

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
259-0001/68/F/W2	WEEK 12	21AUG2013	13:50	28.9	ng/mL	-21.43	
	WEEK 20	16OCT2013	13:20	34.8	ng/mL	-46.22	
	WEEK 28	11DEC2013	11:40	35.8	ng/mL	-50.42	
	WEEK 32	08JAN2014	11:00	38.8	ng/mL	-63.03	
	WEEK 36	05FEB2014	10:15	42.6	ng/mL	-78.99	
	WEEK 40	05MAR2014	13:00	55.1	ng/mL	-131.51	
	WEEK 48	30APR2014	10:45	78.3	ng/mL	-228.99	
	WEEK 52	28MAY2014	10:50	86.4	ng/mL	-263.03	
	END OF TREATMENT	23JUL2014	12:10	94.4	ng/mL	-296.64	
	Minimum Post-baseline	26JUN2013	14:00	23.7	ng/mL	0.42	

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
259-0002/54/F/W2	SCREENING	04SEP2013	12:45	6385.2	ng/mL	.	Rise
	WEEK 4	02OCT2013	11:56	10213.7	ng/mL	-59.96	
	WEEK 8	30OCT2013	12:05	16342.3	ng/mL	-155.94	
	WEEK 12	27NOV2013	11:30	35172.2	ng/mL	-450.84	
	END OF TREATMENT	02JAN2014	11:00	79060.7	ng/mL	-1138.19	
	Minimum Post-baseline	02OCT2013	11:56	10213.7	ng/mL	-59.96	
260-0003/81/M/A7	SCREENING	22OCT2014	14:00	6.7	ng/mL	.	Stable
	WEEK 4	26NOV2014	10:50	6.4	ng/mL	4.48	
	WEEK 8	22DEC2014	11:30	8	ng/mL	-19.4	
	WEEK 12	21JAN2015	11:30	5.7	ng/mL	14.93	

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
260-0003/81/M/A7	WEEK 16	18FEB2015	11:00	4.6	ng/mL	31.34	
	WEEK 20	18MAR2015	11:00	6.7	ng/mL	0	
	WEEK 24	15APR2015	10:30	6.6	ng/mL	1.49	
	WEEK 28	13MAY2015	10:30	7.1	ng/mL	-5.97	
	Minimum Post-baseline	18FEB2015	11:00	4.6	ng/mL	31.34	
301-0005/61/M/A2	SCREENING	17MAY2012	10:00	61.95	ng/mL	.	Rise
	WEEK 4	14JUN2012	10:05	119.28	ng/mL	-92.54	
	WEEK 8	12JUL2012	10:00	195.89	ng/mL	-216.21	
	WEEK 12	09AUG2012	09:20	380.75	ng/mL	-514.61	
	END OF TREATMENT	11SEP2012	10:00	749.5	ng/mL	-1109.85	

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
301-0005/61/M/A2	Minimum Post-baseline	14JUN2012	10:05	119.28	ng/mL	-92.54	
301-0007/55/F/A2	SCREENING	26DEC2012	09:35	47.08	ng/mL	.	Rise
	WEEK 4	25JAN2013	10:10	144.83	ng/mL	-207.63	
	WEEK 8	22FEB2013	09:56	261.43	ng/mL	-455.29	
	Minimum Post-baseline	25JAN2013	10:10	144.83	ng/mL	-207.63	
301-0009/55/M/A2	SCREENING	08JAN2013	09:45	1717.05	ng/mL	.	Rise
	WEEK 4	31JAN2013	09:55	3287.74	ng/mL	-91.48	
	WEEK 8	01MAR2013	09:45	39884.88	ng/mL	-2222.87	
	WEEK 12	28MAR2013	10:00	368935.5	ng/mL	-21386.59	
	Minimum Post-baseline	31JAN2013	09:55	3287.74	ng/mL	-91.48	

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
302-0002/32/F/A2	SCREENING	03NOV2011	11:00	17005.2	ng/mL	.	Rise
	WEEK 4	29NOV2011	10:50	31525.37	ng/mL	-85.39	
	Minimum Post-baseline	29NOV2011	10:50	31525.37	ng/mL	-85.39	
302-0004/57/M/A2	SCREENING	04JAN2012	09:15	32135.74	ng/mL	.	Stable
	WEEK 4	01FEB2012	09:15	34662.02	ng/mL	-7.86	
	WEEK 8	28FEB2012	09:15	40002.9	ng/mL	-24.48	
	Minimum Post-baseline	01FEB2012	09:15	34662.02	ng/mL	-7.86	
302-0007/76/M/A2	SCREENING	08FEB2012	08:44	533.68	ng/mL	.	Rise
	WEEK 4	06MAR2012	09:00	720.18	ng/mL	-34.95	
	WEEK 8	03APR2012	09:10	1161.44	ng/mL	-117.63	

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
302-0007/76/M/A2	WEEK 12	01MAY2012	08:35	2718.3	ng/mL	-409.35	
	END OF TREATMENT	12JUN2012	09:35	2479.68	ng/mL	-364.64	
	Minimum Post-baseline	06MAR2012	09:00	720.18	ng/mL	-34.95	
302-0008/37/M/A2	SCREENING	23FEB2012	09:12	5.62	ng/mL	.	Decline
	WEEK 4	20MAR2012	09:30	2.09	ng/mL	62.81	
	WEEK 8	17APR2012	09:20	13.58	ng/mL	-141.64	
	END OF TREATMENT	19JUN2012	09:00	2.25	ng/mL	59.96	
	Minimum Post-baseline	20MAR2012	09:30	2.09	ng/mL	62.81	
302-0010/45/M/A2	SCREENING	12APR2012	10:35	178.45	ng/mL	.	Decline
	WEEK 4	08MAY2012	09:15	81.81	ng/mL	54.16	

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
302-0010/45/M/A2	WEEK 8	05JUN2012	09:20	133.78	ng/mL	25.03	
	WEEK 12	03JUL2012	08:55	166.36	ng/mL	6.78	
	END OF TREATMENT	06AUG2012	09:40	556	ng/mL	-211.57	
	Minimum Post-baseline	08MAY2012	09:15	81.81	ng/mL	54.16	
302-0011/52/M/A2	SCREENING	17APR2012	11:02	40272.22	ng/mL	.	Rise
	WEEK 4	15MAY2012	09:25	192060.69	ng/mL	-376.91	
	Minimum Post-baseline	15MAY2012	09:25	192060.69	ng/mL	-376.91	
302-0015/60/M/A2	SCREENING	11APR2013	08:40	123162.75	ng/mL	.	Decline
	WEEK 4	07MAY2013	08:55	60462.11	ng/mL	50.91	
	WEEK 8	04JUN2013	09:10	82359.75	ng/mL	33.13	

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
302-0015/60/M/A2	WEEK 12	02JUL2013	08:40	78960.79	ng/mL	35.89	
	Minimum Post-baseline	07MAY2013	08:55	60462.11	ng/mL	50.91	
302-0016/60/M/A2	SCREENING	11APR2013	09:05	98590.5	ng/mL	.	Rise
	WEEK 4	07MAY2013	08:50	192105.75	ng/mL	-94.85	
	WEEK 8	04JUN2013	09:05	146378.25	ng/mL	-48.47	
	WEEK 12	02JUL2013	08:40	159394.16	ng/mL	-61.67	
	Minimum Post-baseline	04JUN2013	09:05	146378.25	ng/mL	-48.47	
302-0019/52/M/A2	SCREENING	09MAY2013	09:15	82.16	ng/mL	.	Decline
	WEEK 4	04JUN2013	09:15	45.83	ng/mL	44.22	
	WEEK 8	02JUL2013	09:10	32.2	ng/mL	60.81	

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
302-0019/52/M/A2	WEEK 12	30JUL2013	09:15	23.84	ng/mL	70.98	
	END OF TREATMENT	29AUG2013	09:20	17.71	ng/mL	78.44	
	Minimum Post-baseline	29AUG2013	09:20	17.71	ng/mL	78.44	
302-0022/65/M/A2	SCREENING	04JUL2013	09:05	17897	ng/mL	.	Rise
	WEEK 4	30JUL2013	09:30	25873.86	ng/mL	-44.57	
	WEEK 8	27AUG2013	09:00	36813.49	ng/mL	-105.7	
	UNSCHEDULED	04OCT2013	08:36	30326.6	ng/mL	-69.45	
	Minimum Post-baseline	30JUL2013	09:30	25873.86	ng/mL	-44.57	
302-0023/68/M/A2	SCREENING	03SEP2013	10:39	11.78	ng/mL	.	Stable
	WEEK 4	01OCT2013	08:44	12.99	ng/mL	-10.27	

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
302-0023/68/M/A2	END OF TREATMENT	14NOV2013	09:54	14.04	ng/mL	-19.19	
	Minimum Post-baseline	01OCT2013	08:44	12.99	ng/mL	-10.27	
302-0024/66/F/A2	SCREENING	17SEP2013	15:41	19.27	ng/mL	.	Rise
	WEEK 4	15OCT2013	08:43	29.35	ng/mL	-52.31	
	WEEK 8	12NOV2013	08:38	37.74	ng/mL	-95.85	
	WEEK 12	10DEC2013	08:45	59.68	ng/mL	-209.7	
	Minimum Post-baseline	15OCT2013	08:43	29.35	ng/mL	-52.31	
302-0025/40/M/A2	SCREENING	17OCT2013	10:05	14937.5	ng/mL	.	Rise
	END OF TREATMENT	10DEC2013	08:38	32360.1	ng/mL	-116.64	
	Minimum Post-baseline	10DEC2013	08:38	32360.1	ng/mL	-116.64	

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
302-0026/49/M/A2	SCREENING	05NOV2013	11:50	9360.06	ng/mL	.	Rise
	WEEK 4	03DEC2013	09:28	10873.3	ng/mL	-16.17	
	WEEK 8	31DEC2013	09:02	14399.6	ng/mL	-53.84	
	WEEK 12	28JAN2014	10:16	14519.7	ng/mL	-55.12	
	WEEK 16	25FEB2014	09:11	12109.3	ng/mL	-29.37	
	WEEK 20	25MAR2014	09:38	20438.5	ng/mL	-118.36	
	WEEK 24	22APR2014	09:38	23836	ng/mL	-154.66	
	WEEK 28	22MAY2014	09:33	31015.39	ng/mL	-231.36	
	WEEK 32	17JUN2014	10:00	44060.9	ng/mL	-370.73	
	WEEK 36	15JUL2014	09:09	61738.7	ng/mL	-559.6	

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Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
302-0026/49/M/A2	END OF TREATMENT	14AUG2014	09:31	65958.9	ng/mL	-604.68	
	Minimum Post-baseline	03DEC2013	09:28	10873.3	ng/mL	-16.17	
303-0001/50/M/A2	SCREENING	20JAN2012	09:20	241.97	ng/mL	.	Stable
	WEEK 4	22FEB2012	13:25	189.73	ng/mL	21.59	
	WEEK 8	21MAR2012	14:30	252.86	ng/mL	-4.5	
	WEEK 12	18APR2012	13:00	270.44	ng/mL	-11.77	
	END OF TREATMENT	18MAY2012	09:25	282.85	ng/mL	-16.89	
	Minimum Post-baseline	22FEB2012	13:25	189.73	ng/mL	21.59	
303-0003/47/M/A2	SCREENING	14NOV2012	10:15	12564.71	ng/mL	.	Rise
	WEEK 4	19DEC2012	10:30	17175.83	ng/mL	-36.7	

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[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
303-0003/47/M/A2	WEEK 8	16JAN2013	10:00	17475.92	ng/mL	-39.09	
	WEEK 12	15FEB2013	14:00	26546.07	ng/mL	-111.27	
	UNS CENTRAL LABS	22FEB2013	15:30	37617.19	ng/mL	-199.39	
	END OF TREATMENT	19MAR2013	10:20	51436.4	ng/mL	-309.37	
	Minimum Post-baseline	19DEC2012	10:30	17175.83	ng/mL	-36.7	
303-0004/18/M/A2	SCREENING	26NOV2012	14:50	341901	ng/mL	.	Rise
	WEEK 4	02JAN2013	14:00	349137	ng/mL	-2.12	
	WEEK 8	30JAN2013	13:30	406723.5	ng/mL	-18.96	
	WEEK 12	27FEB2013	13:50	541092	ng/mL	-58.26	
	END OF TREATMENT	27MAR2013	14:40	734956.5	ng/mL	-114.96	

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
303-0004/18/M/A2	Minimum Post-baseline	02JAN2013	14:00	349137	ng/mL	-2.12	
303-0006/64/M/A2	SCREENING	27MAR2013	15:10	529.97	ng/mL	.	Rise
	WEEK 4	01MAY2013	13:30	1330.25	ng/mL	-151	
	WEEK 8	29MAY2013	13:25	3368	ng/mL	-535.51	
	END OF TREATMENT	19JUN2013	14:20	4714.26	ng/mL	-789.53	
	Minimum Post-baseline	01MAY2013	13:30	1330.25	ng/mL	-151	
303-0007/50/M/A2	SCREENING	10JUL2013	14:35	26798.17	ng/mL	.	Rise
	WEEK 4	14AUG2013	13:30	45355.86	ng/mL	-69.25	
	WEEK 8	11SEP2013	13:25	69511.15	ng/mL	-159.39	
	Minimum Post-baseline	14AUG2013	13:30	45355.86	ng/mL	-69.25	

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
304-0001/54/M/A2	SCREENING	30OCT2012	10:30	1625.37	ng/mL	.	Rise
	WEEK 4	27NOV2012	11:00	4243.6	ng/mL	-161.09	
	END OF TREATMENT	07JAN2013	09:40	27701.82	ng/mL	-1604.34	
	Minimum Post-baseline	27NOV2012	11:00	4243.6	ng/mL	-161.09	
304-0005/58/M/A2	SCREENING	30MAY2013	11:16	5683.61	ng/mL	.	Stable
	WEEK 4	26JUN2013	08:30	5000.5	ng/mL	12.02	
	Minimum Post-baseline	26JUN2013	08:30	5000.5	ng/mL	12.02	
305-0002/57/M/A2	SCREENING	13FEB2012	09:15	36806.09	ng/mL	.	Stable
305-0003/50/M/A2	SCREENING	14FEB2012	15:25	149.28	ng/mL	.	Rise
	WEEK 4	09MAR2012	09:00	290.76	ng/mL	-94.77	

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
305-0003/50/M/A2	WEEK 8	06APR2012	09:00	344.93	ng/mL	-131.06	
	WEEK 12	04MAY2012	09:00	393.35	ng/mL	-163.5	
	WEEK 16	01JUN2012	08:45	252.57	ng/mL	-69.19	
	WEEK 20	29JUN2012	08:52	257.08	ng/mL	-72.21	
	WEEK 24	27JUL2012	08:32	254.42	ng/mL	-70.43	
	END OF TREATMENT	24AUG2012	09:10	296.89	ng/mL	-98.88	
	Minimum Post-baseline	01JUN2012	08:45	252.57	ng/mL	-69.19	
305-0005/48/M/A2	SCREENING	15FEB2012	11:35	444.41	ng/mL	.	Rise
	WEEK 4	15MAR2012	09:09	1426.66	ng/mL	-221.02	
	Minimum Post-baseline	15MAR2012	09:09	1426.66	ng/mL	-221.02	

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
305-0006/65/M/A2	SCREENING	07MAR2012	09:20	168.61	ng/mL	.	Rise
	WEEK 4	28MAR2012	12:15	145.65	ng/mL	13.62	
	WEEK 8	25APR2012	12:30	463.84	ng/mL	-175.1	
	WEEK 12	23MAY2012	12:09	408.51	ng/mL	-142.28	
	WEEK 16	19JUN2012	12:25	1195.5	ng/mL	-609.03	
	WEEK 20	18JUL2012	12:40	2613.65	ng/mL	-1450.12	
	WEEK 24	15AUG2012	12:40	4015.26	ng/mL	-2281.39	
	UNSCHEDULED	27AUG2012	13:19	5324.4	ng/mL	-3057.82	
	Minimum Post-baseline	28MAR2012	12:15	145.65	ng/mL	13.62	
305-0009/45/F/A2	SCREENING	11APR2012	09:30	5.14	ng/mL	.	Stable

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
305-0009/45/F/A2	WEEK 4	01MAY2012	11:50	4.36	ng/mL	15.18	
	WEEK 8	30MAY2012	11:53	4.6	ng/mL	10.51	
	WEEK 12	27JUN2012	12:20	4.18	ng/mL	18.68	
	WEEK 16	25JUL2012	12:50	4.16	ng/mL	19.07	
	WEEK 20	22AUG2012	13:00	4.18	ng/mL	18.68	
	WEEK 24	19SEP2012	13:05	4.07	ng/mL	20.82	
	END OF TREATMENT	17OCT2012	12:53	4.36	ng/mL	15.18	
	Minimum Post-baseline	19SEP2012	13:05	4.07	ng/mL	20.82	
305-0010/64/F/A2	SCREENING	16APR2012	11:20	653.77	ng/mL	.	Rise
	WEEK 4	08MAY2012	12:40	1217.32	ng/mL	-86.2	

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
305-0010/64/F/A2	WEEK 8	05JUN2012	13:35	2603.9	ng/mL	-298.29	
	WEEK 12	04JUL2012	13:00	3825.05	ng/mL	-485.08	
	END OF TREATMENT	07AUG2012	12:07	9584.36	ng/mL	-1366.01	
	Minimum Post-baseline	08MAY2012	12:40	1217.32	ng/mL	-86.2	
305-0011/68/M/A2	SCREENING	20APR2012	12:00	349.4	ng/mL	.	Stable
	WEEK 4	18MAY2012	08:20	512.11	ng/mL	-46.57	
	WEEK 8	15JUN2012	07:50	442.27	ng/mL	-26.58	
	WEEK 12	13JUL2012	07:20	481.63	ng/mL	-37.84	
	WEEK 16	10AUG2012	07:50	460.36	ng/mL	-31.76	
	Minimum Post-baseline	15JUN2012	07:50	442.27	ng/mL	-26.58	

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Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
305-0012/62/F/A2	SCREENING	03MAY2012	15:10	85.95	ng/mL	.	Rise
	WEEK 4	25MAY2012	08:20	80.53	ng/mL	6.31	
	WEEK 8	22JUN2012	08:20	49.58	ng/mL	42.32	
	WEEK 12	20JUL2012	09:02	122.12	ng/mL	-42.08	
	WEEK 16	17AUG2012	07:42	767.24	ng/mL	-792.66	
	WEEK 20	14SEP2012	08:11	1314.73	ng/mL	-1429.65	
	WEEK 24	12OCT2012	07:56	1632.18	ng/mL	-1798.99	
	WEEK 28	09NOV2012	07:55	1920.13	ng/mL	-2134.01	
	WEEK 32	07DEC2012	07:40	1878.65	ng/mL	-2085.75	
	WEEK 36	04JAN2013	07:55	2182.03	ng/mL	-2438.72	

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Serum Alpha Fetoprotein Response
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Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
305-0012/62/F/A2	END OF TREATMENT	01FEB2013	10:40	2936.43	ng/mL	-3316.44	
	Minimum Post-baseline	22JUN2012	08:20	49.58	ng/mL	42.32	
305-0014/61/F/A2	SCREENING	04JUL2012	08:00	421.78	ng/mL	.	Rise
	WEEK 4	31JUL2012	11:30	515.86	ng/mL	-22.31	
	WEEK 8	28AUG2012	12:22	882.15	ng/mL	-109.15	
	WEEK 12	25SEP2012	12:09	1765.63	ng/mL	-318.61	
	END OF TREATMENT	23OCT2012	15:30	3537.14	ng/mL	-738.62	
	Minimum Post-baseline	31JUL2012	11:30	515.86	ng/mL	-22.31	
305-0019/35/M/A2	SCREENING	05SEP2012	10:33	12868.05	ng/mL	.	Rise
	WEEK 4	02OCT2012	11:55	39543.76	ng/mL	-207.3	

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Serum Alpha Fetoprotein Response
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Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
305-0019/35/M/A2	WEEK 8	30OCT2012	12:33	24482.8	ng/mL	-90.26	
	Minimum Post-baseline	30OCT2012	12:33	24482.8	ng/mL	-90.26	
305-0023/54/M/A2	SCREENING	02JAN2013	09:45	31091.48	ng/mL	.	Rise
	WEEK 4	29JAN2013	12:10	44505.42	ng/mL	-43.14	
	WEEK 8	26FEB2013	12:09	94168.5	ng/mL	-202.88	
	WEEK 12	29MAR2013	07:40	158388	ng/mL	-409.43	
	WEEK 16	25APR2013	08:10	215673	ng/mL	-593.67	
	END OF TREATMENT	11JUN2013	12:00	357863.2	ng/mL	-1051	
	Minimum Post-baseline	29JAN2013	12:10	44505.42	ng/mL	-43.14	
305-0025/77/F/A2	SCREENING	15JAN2013	14:40	3.5	ng/mL	.	Rise

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Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
305-0025/77/F/A2	WEEK 4	15FEB2013	12:15	3.25	ng/mL	7.14	
	WEEK 8	12MAR2013	11:45	2.76	ng/mL	21.14	
	UNSCHEDULED	07APR2013	11:52	5.5	ng/mL	-57.14	
	WEEK 12	09APR2013	10:50	4.36	ng/mL	-24.57	
	Minimum Post-baseline	12MAR2013	11:45	2.76	ng/mL	21.14	
305-0026/45/M/A2	SCREENING	21FEB2013	11:30	38.33	ng/mL	.	Stable
	WEEK 4	19MAR2013	12:40	39.09	ng/mL	-1.98	
	WEEK 8	16APR2013	13:00	36.42	ng/mL	4.98	
	WEEK 12	14MAY2013	13:05	37.77	ng/mL	1.46	
	WEEK 20	09JUL2013	13:05	55.97	ng/mL	-46.02	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
305-0026/45/M/A2	WEEK 24	06AUG2013	13:00	30.17	ng/mL	21.29	
	Minimum Post-baseline	06AUG2013	13:00	30.17	ng/mL	21.29	
305-0028/73/F/A2	SCREENING	13MAR2013	14:00	441.77	ng/mL	.	Decline
	WEEK 4	03APR2013	13:00	576.92	ng/mL	-30.59	
	WEEK 8	30APR2013	13:22	436.97	ng/mL	1.09	
	WEEK 12	29MAY2013	12:50	148.96	ng/mL	66.28	
	Minimum Post-baseline	29MAY2013	12:50	148.96	ng/mL	66.28	
305-0030/61/M/A2	SCREENING	28MAR2013	10:00	273.58	ng/mL	.	Decline
	WEEK 4	23APR2013	12:00	118.91	ng/mL	56.54	
	UNSCHEDULED	27MAY2013	05:22	114.4	ng/mL	58.18	

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
305-0030/61/M/A2	Minimum Post-baseline	27MAY2013	05:22	114.4	ng/mL	58.18	
305-0031/29/M/A2	SCREENING	26MAR2013	17:58	2.37	ng/mL	.	Stable
	WEEK 4	26APR2013	09:33	2.36	ng/mL	0.42	
	Minimum Post-baseline	26APR2013	09:33	2.36	ng/mL	0.42	
305-0034/53/M/A2	SCREENING	26JUN2013	15:15	84395.07	ng/mL	.	Rise
	WEEK 4	22JUL2013	11:20	165890.81	ng/mL	-96.56	
	UNSCHEDULED	01AUG2013	14:34	156969.2	ng/ml	-85.99	
	Minimum Post-baseline	01AUG2013	14:34	156969.2	ng/ml	-85.99	
305-0036/38/M/A2	SCREENING	27AUG2013	15:03	289	ng/mL	.	Stable
	WEEK 4	26SEP2013	08:30	211.71	ng/mL	26.74	

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
305-0036/38/M/A2	WEEK 8	24OCT2013	08:15	244.04	ng/mL	15.56	
	WEEK 12	19NOV2013	09:32	156.49	ng/mL	45.85	
	Minimum Post-baseline	19NOV2013	09:32	156.49	ng/mL	45.85	
305-0037/50/M/A2	SCREENING	17OCT2013	15:07	376.78	ng/mL	.	Stable
	WEEK 4	14NOV2013	09:00	465.16	ng/mL	-23.46	
	WEEK 8	12DEC2013	09:07	552.55	ng/mL	-46.65	
	WEEK 12	09JAN2014	09:20	486.8	ng/mL	-29.2	
	END OF TREATMENT	11FEB2014	10:30	366.02	ng/mL	2.86	
	Minimum Post-baseline	11FEB2014	10:30	366.02	ng/mL	2.86	
305-0039/35/M/A2	SCREENING	22NOV2013	15:25	264.5	ng/mL	.	Stable

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
305-0039/35/M/A2	WEEK 4	19DEC2013	10:50	388.35	ng/mL	-46.82	
	Minimum Post-baseline	19DEC2013	10:50	388.35	ng/mL	-46.82	
305-0040/61/M/A2	SCREENING	11NOV2013	08:57	1504.43	ng/mL	.	Stable
305-0043/70/M/A2	SCREENING	27JUN2014	09:00	1266.28	ng/mL	.	Rise
	WEEK 4	22JUL2014	13:00	1291.45	ng/mL	-1.99	
	WEEK 8	19AUG2014	13:00	1577.02	ng/mL	-24.54	
	WEEK 12	16SEP2014	10:51	2538.46	ng/mL	-100.47	
	END OF TREATMENT	17OCT2014	12:50	2040.08	ng/mL	-61.11	
	Minimum Post-baseline	22JUL2014	13:00	1291.45	ng/mL	-1.99	
305-0044/67/M/A2	SCREENING	01JUL2014	16:30	83.59	ng/mL	.	Rise

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
305-0044/67/M/A2	WEEK 4	29JUL2014	12:35	123.58	ng/mL	-47.84	
	WEEK 8	26AUG2014	12:50	185.33	ng/mL	-121.71	
	WEEK 12	26SEP2014	13:00	343.07	ng/mL	-310.42	
	Minimum Post-baseline	29JUL2014	12:35	123.58	ng/mL	-47.84	
305-0045/65/M/A2	SCREENING	06OCT2014	08:06	1022847.2	ng/mL	.	Stable
	WEEK 4	07NOV2014	07:43	1167075.2	ng/mL	-14.1	
	Minimum Post-baseline	07NOV2014	07:43	1167075.2	ng/mL	-14.1	
305-0047/58/M/A2	SCREENING	24DEC2014	09:30	826.59	ng/mL	.	Stable
	WEEK 4	14JAN2015	12:55	949.79	ng/mL	-14.9	
	Minimum Post-baseline	14JAN2015	12:55	949.79	ng/mL	-14.9	

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[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
305-0048/55/M/A2	SCREENING	10FEB2015	15:10	13.43	ng/mL	.	Rise
	WEEK 4	20MAR2015	12:50	9.84	ng/mL	26.73	
	WEEK 8	14APR2015	12:30	14.48	ng/mL	-7.82	
	WEEK 12	12MAY2015	13:07	20.5	ng/mL	-52.64	
	END OF TREATMENT	18JUN2015	10:00	21.33	ng/mL	-58.82	
	Minimum Post-baseline	20MAR2015	12:50	9.84	ng/mL	26.73	
306-0001/56/M/A2	SCREENING	13FEB2012	08:30	343.6	ng/mL	.	Rise
	WEEK 4	09MAR2012	13:30	528.78	ng/mL	-53.89	
	WEEK 8	06APR2012	13:30	818.35	ng/mL	-138.17	
	WEEK 12	04MAY2012	09:00	817.5	ng/mL	-137.92	

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
306-0001/56/M/A2	Minimum Post-baseline	09MAR2012	13:30	528.78	ng/mL	-53.89	
306-0002/73/M/A2	SCREENING	09FEB2012	09:30	1590	ng/mL	.	Rise
	WEEK 4	06MAR2012	09:30	4693.36	ng/mL	-195.18	
	WEEK 8	03APR2012	08:30	10972.55	ng/mL	-590.1	
	WEEK 12	30APR2012	15:00	26915.59	ng/mL	-1592.8	
	END OF TREATMENT	22MAY2012	08:30	17309.88	ng/mL	-988.67	
	Minimum Post-baseline	06MAR2012	09:30	4693.36	ng/mL	-195.18	
306-0005/69/F/A2	SCREENING	22FEB2012	10:30	1990.75	ng/mL	.	Rise
	WEEK 4	16MAR2012	09:00	8659.91	ng/mL	-335.01	
	WEEK 8	13APR2012	09:00	18804.52	ng/mL	-844.59	

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
306-0005/69/F/A2	END OF TREATMENT	25MAY2012	09:10	41615.46	ng/mL	-1990.44	
	Minimum Post-baseline	16MAR2012	09:00	8659.91	ng/mL	-335.01	
306-0006/43/M/A2	SCREENING	13MAR2012	10:00	49619.35	ng/mL	.	Rise
	WEEK 4	10APR2012	13:00	150344.09	ng/mL	-202.99	
	Minimum Post-baseline	10APR2012	13:00	150344.09	ng/mL	-202.99	
306-0007/56/M/A2	SCREENING	01MAR2012	10:30	952.6	ng/mL	.	Rise
	WEEK 4	26MAR2012	13:30	2539.74	ng/mL	-166.61	
	Minimum Post-baseline	26MAR2012	13:30	2539.74	ng/mL	-166.61	
306-0008/40/M/A2	SCREENING	07MAR2012	10:30	667621.5	ng/mL	.	Rise
	WEEK 4	02APR2012	09:00	845205	ng/mL	-26.6	

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
306-0008/40/M/A2	WEEK 8	30APR2012	09:00	1529811	ng/mL	-129.14	
	Minimum Post-baseline	02APR2012	09:00	845205	ng/mL	-26.6	
306-0011/47/M/A2	SCREENING	13MAR2012	13:30	12.1	ng/mL	.	Stable
	WEEK 4	05APR2012	10:00	13.68	ng/mL	-13.06	
	WEEK 8	03MAY2012	10:00	11.56	ng/mL	4.46	
	WEEK 12	30MAY2012	10:00	12.61	ng/mL	-4.21	
	Minimum Post-baseline	03MAY2012	10:00	11.56	ng/mL	4.46	
306-0012/61/M/A2	SCREENING	29MAR2012	10:06	141.57	ng/mL	.	Rise
	WEEK 4	25APR2012	10:30	164.17	ng/mL	-15.96	
	WEEK 8	21MAY2012	09:00	198.87	ng/mL	-40.47	

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
306-0012/61/M/A2	WEEK 12	19JUN2012	09:00	241.02	ng/mL	-70.25	
	WEEK 16	17JUL2012	09:40	437.26	ng/mL	-208.86	
	WEEK 20	13AUG2012	09:35	681.9	ng/mL	-381.67	
	WEEK 24	11SEP2012	09:15	774.3	ng/mL	-446.94	
	END OF TREATMENT	16OCT2012	09:00	1007.64	ng/mL	-611.76	
	Minimum Post-baseline	25APR2012	10:30	164.17	ng/mL	-15.96	
306-0014/47/M/A2	SCREENING	13APR2012	11:00	5764.64	ng/mL	.	Rise
	WEEK 4	11MAY2012	08:30	22893.37	ng/mL	-297.13	
	Minimum Post-baseline	11MAY2012	08:30	22893.37	ng/mL	-297.13	
306-0017/49/M/A2	SCREENING	09JUL2012	09:00	1850.84	ng/mL	.	Stable

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
306-0017/49/M/A2	WEEK 4	02AUG2012	09:00	2626.24	ng/mL	-41.89	
	END OF TREATMENT	27SEP2012	08:50	2687.45	ng/mL	-45.2	
	Minimum Post-baseline	02AUG2012	09:00	2626.24	ng/mL	-41.89	
306-0019/78/M/A2	SCREENING	20AUG2012	09:10	425.07	ng/mL	.	Rise
	WEEK 4	13SEP2012	10:00	567.92	ng/mL	-33.61	
	WEEK 8	08OCT2012	08:20	755.13	ng/mL	-77.65	
	WEEK 12	05NOV2012	08:20	1305.71	ng/mL	-207.18	
	END OF TREATMENT	03DEC2012	08:20	1778.28	ng/mL	-318.35	
	Minimum Post-baseline	13SEP2012	10:00	567.92	ng/mL	-33.61	
306-0020/63/M/A2	SCREENING	27SEP2012	08:20	40.18	ng/mL	.	Rise

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
306-0020/63/M/A2	WEEK 4	25OCT2012	09:00	83.53	ng/mL	-107.89	
	WEEK 8	22NOV2012	09:00	81.6	ng/mL	-103.09	
	WEEK 12	20DEC2012	09:30	115.18	ng/mL	-186.66	
	END OF TREATMENT	21JAN2013	09:00	92.27	ng/mL	-129.64	
	Minimum Post-baseline	22NOV2012	09:00	81.6	ng/mL	-103.09	
306-0023/68/M/A2	SCREENING	20NOV2012	09:00	18.1	ng/mL	.	Rise
	WEEK 4	18DEC2012	11:00	63.84	ng/mL	-252.71	
	END OF TREATMENT	06FEB2013	10:00	180.01	ng/mL	-894.53	
	Minimum Post-baseline	18DEC2012	11:00	63.84	ng/mL	-252.71	
306-0026/58/M/A2	SCREENING	24JAN2013	10:00	82332.25	ng/mL	.	Decline

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
306-0026/58/M/A2	WEEK 4	25FEB2013	13:50	66598.04	ng/mL	19.11	
	WEEK 8	28MAR2013	09:00	37146.81	ng/mL	54.88	
	WEEK 12	25APR2013	08:30	16347.15	ng/mL	80.14	
	WEEK 16	23MAY2013	09:00	1257.92	ng/mL	98.47	
	WEEK 20	20JUN2013	09:30	281.14	ng/mL	99.66	
	WEEK 24	18JUL2013	09:00	202.13	ng/mL	99.75	
	WEEK 28	15AUG2013	09:00	137.73	ng/mL	99.83	
	WEEK 32	12SEP2013	09:00	206.58	ng/mL	99.75	
	WEEK 36	08OCT2013	08:30	224.05	ng/mL	99.73	
	END OF TREATMENT	07NOV2013	08:50	259	ng/mL	99.69	

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
306-0026/58/M/A2	Minimum Post-baseline	15AUG2013	09:00	137.73	ng/mL	99.83	
306-0027/67/M/A2	SCREENING	06FEB2013	13:00	826.53	ng/mL	.	Rise
	WEEK 4	13MAR2013	10:00	921.97	ng/mL	-11.55	
	WEEK 8	10APR2013	09:30	1011.61	ng/mL	-22.39	
	WEEK 12	08MAY2013	09:30	826.03	ng/mL	0.06	
	WEEK 16	05JUN2013	09:30	1150.31	ng/mL	-39.17	
	WEEK 20	03JUL2013	09:30	1242.94	ng/mL	-50.38	
	WEEK 24	31JUL2013	10:00	1464.69	ng/mL	-77.21	
	WEEK 28	28AUG2013	10:00	1709.39	ng/mL	-106.82	
	WEEK 32	25SEP2013	09:00	1797.23	ng/mL	-117.44	

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
306-0027/67/M/A2	WEEK 36	23OCT2013	09:00	1577.88	ng/mL	-90.9	
	WEEK 40	20NOV2013	09:30	1555.14	ng/mL	-88.15	
	WEEK 44	18DEC2013	09:30	1526.6	ng/mL	-84.7	
	WEEK 48	15JAN2014	09:30	1448.78	ng/mL	-75.28	
	WEEK 52	12FEB2014	09:00	1280.87	ng/mL	-54.97	
	WEEK 56	12MAR2014	09:30	1098.5	ng/mL	-32.91	
	WEEK 60	09APR2014	09:30	1106.31	ng/mL	-33.85	
	WEEK 64	07MAY2014	09:40	1062.86	ng/mL	-28.59	
	WEEK 68	06JUN2014	09:40	922.2	ng/mL	-11.57	
	WEEK 72	02JUL2014	09:30	805.22	ng/mL	2.58	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
306-0027/67/M/A2	END OF TREATMENT	06AUG2014	09:30	991.12	ng/mL	-19.91	
	Minimum Post-baseline	02JUL2014	09:30	805.22	ng/mL	2.58	
306-0030/63/M/A2	SCREENING	12APR2013	11:30	5.01	ng/mL	.	Stable
	WEEK 4	14MAY2013	09:00	5.71	ng/mL	-13.97	
	Minimum Post-baseline	14MAY2013	09:00	5.71	ng/mL	-13.97	
306-0031/40/M/A2	SCREENING	07MAY2013	11:00	1909.99	ng/mL	.	Rise
	WEEK 4	05JUN2013	09:30	2027.02	ng/mL	-6.13	
	WEEK 8	03JUL2013	09:30	3094.33	ng/mL	-62.01	
	END OF TREATMENT	20AUG2013	10:00	4655.24	ng/mL	-143.73	
	Minimum Post-baseline	05JUN2013	09:30	2027.02	ng/mL	-6.13	

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
306-0034/65/M/A2	SCREENING	20JUN2013	10:30	7838.56	ng/mL	.	Stable
	WEEK 4	25JUL2013	13:30	10703.02	ng/mL	-36.54	
	Minimum Post-baseline	25JUL2013	13:30	10703.02	ng/mL	-36.54	
306-0035/48/M/A2	SCREENING	27JUN2013	10:00	14.2	ng/mL	.	Rise
	WEEK 4	29JUL2013	08:40	24.76	ng/mL	-74.37	
	WEEK 8	26AUG2013	09:00	58.33	ng/mL	-310.77	
	END OF TREATMENT	23SEP2013	09:00	185.74	ng/mL	-1208.03	
	Minimum Post-baseline	29JUL2013	08:40	24.76	ng/mL	-74.37	
306-0036/73/M/A2	SCREENING	02JUL2013	10:00	14.81	ng/mL	.	Rise
	WEEK 4	30JUL2013	08:40	33.18	ng/mL	-124.04	

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
306-0036/73/M/A2	WEEK 8	27AUG2013	08:30	209.8	ng/mL	-1316.61	
	END OF TREATMENT	24SEP2013	08:30	554.06	ng/mL	-3641.12	
	Minimum Post-baseline	30JUL2013	08:40	33.18	ng/mL	-124.04	
306-0038/66/M/A2	SCREENING	09AUG2013	13:30	503.57	ng/mL	.	Rise
	WEEK 4	11SEP2013	08:30	621.05	ng/mL	-23.33	
	WEEK 8	09OCT2013	08:30	1287.43	ng/mL	-155.66	
	WEEK 12	06NOV2013	08:30	2719.55	ng/mL	-440.05	
	END OF TREATMENT	03DEC2013	08:30	3979.8	ng/mL	-690.32	
	Minimum Post-baseline	11SEP2013	08:30	621.05	ng/mL	-23.33	
306-0039/62/M/A2	SCREENING	09AUG2013	13:30	17105.77	ng/mL	.	Decline

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
306-0039/62/M/A2	WEEK 4	10SEP2013	09:00	14191.07	ng/mL	17.04	
	WEEK 8	08OCT2013	08:30	12925.1	ng/mL	24.44	
	WEEK 12	05NOV2013	08:30	10803.83	ng/mL	36.84	
	END OF TREATMENT	03DEC2013	08:30	2662.59	ng/mL	84.43	
	Minimum Post-baseline	03DEC2013	08:30	2662.59	ng/mL	84.43	
306-0040/44/F/A2	SCREENING	17SEP2013	10:00	35725.72	ng/mL	.	Rise
	WEEK 4	15OCT2013	10:00	48332.54	ng/mL	-35.29	
	WEEK 8	12NOV2013	09:30	43849.12	ng/mL	-22.74	
	WEEK 12	12DEC2013	10:00	82412.97	ng/mL	-130.68	
	WEEK 16	07JAN2014	09:30	124189	ng/mL	-247.62	

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[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
306-0040/44/F/A2	WEEK 20	07FEB2014	12:00	125351.83	ng/mL	-250.87	
	WEEK 24	04MAR2014	10:30	338430.8	ng/mL	-847.3	
	END OF TREATMENT	08APR2014	10:30	143468.48	ng/mL	-301.58	
	Minimum Post-baseline	12NOV2013	09:30	43849.12	ng/mL	-22.74	
306-0041/62/M/A2	SCREENING	18OCT2013	10:30	1.77	ng/mL	.	Rise
	WEEK 4	22NOV2013	09:30	2.91	ng/mL	-64.41	
	WEEK 8	20DEC2013	08:30	2.79	ng/mL	-57.63	
	WEEK 12	17JAN2014	09:00	2.22	ng/mL	-25.42	
	WEEK 16	11FEB2014	09:30	1.69	ng/mL	4.52	
	UNSCHEDULED	21FEB2014	10:36	2	ng/mL	-12.99	

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
306-0041/62/M/A2	Minimum Post-baseline	11FEB2014	09:30	1.69	ng/mL	4.52	
306-0043/56/M/A2	SCREENING	08MAY2014	10:30	767.77	ng/mL	.	Stable
	WEEK 4	09JUN2014	09:20	615.04	ng/mL	19.89	
	WEEK 8	10JUL2014	09:00	484.56	ng/mL	36.89	
	WEEK 12	04AUG2014	09:00	455.19	ng/mL	40.71	
	END OF TREATMENT	04SEP2014	09:00	457.2	ng/mL	40.45	
	Minimum Post-baseline	04AUG2014	09:00	455.19	ng/mL	40.71	
307-0002/61/M/A2	SCREENING	31OCT2011	10:30	323.19	ng/mL	.	Rise
	WEEK 4	25NOV2011	11:05	498.29	ng/mL	-54.18	
	WEEK 8	22DEC2011	10:25	753.87	ng/mL	-133.26	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

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Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
307-0002/61/M/A2	WEEK 12	19JAN2012	13:26	1323.1	ng/mL	-309.39	
	END OF TREATMENT	21FEB2012	12:00	3197.16	ng/mL	-889.25	
	Minimum Post-baseline	25NOV2011	11:05	498.29	ng/mL	-54.18	
307-0003/68/M/A2	SCREENING	08NOV2011	08:00	8.69	ng/mL	.	Rise
	WEEK 4	29NOV2011	09:10	8.9	ng/mL	-2.42	
	WEEK 8	27DEC2011	10:45	7.43	ng/mL	14.5	
	WEEK 12	27JAN2012	08:45	5.8	ng/mL	33.26	
	WEEK 16	21FEB2012	08:46	5.12	ng/mL	41.08	
	WEEK 20	20MAR2012	08:14	5.61	ng/mL	35.44	
	WEEK 24	16APR2012	09:50	7.88	ng/mL	9.32	

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Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
307-0003/68/M/A2	WEEK 28	15MAY2012	10:25	20.01	ng/mL	-130.26	
	WEEK 32	14JUN2012	10:25	46.13	ng/mL	-430.84	
	WEEK 36	10JUL2012	10:25	57.61	ng/mL	-562.95	
	END OF TREATMENT	17AUG2012	11:00	77.15	ng/mL	-787.8	
	Minimum Post-baseline	21FEB2012	08:46	5.12	ng/mL	41.08	
307-0004/60/M/A2	SCREENING	08NOV2011	09:09	5829.3	ng/mL	.	Rise
	WEEK 4	29NOV2011	09:20	14557.48	ng/mL	-149.73	
	WEEK 8	27DEC2011	08:35	25463.71	ng/mL	-336.82	
	Minimum Post-baseline	29NOV2011	09:20	14557.48	ng/mL	-149.73	
307-0008/58/M/A2	SCREENING	13DEC2011	08:30	1614.74	ng/mL	.	Rise

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Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
307-0008/58/M/A2	WEEK 4	10JAN2012	08:54	1552.36	ng/mL	3.86	
	WEEK 8	07FEB2012	08:40	2585.33	ng/mL	-60.11	
	WEEK 12	08MAR2012	08:40	3654.21	ng/mL	-126.3	
	END OF TREATMENT	27MAR2012	08:40	13596.34	ng/mL	-742.01	
	Minimum Post-baseline	10JAN2012	08:54	1552.36	ng/mL	3.86	
307-0011/75/M/A2	SCREENING	31JAN2012	11:55	5.28	ng/mL	.	Stable
	WEEK 4	29FEB2012	08:54	3.57	ng/mL	32.39	
	Minimum Post-baseline	29FEB2012	08:54	3.57	ng/mL	32.39	
307-0014/61/M/A2	SCREENING	14FEB2012	09:13	45994.88	ng/mL	.	Decline
	WEEK 4	08MAR2012	08:30	78.47	ng/mL	99.83	

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Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
307-0014/61/M/A2	WEEK 8	05APR2012	13:30	186.91	ng/mL	99.59	
	WEEK 12	03MAY2012	13:40	683.57	ng/mL	98.51	
	WEEK 16	31MAY2012	13:23	686.32	ng/mL	98.51	
	WEEK 20	28JUN2012	13:28	691.83	ng/mL	98.5	
	WEEK 24	26JUL2012	09:09	718.55	ng/mL	98.44	
	END OF TREATMENT	28AUG2012	08:33	1107.43	ng/mL	97.59	
	Minimum Post-baseline	08MAR2012	08:30	78.47	ng/mL	99.83	
307-0018/70/M/A2	SCREENING	11JUN2012	09:40	23.88	ng/mL	.	Decline
	WEEK 4	05JUL2012	14:00	21.52	ng/mL	9.88	
	WEEK 8	03AUG2012	10:30	26.87	ng/mL	-12.52	

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Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
307-0018/70/M/A2	WEEK 12	30AUG2012	09:45	23.71	ng/mL	0.71	
	WEEK 16	27SEP2012	08:52	22.42	ng/mL	6.11	
	WEEK 20	25OCT2012	08:50	17.13	ng/mL	28.27	
	WEEK 24	22NOV2012	09:20	15.69	ng/mL	34.3	
	WEEK 28	20DEC2012	09:07	16.39	ng/mL	31.37	
	WEEK 32	17JAN2013	08:42	17.69	ng/mL	25.92	
	WEEK 36	14FEB2013	09:18	15.81	ng/mL	33.79	
	WEEK 40	14MAR2013	08:34	15.15	ng/mL	36.56	
	WEEK 44	11APR2013	08:55	13.64	ng/mL	42.88	
	WEEK 48	09MAY2013	09:25	12.66	ng/mL	46.98	

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(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
307-0018/70/M/A2	END OF TREATMENT	10JUN2013	08:50	3.18	ng/mL	86.68	
	Minimum Post-baseline	10JUN2013	08:50	3.18	ng/mL	86.68	
307-0020/68/F/A2	SCREENING	14AUG2012	10:20	24.5	ng/mL	.	Rise
	WEEK 4	04SEP2012	11:15	26.02	ng/mL	-6.2	
	WEEK 8	02OCT2012	11:10	60.33	ng/mL	-146.24	
	WEEK 12	30OCT2012	10:08	152.66	ng/mL	-523.1	
	Minimum Post-baseline	04SEP2012	11:15	26.02	ng/mL	-6.2	
307-0022/59/M/A2	SCREENING	21NOV2012	09:25	3174.64	ng/mL	.	Rise
	UNS CENTRAL LABS	23NOV2012	10:20	3214.62	ng/mL	-1.26	
	WEEK 4	17DEC2012	10:10	11178.97	ng/mL	-252.13	

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Serum Alpha Fetoprotein Response
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Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
307-0022/59/M/A2	WEEK 8	14JAN2013	08:31	16674.5	ng/mL	-425.24	
	WEEK 12	14FEB2013	09:53	24731.04	ng/mL	-679.02	
	END OF TREATMENT	18MAR2013	12:15	39534.69	ng/mL	-1145.33	
	Minimum Post-baseline	23NOV2012	10:20	3214.62	ng/mL	-1.26	
307-0025/68/M/A2	SCREENING	13DEC2012	10:00	915.4	ng/mL	.	Rise
	WEEK 4	10JAN2013	09:55	893.95	ng/mL	2.34	
	WEEK 8	05FEB2013	12:00	1039.01	ng/mL	-13.5	
	WEEK 12	07MAR2013	09:40	1387.62	ng/mL	-51.59	
	WEEK 16	03APR2013	09:50	1354.22	ng/mL	-47.94	
	WEEK 20	02MAY2013	09:15	1601.43	ng/mL	-74.94	

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307-0025/68/M/A2	WEEK 24	30MAY2013	10:10	1512.94	ng/mL	-65.28	
	Minimum Post-baseline	10JAN2013	09:55	893.95	ng/mL	2.34	
307-0026/65/M/A2	SCREENING	25DEC2012	10:00	323.59	ng/mL	.	Rise
	WEEK 4	15JAN2013	09:00	409.09	ng/mL	-26.42	
	WEEK 8	14FEB2013	09:10	503.59	ng/mL	-55.63	
	WEEK 12	12MAR2013	09:50	548.88	ng/mL	-69.62	
	WEEK 16	09APR2013	08:20	649.51	ng/mL	-100.72	
	WEEK 20	07MAY2013	08:32	1029.16	ng/mL	-218.04	
	WEEK 24	04JUN2013	11:05	2869.76	ng/mL	-786.85	
	Minimum Post-baseline	15JAN2013	09:00	409.09	ng/mL	-26.42	

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307-0030/53/M/A2	SCREENING	01MAR2013	09:35	77133.75	ng/mL	.	Rise
	WEEK 4	25MAR2013	09:36	150850.5	ng/mL	-95.57	
	WEEK 8	22APR2013	12:07	152659.5	ng/mL	-97.92	
	Minimum Post-baseline	25MAR2013	09:36	150850.5	ng/mL	-95.57	
307-0031/60/M/A2	SCREENING	12MAR2013	11:55	11667.7	ng/mL	.	Rise
	WEEK 4	03APR2013	09:15	13040.4	ng/mL	-11.76	
	WEEK 8	02MAY2013	09:25	11266.36	ng/mL	3.44	
	WEEK 12	30MAY2013	10:26	12403.76	ng/mL	-6.31	
	WEEK 16	27JUN2013	09:15	13367.35	ng/mL	-14.57	
	WEEK 20	25JUL2013	10:30	22523.11	ng/mL	-93.04	

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Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
307-0031/60/M/A2	WEEK 24	22AUG2013	10:25	34962.35	ng/mL	-199.65	
	WEEK 28	17SEP2013	11:57	63168.43	ng/mL	-441.4	
	WEEK 32	17OCT2013	09:18	140744.51	ng/mL	-1106.27	
	WEEK 36	14NOV2013	09:40	320250.8	ng/mL	-2644.76	
	Minimum Post-baseline	02MAY2013	09:25	11266.36	ng/mL	3.44	
307-0032/74/F/A2	SCREENING	09APR2013	13:40	2.59	ng/mL	.	Stable
	WEEK 4	02MAY2013	13:20	2.09	ng/mL	19.31	
	Minimum Post-baseline	02MAY2013	13:20	2.09	ng/mL	19.31	
307-0037/61/M/A2	SCREENING	30SEP2013	09:53	92.93	ng/mL	.	Rise
	WEEK 4	24OCT2013	13:13	148.22	ng/mL	-59.5	

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[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
307-0037/61/M/A2	END OF TREATMENT	14NOV2013	10:34	193.45	ng/mL	-108.17	
	Minimum Post-baseline	24OCT2013	13:13	148.22	ng/mL	-59.5	
307-0039/51/M/A2	SCREENING	31OCT2013	11:14	41.47	ng/mL	.	Rise
	WEEK 4	27NOV2013	09:15	135.51	ng/mL	-226.77	
	WEEK 8	23DEC2013	09:05	301.96	ng/mL	-628.14	
	WEEK 12	21JAN2014	10:13	531.4	ng/mL	-1181.41	
	END OF TREATMENT	25FEB2014	08:55	1581.45	ng/mL	-3713.48	
	Minimum Post-baseline	27NOV2013	09:15	135.51	ng/mL	-226.77	
307-0040/65/M/A2	SCREENING	22MAY2014	09:35	13493.21	ng/mL	.	Stable
	WEEK 4	17JUN2014	13:40	17174.56	ng/mL	-27.28	

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[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
307-0040/65/M/A2	Minimum Post-baseline	17JUN2014	13:40	17174.56	ng/mL	-27.28	
307-0043/54/M/A2	SCREENING	20JUN2014	11:10	33480.69	ng/mL	.	Rise
	WEEK 4	15JUL2014	08:59	40888.02	ng/mL	-22.12	
	WEEK 8	12AUG2014	09:04	63528.32	ng/mL	-89.75	
	WEEK 12	09SEP2014	09:30	105226.13	ng/mL	-214.29	
	WEEK 16	08OCT2014	09:04	180696.34	ng/mL	-439.7	
	Minimum Post-baseline	15JUL2014	08:59	40888.02	ng/mL	-22.12	
307-0044/53/M/A2	SCREENING	23JUN2014	09:45	1021.9	ng/mL	.	Rise
	END OF TREATMENT	07AUG2014	11:15	2117.13	ng/mL	-107.18	
	Minimum Post-baseline	07AUG2014	11:15	2117.13	ng/mL	-107.18	

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
307-0045/48/M/A2	SCREENING	30JUN2014	12:30	31.62	ng/mL	.	Rise
	WEEK 4	28JUL2014	11:15	150.01	ng/mL	-374.41	
	WEEK 8	25AUG2014	09:55	406.38	ng/mL	-1185.2	
	WEEK 12	22SEP2014	10:43	1232.42	ng/mL	-3797.6	
	Minimum Post-baseline	28JUL2014	11:15	150.01	ng/mL	-374.41	
307-0046/46/M/A2	SCREENING	08JUL2014	13:12	3126.31	ng/mL	.	Stable
	END OF TREATMENT	19AUG2014	15:00	2797.7	ng/mL	10.51	
	Minimum Post-baseline	19AUG2014	15:00	2797.7	ng/mL	10.51	
308-0003/54/M/A2	SCREENING	24JAN2013	14:00	3855.14	ng/mL	.	Rise
	WEEK 4	19FEB2013	09:05	3092.71	ng/mL	19.78	

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
308-0003/54/M/A2	WEEK 8	19MAR2013	09:10	2212.38	ng/mL	42.61	
	WEEK 12	16APR2013	09:30	2278.46	ng/mL	40.9	
	WEEK 16	14MAY2013	09:25	4278.99	ng/mL	-10.99	
	WEEK 20	11JUN2013	09:30	6740.74	ng/mL	-74.85	
	WEEK 24	09JUL2013	09:05	7255.36	ng/mL	-88.2	
	UNSCHEDULED	08AUG2013	08:33	7728	ng/mL	-100.46	
	WEEK 32	03SEP2013	09:00	8079.14	ng/mL	-109.57	
	WEEK 36	01OCT2013	12:20	7086.21	ng/mL	-83.81	
	Minimum Post-baseline	19MAR2013	09:10	2212.38	ng/mL	42.61	
308-0005/68/F/A2	SCREENING	24APR2013	11:00	35158.69	ng/mL	.	Rise

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
308-0005/68/F/A2	WEEK 4	21MAY2013	09:05	60646.7	ng/mL	-72.49	
	WEEK 8	18JUN2013	08:55	77767.97	ng/mL	-121.19	
	WEEK 12	16JUL2013	09:00	167553.95	ng/mL	-376.56	
	END OF TREATMENT	15AUG2013	13:00	247672.2	ng/mL	-604.44	
	Minimum Post-baseline	21MAY2013	09:05	60646.7	ng/mL	-72.49	
309-0001/46/M/A2	SCREENING	29MAY2012	13:00	64.35	ng/mL	.	Rise
	WEEK 4	02JUL2012	16:00	129.41	ng/mL	-101.1	
	WEEK 8	30JUL2012	15:35	261.06	ng/mL	-305.69	
	WEEK 12	27AUG2012	16:10	390.18	ng/mL	-506.34	
	END OF TREATMENT	24SEP2012	16:15	478.93	ng/mL	-644.26	

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
309-0001/46/M/A2	Minimum Post-baseline	02JUL2012	16:00	129.41	ng/mL	-101.1	
309-0002/56/M/A2	SCREENING	04JUN2012	10:35	295671	ng/mL	.	Stable
309-0003/52/F/A2	SCREENING	11JUN2012	10:50	8608.83	ng/mL	.	Rise
	WEEK 4	11JUL2012	10:30	14754.28	ng/mL	-71.39	
	WEEK 8	08AUG2012	10:10	25875.47	ng/mL	-200.57	
	WEEK 12	05SEP2012	10:30	26335.4	ng/mL	-205.91	
	END OF TREATMENT	01OCT2012	12:35	16120.99	ng/mL	-87.26	
	Minimum Post-baseline	11JUL2012	10:30	14754.28	ng/mL	-71.39	
309-0004/55/M/A2	SCREENING	14JUN2012	11:50	386.42	ng/mL	.	Stable
309-0008/38/M/A2	SCREENING	08FEB2013	11:50	3207.35	ng/mL	.	Stable

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
309-0008/38/M/A2	WEEK 4	14MAR2013	09:45	1883.02	ng/mL	41.29	
	WEEK 8	11APR2013	09:30	2464.63	ng/mL	23.16	
	WEEK 12	09MAY2013	09:30	2334.99	ng/mL	27.2	
	Minimum Post-baseline	14MAR2013	09:45	1883.02	ng/mL	41.29	
309-0010/47/M/A2	SCREENING	13MAR2013	11:35	4.97	ng/mL	.	Stable
	WEEK 4	15APR2013	12:35	4.2	ng/mL	15.49	
	WEEK 8	13MAY2013	13:10	3.99	ng/mL	19.72	
	WEEK 12	10JUN2013	11:10	3.18	ng/mL	36.02	
	WEEK 16	08JUL2013	09:20	3.35	ng/mL	32.6	
	WEEK 20	05AUG2013	10:20	3.35	ng/mL	32.6	

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
309-0010/47/M/A2	WEEK 24	02SEP2013	09:15	3.41	ng/mL	31.39	
	WEEK 28	30SEP2013	10:25	4.66	ng/mL	6.24	
	WEEK 32	28OCT2013	10:05	5.12	ng/mL	-3.02	
	WEEK 36	25NOV2013	09:30	5.21	ng/mL	-4.83	
	WEEK 40	23DEC2013	09:58	4.71	ng/mL	5.23	
	WEEK 44	20JAN2014	11:20	4.34	ng/mL	12.68	
	WEEK 48	17FEB2014	09:40	4.21	ng/mL	15.29	
	WEEK 52	17MAR2014	09:45	4.36	ng/mL	12.27	
	WEEK 56	14APR2014	09:30	3.77	ng/mL	24.14	
	WEEK 60	12MAY2014	09:50	3.41	ng/mL	31.39	

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
309-0010/47/M/A2	WEEK 64	09JUN2014	10:50	3.48	ng/mL	29.98	
	WEEK 68	07JUL2014	09:44	3.55	ng/mL	28.57	
	WEEK 72	04AUG2014	09:50	2.99	ng/mL	39.84	
	WEEK 76	01SEP2014	10:15	3.1	ng/mL	37.63	
	WEEK 80	29SEP2014	10:12	3.52	ng/mL	29.18	
	WEEK 84	27OCT2014	09:55	3.87	ng/mL	22.13	
	END OF TREATMENT	24NOV2014	09:40	4.01	ng/mL	19.32	
	Minimum Post-baseline	04AUG2014	09:50	2.99	ng/mL	39.84	
309-0011/59/M/A2	SCREENING	28MAR2013	15:10	546.87	ng/mL	.	Rise
	WEEK 4	29APR2013	14:50	887.42	ng/mL	-62.27	

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
309-0011/59/M/A2	WEEK 8	27MAY2013	14:15	1420.74	ng/mL	-159.79	
	WEEK 12	24JUN2013	15:40	1371.71	ng/mL	-150.83	
	Minimum Post-baseline	29APR2013	14:50	887.42	ng/mL	-62.27	
309-0012/82/M/A2	SCREENING	13MAY2013	12:00	147.46	ng/mL	.	Rise
	WEEK 4	13JUN2013	10:05	310.03	ng/mL	-110.25	
	WEEK 8	11JUL2013	09:50	212.33	ng/mL	-43.99	
	WEEK 12	08AUG2013	10:05	298.36	ng/mL	-102.33	
	END OF TREATMENT	02SEP2013	15:33	285.18	ng/mL	-93.39	
	Minimum Post-baseline	11JUL2013	09:50	212.33	ng/mL	-43.99	
309-0015/62/M/A2	SCREENING	18JUN2013	13:35	180.79	ng/mL	.	Rise

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Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
309-0015/62/M/A2	WEEK 4	15JUL2013	09:30	196.89	ng/mL	-8.91	
	WEEK 8	12AUG2013	10:50	309.33	ng/mL	-71.1	
	WEEK 12	09SEP2013	10:49	264.95	ng/mL	-46.55	
	END OF TREATMENT	03OCT2013	14:20	210.65	ng/mL	-16.52	
	Minimum Post-baseline	15JUL2013	09:30	196.89	ng/mL	-8.91	
309-0016/72/F/A2	SCREENING	26AUG2013	11:20	151.47	ng/mL	.	Rise
	WEEK 4	26SEP2013	10:00	261.14	ng/mL	-72.4	
	WEEK 8	24OCT2013	09:05	507.41	ng/mL	-234.99	
	WEEK 12	21NOV2013	09:28	1074.02	ng/mL	-609.06	
	END OF TREATMENT	16DEC2013	11:30	2212.03	ng/mL	-1360.37	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
309-0016/72/F/A2	Minimum Post-baseline	26SEP2013	10:00	261.14	ng/mL	-72.4	
309-0017/73/F/A2	SCREENING	20NOV2013	12:50	8.02	ng/mL	.	Rise
	WEEK 4	23DEC2013	11:15	22.14	ng/mL	-176.06	
	WEEK 8	20JAN2014	11:00	52.29	ng/mL	-552	
	WEEK 12	17FEB2014	11:30	61.31	ng/mL	-664.46	
	END OF TREATMENT	17MAR2014	14:20	133.15	ng/mL	-1560.22	
	Minimum Post-baseline	23DEC2013	11:15	22.14	ng/mL	-176.06	
309-0018/82/M/A2	SCREENING	03JUN2014	12:30	48690.66	ng/mL	.	Rise
	WEEK 4	07JUL2014	12:10	49399.83	ng/mL	-1.46	
	WEEK 8	04AUG2014	10:44	63058.1	ng/mL	-29.51	

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
309-0018/82/M/A2	WEEK 12	01SEP2014	09:40	85825.71	ng/mL	-76.27	
	END OF TREATMENT	25SEP2014	11:14	147189.14	ng/mL	-202.29	
	Minimum Post-baseline	07JUL2014	12:10	49399.83	ng/mL	-1.46	
309-0021/54/F/A2	SCREENING	04JUL2014	12:15	4509.7	ng/mL	.	Rise
	WEEK 4	07AUG2014	11:50	5150.83	ng/mL	-14.22	
	UNSCHEDULED	21AUG2014	10:43	6070	ng/ml	-34.6	
	WEEK 8	04SEP2014	09:55	7961.02	ng/mL	-76.53	
	END OF TREATMENT	16OCT2014	10:10	31759.42	ng/mL	-604.25	
	Minimum Post-baseline	07AUG2014	11:50	5150.83	ng/mL	-14.22	
309-0025/49/M/A2	SCREENING	12AUG2014	13:35	803232.8	ng/mL	.	Stable

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
309-0026/41/M/A2	SCREENING	09SEP2014	14:00	101739.22	ng/mL	.	Stable
	WEEK 4	13OCT2014	09:45	117800.15	ng/mL	-15.79	
	WEEK 8	10NOV2014	11:10	63083.59	ng/mL	37.99	
	WEEK 12	08DEC2014	11:15	116217.1	ng/mL	-14.23	
	WEEK 16	05JAN2015	12:20	87050.11	ng/mL	14.44	
	Minimum Post-baseline	10NOV2014	11:10	63083.59	ng/mL	37.99	
309-0028/62/M/A2	SCREENING	22OCT2014	12:00	934.5	ng/mL	.	Rise
	WEEK 4	24NOV2014	11:10	987.14	ng/mL	-5.63	
	WEEK 8	22DEC2014	08:40	1299.22	ng/mL	-39.03	
	WEEK 12	19JAN2015	09:00	2506.76	ng/mL	-168.25	

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
309-0028/62/M/A2	WEEK 16	16FEB2015	09:10	5351.65	ng/mL	-472.68	
	WEEK 20	16MAR2015	08:50	14489	ng/mL	-1450.45	
	WEEK 24	13APR2015	09:32	86522	ng/mL	-9158.64	
	END OF TREATMENT	11MAY2015	09:30	280731	ng/mL	-29940.77	
	Minimum Post-baseline	24NOV2014	11:10	987.14	ng/mL	-5.63	
309-0030/33/M/A2	SCREENING	04DEC2014	13:30	18.86	ng/mL	.	Rise
	WEEK 4	05JAN2015	11:25	46.62	ng/mL	-147.19	
	WEEK 8	02FEB2015	10:10	67.03	ng/mL	-255.41	
	Minimum Post-baseline	05JAN2015	11:25	46.62	ng/mL	-147.19	
309-0031/34/M/A2	SCREENING	18DEC2014	13:25	260539.6	ng/mL	.	Rise

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
309-0031/34/M/A2	WEEK 4	15JAN2015	10:50	693425.6	ng/mL	-166.15	
	WEEK 8	12FEB2015	10:40	1035169.2	ng/mL	-297.32	
	Minimum Post-baseline	15JAN2015	10:50	693425.6	ng/mL	-166.15	
309-0032/63/M/A2	SCREENING	26DEC2014	12:20	12216.06	ng/mL	.	Rise
	WEEK 4	29JAN2015	10:20	6151.04	ng/mL	49.65	
	WEEK 8	26FEB2015	09:55	13748.19	ng/mL	-12.54	
	WEEK 11	17MAR2015	16:45	48470	ng/mL	-296.77	
	WEEK 12	26MAR2015	09:40	62195	ng/mL	-409.12	
	Minimum Post-baseline	29JAN2015	10:20	6151.04	ng/mL	49.65	
309-0033/78/F/A2	SCREENING	16JAN2015	12:30	70.15	ng/mL	.	Rise

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
309-0033/78/F/A2	WEEK 4	17FEB2015	13:10	63.44	ng/mL	9.57	
	WEEK 8	17MAR2015	16:10	112.8	ng/mL	-60.8	
	WEEK 12	16APR2015	11:20	75.05	ng/mL	-6.99	
	WEEK 16	14MAY2015	10:55	80.66	ng/mL	-14.98	
	WEEK 20	11JUN2015	11:00	116	ng/mL	-65.36	
	Minimum Post-baseline	17FEB2015	13:10	63.44	ng/mL	9.57	
310-0001/61/M/A2	SCREENING	12JUN2012	14:25	8.3	ng/mL	.	Stable
	WEEK 4	10JUL2012	13:10	9.21	ng/mL	-10.96	
	WEEK 8	07AUG2012	13:35	10.14	ng/mL	-22.17	
	END OF TREATMENT	14SEP2012	08:45	6.76	ng/mL	18.55	

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
310-0001/61/M/A2	Minimum Post-baseline	14SEP2012	08:45	6.76	ng/mL	18.55	
310-0002/55/M/A2	SCREENING	28JUN2012	10:25	56670.7	ng/mL	.	Rise
	WEEK 4	31JUL2012	13:10	188940	ng/mL	-233.4	
	END OF TREATMENT	06SEP2012	10:55	339690	ng/mL	-499.41	
	Minimum Post-baseline	31JUL2012	13:10	188940	ng/mL	-233.4	
310-0003/61/M/A2	SCREENING	23JAN2013	10:00	4.45	ng/mL	.	Stable
	WEEK 4	27FEB2013	08:50	5.32	ng/mL	-19.55	
	WEEK 8	27MAR2013	09:30	5.31	ng/mL	-19.33	
	WEEK 12	24APR2013	09:15	5.69	ng/mL	-27.87	
	Minimum Post-baseline	27MAR2013	09:30	5.31	ng/mL	-19.33	

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
310-0008/49/M/A2	SCREENING	11JUN2013	09:30	14.55	ng/mL	.	Stable
310-0012/73/M/A2	SCREENING	01NOV2013	08:40	2270.42	ng/mL	.	Decline
	WEEK 4	26NOV2013	14:29	1234.39	ng/mL	45.63	
	WEEK 8	26DEC2013	09:08	978.66	ng/mL	56.9	
	WEEK 12	23JAN2014	09:05	2593.29	ng/mL	-14.22	
	WEEK 16	18FEB2014	13:30	4839.2	ng/mL	-113.14	
	WEEK 20	18MAR2014	13:30	19513.71	ng/mL	-759.48	
	Minimum Post-baseline	26DEC2013	09:08	978.66	ng/mL	56.9	
310-0013/54/M/A2	SCREENING	22AUG2014	07:59	13.49	ng/mL	.	Stable
	WEEK 4	24SEP2014	08:10	13.91	ng/mL	-3.11	

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
310-0013/54/M/A2	WEEK 8	22OCT2014	07:49	13.97	ng/mL	-3.56	
	END OF TREATMENT	17DEC2014	08:07	16.59	ng/mL	-22.98	
	Minimum Post-baseline	24SEP2014	08:10	13.91	ng/mL	-3.11	
311-0002/60/M/A2	SCREENING	08AUG2013	09:10	91.9	ng/mL	.	Rise
	WEEK 4	04SEP2013	11:40	94.07	ng/mL	-2.36	
	WEEK 8	02OCT2013	10:10	140.9	ng/mL	-53.32	
	UNSCHEDULED	10OCT2013	15:29	199.86	ng/ml	-117.48	
	Minimum Post-baseline	04SEP2013	11:40	94.07	ng/mL	-2.36	
311-0007/55/M/A2	SCREENING	11NOV2013	14:00	43447.83	ng/mL	.	Rise
	WEEK 4	09DEC2013	10:30	68030.58	ng/mL	-56.58	

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
311-0007/55/M/A2	WEEK 8	08JAN2014	14:15	99587	ng/mL	-129.21	
	END OF TREATMENT	24FEB2014	09:50	193562.14	ng/mL	-345.5	
	Minimum Post-baseline	09DEC2013	10:30	68030.58	ng/mL	-56.58	
311-0008/71/M/A2	SCREENING	14MAY2014	15:00	724.27	ng/mL	.	Rise
	WEEK 4	11JUN2014	11:27	1055.85	ng/mL	-45.78	
	WEEK 8	08JUL2014	08:45	1658.36	ng/mL	-128.97	
	Minimum Post-baseline	11JUN2014	11:27	1055.85	ng/mL	-45.78	
401-0003/36/M/A7	SCREENING	24JUN2013	10:20	5571.2	ng/ml	.	Decline
	WEEK 4	17JUL2013	09:46	6815.1	ng/ml	-22.33	
	WEEK 8	13AUG2013	10:21	4472.7	ng/ml	19.72	

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[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
401-0003/36/M/A7	UNSCHEDULED	03SEP2013	10:32	5694.8	ng/ml	-2.22	
	END OF TREATMENT	30SEP2013	11:00	1407.3	ng/ml	74.74	
	Minimum Post-baseline	30SEP2013	11:00	1407.3	ng/ml	74.74	
401-0005/58/M/A7	SCREENING	10OCT2013	08:14	26836.4	ng/ml	.	Rise
	WEEK 4	05NOV2013	08:05	36947.1	ng/ml	-37.68	
	WEEK 8	06DEC2013	12:24	42154.4	ng/ml	-57.08	
	END OF TREATMENT	14JAN2014	04:00	75544.7	ng/ml	-181.5	
	Minimum Post-baseline	05NOV2013	08:05	36947.1	ng/ml	-37.68	
402-0003/75/M/A7	SCREENING	25APR2013	12:51	1.7	ng/ml	.	Decline
	WEEK 4	21MAY2013	12:27	1.2	ng/ml	29.41	

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
402-0003/75/M/A7	WEEK 8	19JUN2013	11:52	1.8	ng/ml	-5.88	
	WEEK 12	16JUL2013	12:00	1.3	ng/ml	23.53	
	WEEK 16	13AUG2013	11:31	1.6	ng/ml	5.88	
	WEEK 20	10SEP2013	11:14	0.8	ng/ml	52.94	
	WEEK 24	08OCT2013	12:53	0.7	ng/ml	58.82	
	Minimum Post-baseline	08OCT2013	12:53	0.7	ng/ml	58.82	
402-0006/71/M/A7	SCREENING	25APR2013	10:17	1412.1	ng/ml	.	Stable
	WEEK 3	21MAY2013	11:08	1918.6	ng/ml	-35.87	
	Minimum Post-baseline	21MAY2013	11:08	1918.6	ng/ml	-35.87	
402-0008/43/M/A7	SCREENING	08MAY2013	14:30	24336	ng/ml	.	Stable

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
402-0009/70/M/A7	SCREENING	09MAY2013	13:20	2315.6	ng/ml	.	Rise
	WEEK 4	07JUN2013	08:42	5265.5	ng/ml	-127.39	
	WEEK 8	04JUL2013	08:17	10184	ng/ml	-339.8	
	END OF TREATMENT	11JUL2013	10:04	15142	ng/ml	-553.91	
	Minimum Post-baseline	07JUN2013	08:42	5265.5	ng/ml	-127.39	
402-0011/64/M/A7	SCREENING	14MAY2013	11:39	1.5	ng/ml	.	Stable
	WEEK 4	13JUN2013	10:16	0.9	ng/ml	40	
	UNSCHEDULED	11JUL2013	09:04	1.2	ng/ml	20	
	END OF TREATMENT	05AUG2013	13:46	0.9	ng/ml	40	
	Minimum Post-baseline	13JUN2013	10:16	0.9	ng/ml	40	

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
402-0017/50/M/A7	SCREENING	11JUN2013	12:23	108710	ng/ml	.	Rise
	WEEK 4	08JUL2013	13:11	209110	ng/ml	-92.36	
	Minimum Post-baseline	08JUL2013	13:11	209110	ng/ml	-92.36	
402-0018/48/M/A7	SCREENING	12JUN2013	12:34	1.6	ng/ml	.	Rise
	WEEK 4	15JUL2013	11:42	3.9	ng/ml	-143.75	
	WEEK 8	12AUG2013	11:38	8	ng/ml	-400	
	WEEK 12	09SEP2013	12:20	7.6	ng/ml	-375	
	Minimum Post-baseline	15JUL2013	11:42	3.9	ng/ml	-143.75	
402-0019/54/M/A7	SCREENING	25JUN2013	14:00	6348.9	ng/ml	.	Rise
	WEEK 4	22JUL2013	12:21	8417	ng/ml	-32.57	

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
402-0019/54/M/A7	WEEK 8	19AUG2013	13:50	20661	ng/ml	-225.43	
	Minimum Post-baseline	22JUL2013	12:21	8417	ng/ml	-32.57	
402-0021/64/M/A7	SCREENING	01AUG2013	10:25	365.2	ng/ml	.	Rise
	WEEK 4	03SEP2013	12:31	387	ng/ml	-5.97	
	WEEK 8	01OCT2013	12:20	467.1	ng/ml	-27.9	
	WEEK 12	29OCT2013	11:32	392.4	ng/ml	-7.45	
	WEEK 16	26NOV2013	11:58	518.3	ng/ml	-41.92	
	WEEK 20	24DEC2013	11:16	636.1	ng/ml	-74.18	
	WEEK 24	21JAN2014	11:47	764.6	ng/ml	-109.36	
	WEEK 28	18FEB2014	11:52	1275.4	ng/ml	-249.23	

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
402-0021/64/M/A7	WEEK 32	18MAR2014	11:49	1404.2	ng/ml	-284.5	
	WEEK 36	15APR2014	11:56	1466.4	ng/ml	-301.53	
	WEEK 40	13MAY2014	11:26	919	ng/ml	-151.64	
	WEEK 44	10JUN2014	12:49	1175.4	ng/ml	-221.85	
	WEEK 48	08JUL2014	12:17	1036.4	ng/ml	-183.79	
	WEEK 60	29SEP2014	09:12	928	ng/ml	-154.11	
	END OF TREATMENT	04NOV2014	11:34	898.2	ng/ml	-145.95	
	Minimum Post-baseline	03SEP2013	12:31	387	ng/ml	-5.97	
402-0024/57/M/A7	SCREENING	23AUG2013	11:39	139.5	ng/ml	.	Stable
402-0025/58/M/A7	SCREENING	16SEP2013	15:18	524.6	ng/ml	.	Stable

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
402-0025/58/M/A7	WEEK 4	17OCT2013	09:48	666.8	ng/ml	-27.11	
	Minimum Post-baseline	17OCT2013	09:48	666.8	ng/ml	-27.11	
402-0027/52/M/A7	SCREENING	25SEP2013	16:09	5.3	ng/ml	.	Rise
	WEEK 4	23OCT2013	13:38	14.8	ng/ml	-179.25	
	Minimum Post-baseline	23OCT2013	13:38	14.8	ng/ml	-179.25	
402-0028/60/M/A7	SCREENING	26SEP2013	14:09	93800	ng/ml	.	Rise
	WEEK 4	22OCT2013	12:18	258990	ng/ml	-176.11	
	Minimum Post-baseline	22OCT2013	12:18	258990	ng/ml	-176.11	
402-0031/65/M/A7	SCREENING	05NOV2013	14:05	1.4	ng/ml	.	Decline
	WEEK 4	06DEC2013	08:06	0.7	ng/ml	50	

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
402-0031/65/M/A7	Minimum Post-baseline	06DEC2013	08:06	0.7	ng/ml	50	
402-0033/63/F/A7	SCREENING	Unknown		.		.	
402-0035/44/M/A7	SCREENING	24DEC2013	12:06	29225	ng/ml	.	Stable
403-0001/55/M/A7	SCREENING	20MAY2013	15:41	4938.17	ng/mL	.	Rise
	WEEK 4	12JUN2013	08:38	8131.6	ng/mL	-64.67	
	WEEK 7	03JUL2013	08:56	8973.67	ng/mL	-81.72	
	END OF TREATMENT	29JUL2013	08:27	10453.14	ng/mL	-111.68	
	Minimum Post-baseline	12JUN2013	08:38	8131.6	ng/mL	-64.67	
403-0002/52/M/A7	SCREENING	11JUN2013	15:23	11.53	ng/mL	.	Rise
	WEEK 4	03JUL2013	09:30	31.96	ng/mL	-177.19	

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
403-0002/52/M/A7	WEEK 8	31JUL2013	08:14	147.72	ng/mL	-1181.18	
	END OF TREATMENT	12SEP2013	08:26	864.6	ng/mL	-7398.7	
	Minimum Post-baseline	03JUL2013	09:30	31.96	ng/mL	-177.19	
403-0005/50/F/A7	SCREENING	15JUL2013	15:04	120000	ng/mL	.	Stable
	END OF TREATMENT	30AUG2013	12:17	120000	ng/mL	0	
	Minimum Post-baseline	30AUG2013	12:17	120000	ng/mL	0	
403-0006/66/M/A7	SCREENING	25JUL2013	09:45	110.68	ng/mL	.	Rise
	WEEK 4	22AUG2013	08:56	215.49	ng/mL	-94.7	
	WEEK 8	16SEP2013	10:36	270.73	ng/mL	-144.61	
	WEEK 12	17OCT2013	08:35	336.35	ng/mL	-203.89	

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
403-0006/66/M/A7	END OF TREATMENT	05DEC2013	08:48	156.44	ng/mL	-41.34	
	Minimum Post-baseline	05DEC2013	08:48	156.44	ng/mL	-41.34	
403-0007/64/M/MIX	SCREENING	21AUG2013	13:27	998.81	ng/mL	.	Rise
	WEEK 4	11SEP2013	13:56	1263.91	ng/mL	-26.54	
	UNSCHEDULED	02OCT2013	11:23	1031.67	ng/mL	-3.29	
	WEEK 8	08OCT2013	11:10	1647.06	ng/mL	-64.9	
	WEEK 12	07NOV2013	11:58	2914.14	ng/mL	-191.76	
	Minimum Post-baseline	02OCT2013	11:23	1031.67	ng/mL	-3.29	
404-0001/71/M/A7	SCREENING	08JUL2013	08:59	3.64	ng/mL	.	Stable
	WEEK 4	12AUG2013	08:53	2.93	ng/mL	19.51	

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
404-0001/71/M/A7	Minimum Post-baseline	12AUG2013	08:53	2.93	ng/mL	19.51	
404-0002/56/F/A7	SCREENING	16AUG2013	10:45	8.24	ng/mL	.	Stable
	WEEK 4	12SEP2013	09:29	9.47	ng/mL	-14.93	
	UNSCHEDULED	10OCT2013	20:28	12.2	ng/mL	-48.06	
	Minimum Post-baseline	12SEP2013	09:29	9.47	ng/mL	-14.93	
405-0002/46/M/A7	SCREENING	Unknown		.		.	
405-0004/38/M/A7	SCREENING	19APR2013	11:30	1044.7	ng/mL	.	Rise
	WEEK 4	15MAY2013	12:20	1441.2	ng/mL	-37.95	
	WEEK 8	10JUN2013	09:29	1789.5	ng/mL	-71.29	
	WEEK 12	10JUL2013	11:50	2085.1	ng/mL	-99.59	

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
405-0004/38/M/A7	END OF TREATMENT	07AUG2013	12:14	2330	ng/mL	-123.03	
	Minimum Post-baseline	15MAY2013	12:20	1441.2	ng/mL	-37.95	
405-0006/62/M/A7	SCREENING	23APR2013	10:21	261125	ng/mL	.	Rise
	WEEK 4	22MAY2013	10:38	467285	ng/mL	-78.95	
	Minimum Post-baseline	22MAY2013	10:38	467285	ng/mL	-78.95	
405-0007/53/M/A7	SCREENING	23APR2013	16:58	160.2	ng/mL	.	Rise
	WEEK 4	28MAY2013	10:44	195.2	ng/mL	-21.85	
	WEEK 8	25JUN2013	10:30	269.3	ng/mL	-68.1	
	WEEK 12	23JUL2013	11:35	269	ng/mL	-67.92	
	WEEK 16	20AUG2013	11:08	392.9	ng/mL	-145.26	

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
405-0007/53/M/A7	WEEK 21	26SEP2013	11:44	4367	ng/mL	-2625.97	
	Minimum Post-baseline	28MAY2013	10:44	195.2	ng/mL	-21.85	
405-0009/50/M/A7	SCREENING	07MAY2013	12:08	62.9	ng/ml	.	Rise
	WEEK 4	05JUN2013	12:49	102	ng/ml	-62.16	
	WEEK 8	03JUL2013	13:48	127.9	ng/ml	-103.34	
	Minimum Post-baseline	05JUN2013	12:49	102	ng/ml	-62.16	
405-0010/39/M/A7	SCREENING	Unknown		.		.	
	WEEK 4	11JUN2013	10:13	13039.8	ng/ml	.	
	WEEK 8	08JUL2013	10:12	30226	ng/ml	.	
	WEEK 12	06AUG2013	10:20	31847	ng/ml	.	

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
405-0010/39/M/A7	Minimum Post-baseline	11JUN2013	10:13	13039.8	ng/ml	.	
405-0011/63/M/A7	SCREENING	08MAY2013	19:18	882.6	ng/mL	.	Rise
	WEEK 4	03JUN2013	10:03	746.8	ng/mL	15.39	
	WEEK 8	01JUL2013	09:36	1345.5	ng/mL	-52.45	
	WEEK 12	29JUL2013	09:17	2232.7	ng/mL	-152.97	
	WEEK 16	26AUG2013	09:06	3799	ng/mL	-330.43	
	WEEK 20	23SEP2013	08:44	6432.8	ng/mL	-628.85	
	WEEK 24	21OCT2013	09:12	8165	ng/mL	-825.11	
	END OF TREATMENT	21NOV2013	11:37	14504.4	ng/mL	-1543.37	
	Minimum Post-baseline	03JUN2013	10:03	746.8	ng/mL	15.39	

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
405-0013/45/M/A7	SCREENING	13MAY2013	12:44	59014	ng/mL	.	Stable
	WEEK 4	10JUN2013	09:50	60267	ng/mL	-2.12	
	WEEK 8	08JUL2013	09:58	52930	ng/mL	10.31	
	WEEK 12	05AUG2013	09:23	58657	ng/mL	0.6	
	WEEK 16	02SEP2013	09:58	79337	ng/mL	-34.44	
	END OF TREATMENT	16SEP2013	09:25	81322	ng/mL	-37.8	
	Minimum Post-baseline	08JUL2013	09:58	52930	ng/mL	10.31	
405-0014/35/M/A7	SCREENING	23MAY2013	17:31	3267.8	ng/ml	.	Rise
	WEEK 4	19JUN2013	14:15	18402.6	ng/ml	-463.15	
	Minimum Post-baseline	19JUN2013	14:15	18402.6	ng/ml	-463.15	

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
405-0016/41/M/A7	SCREENING	27MAY2013	09:34	867.2	ng/mL	.	Rise
	WEEK 4	17JUN2013	09:29	1990.8	ng/mL	-129.57	
	Minimum Post-baseline	17JUN2013	09:29	1990.8	ng/mL	-129.57	
405-0018/70/F/A7	SCREENING	07JUN2013	15:32	1125266	ng/ml	.	Stable
405-0020/69/M/A7	SCREENING	12JUN2013	11:22	3	ng/mL	.	Stable
	WEEK 4	10JUL2013	11:12	3	ng/mL	0	
	WEEK 8	07AUG2013	10:43	2.1	ng/mL	30	
	WEEK 12	04SEP2013	09:18	2.3	ng/mL	23.33	
	WEEK 16	30SEP2013	09:43	2.4	ng/mL	20	
	WEEK 20	30OCT2013	10:47	2.7	ng/mL	10	

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
405-0020/69/M/A7	WEEK 24	27NOV2013	10:50	2.7	ng/mL	10	
	WEEK 28	23DEC2013	09:14	2.3	ng/mL	23.33	
	WEEK 32	22JAN2014	10:52	2.7	ng/mL	10	
	WEEK 36	19FEB2014	10:05	2.7	ng/mL	10	
	WEEK 40	19MAR2014	11:03	2.6	ng/mL	13.33	
	WEEK 44	14APR2014	10:44	3	ng/mL	0	
	WEEK 48	14MAY2014	09:59	3.2	ng/mL	-6.67	
	Minimum Post-baseline	07AUG2013	10:43	2.1	ng/mL	30	
405-0021/47/M/A7	SCREENING	17JUN2013	13:34	2735.1	ng/ml	.	Decline
	WEEK 4	10JUL2013	11:57	2482.6	ng/ml	9.23	

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
405-0021/47/M/A7	WEEK 8	07AUG2013	12:15	2455.6	ng/ml	10.22	
	WEEK 12	04SEP2013	11:19	2507.5	ng/ml	8.32	
	WEEK 16	02OCT2013	11:54	2519.2	ng/ml	7.89	
	WEEK 20	30OCT2013	12:05	2259.7	ng/ml	17.38	
	WEEK 24	27NOV2013	12:00	2016.6	ng/ml	26.27	
	WEEK 28	23DEC2013	09:05	1962.3	ng/ml	28.25	
	WEEK 32	22JAN2014	12:22	1512.1	ng/ml	44.72	
	WEEK 36	17FEB2014	09:51	1464.4	ng/ml	46.46	
	WEEK 40	17MAR2014	09:27	986.4	ng/ml	63.94	
	WEEK 44	18APR2014	10:40	1512.3	ng/ml	44.71	

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
405-0021/47/M/A7	WEEK 48	14MAY2014	12:03	1679.1	ng/ml	38.61	
	WEEK 52	09JUN2014	10:07	1395.3	ng/ml	48.99	
	UNSCHEDULED	09JUL2014	11:55	1345.7	ng/mL	50.8	
	WEEK 56	14JUL2014	09:03	1188.4	ng/ml	56.55	
	Minimum Post-baseline	17MAR2014	09:27	986.4	ng/ml	63.94	
405-0022/65/M/A7	SCREENING	04JUL2013	12:42	36257	ng/ml	.	Rise
	WEEK 4	22JUL2013	10:51	35287	ng/ml	2.68	
	WEEK 8	21AUG2013	10:56	69079	ng/ml	-90.53	
	WEEK 12	16SEP2013	09:57	65722	ng/ml	-81.27	
	WEEK 16	14OCT2013	09:47	119204	ng/ml	-228.78	

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Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

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Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
405-0022/65/M/A7	WEEK 20	13NOV2013	10:21	172088	ng/ml	-374.63	
	WEEK 24	11DEC2013	10:51	299187	ng/ml	-725.18	
	END OF TREATMENT	13JAN2014	10:02	481536	ng/ml	-1228.12	
	Minimum Post-baseline	22JUL2013	10:51	35287	ng/ml	2.68	
405-0023/46/M/A7	SCREENING	17JUN2013	09:30	8521.5	ng/ml	.	Stable
	WEEK 4	08JUL2013	09:58	10533.9	ng/ml	-23.62	
	WEEK 8	05AUG2013	09:40	11148.8	ng/ml	-30.83	
	WEEK 12	02SEP2013	09:49	12774.7	ng/ml	-49.91	
	Minimum Post-baseline	08JUL2013	09:58	10533.9	ng/ml	-23.62	
405-0025/47/M/A7	SCREENING	24JUN2013	10:31	17.1	ng/mL	.	Stable

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
405-0028/67/M/A7	SCREENING	17JUL2013	11:04	5.7	ng/mL	.	Rise
	WEEK 4	14AUG2013	11:16	12.8	ng/mL	-124.56	
	WEEK 8	11SEP2013	10:59	8.2	ng/mL	-43.86	
	WEEK 12	07OCT2013	08:48	6.8	ng/mL	-19.3	
	Minimum Post-baseline	07OCT2013	08:48	6.8	ng/mL	-19.3	
405-0030/35/M/A7	SCREENING	17JUL2013	16:38	297	ng/mL	.	Rise
	WEEK 4	19AUG2013	08:53	1811.3	ng/mL	-509.87	
	WEEK 8	16SEP2013	09:18	4036.9	ng/mL	-1259.23	
	END OF TREATMENT	18OCT2013	11:20	7819.7	ng/mL	-2532.9	
	Minimum Post-baseline	19AUG2013	08:53	1811.3	ng/mL	-509.87	

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[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
405-0032/69/M/A7	SCREENING	19JUL2013	14:41	349.3	ng/ml	.	Rise
	WEEK 4	12AUG2013	08:41	534.3	ng/ml	-52.96	
	WEEK 8	09SEP2013	08:01	394.5	ng/ml	-12.94	
	WEEK 12	08OCT2013	08:09	442.6	ng/ml	-26.71	
	WEEK 16	04NOV2013	08:40	467.9	ng/ml	-33.95	
	WEEK 24	30DEC2013	08:32	607.7	ng/ml	-73.98	
	WEEK 28	27JAN2014	08:50	608.8	ng/ml	-74.29	
	WEEK 32	24FEB2014	09:06	809.5	ng/ml	-131.75	
	WEEK 36	24MAR2014	08:28	1431.4	ng/ml	-309.79	
	WEEK 40	21APR2014	08:53	2014.4	ng/ml	-476.7	

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
405-0032/69/M/A7	WEEK 44	19MAY2014	09:19	3262.1	ng/ml	-833.9	
	WEEK 48	16JUN2014	09:14	7090	ng/ml	-1929.77	
	WEEK 52	14JUL2014	09:05	7968.6	ng/ml	-2181.31	
	WEEK 56	12AUG2014	08:45	9799.5	ng/ml	-2705.47	
	WEEK 60	05SEP2014	09:14	26181	ng/ml	-7395.28	
	END OF TREATMENT	07OCT2014	08:48	34341	ng/ml	-9731.38	
	Minimum Post-baseline	09SEP2013	08:01	394.5	ng/ml	-12.94	
405-0033/43/M/A7	SCREENING	29JUL2013	11:33	5.5	ng/mL	.	Rise
	WEEK 4	28AUG2013	11:37	12	ng/mL	-118.18	
	WEEK 8	25SEP2013	11:57	48.6	ng/mL	-783.64	

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
405-0033/43/M/A7	WEEK 12	23OCT2013	12:20	123.3	ng/mL	-2141.82	
	Minimum Post-baseline	28AUG2013	11:37	12	ng/mL	-118.18	
405-0034/61/M/A7	SCREENING	29JUL2013	10:19	12.5	ng/ml	.	Stable
	WEEK 4	28AUG2013	10:04	17.7	ng/ml	-41.6	
	WEEK 8	25SEP2013	09:53	18.1	ng/ml	-44.8	
	WEEK 12	23OCT2013	10:29	16.9	ng/ml	-35.2	
	END OF TREATMENT	25NOV2013	09:34	17.9	ng/ml	-43.2	
	Minimum Post-baseline	23OCT2013	10:29	16.9	ng/ml	-35.2	
405-0035/66/M/A7	SCREENING	19AUG2013	08:53	3.4	ng/ml	.	Stable
	WEEK 4	11SEP2013	11:38	3.9	ng/ml	-14.71	

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
405-0035/66/M/A7	WEEK 8	11OCT2013	09:00	4.3	ng/ml	-26.47	
	Minimum Post-baseline	11SEP2013	11:38	3.9	ng/ml	-14.71	
405-0039/73/M/A7	SCREENING	09SEP2013	08:44	37	ng/mL	.	Rise
	WEEK 4	07OCT2013	06:28	47.2	ng/mL	-27.57	
	WEEK 8	04NOV2013	06:37	58.1	ng/mL	-57.03	
	WEEK 12	29NOV2013	06:28	53	ng/mL	-43.24	
	END OF TREATMENT	30DEC2013	06:42	62.5	ng/mL	-68.92	
	Minimum Post-baseline	07OCT2013	06:28	47.2	ng/mL	-27.57	
405-0040/65/M/A7	SCREENING	09SEP2013	12:16	2.4	ng/ml	.	Stable
	WEEK 4	14OCT2013	09:46	2.4	ng/ml	0	

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
405-0040/65/M/A7	WEEK 8	11NOV2013	09:04	1.8	ng/ml	25	
	WEEK 12	09DEC2013	08:35	1.7	ng/ml	29.17	
	END OF TREATMENT	13JAN2014	10:07	1.9	ng/ml	20.83	
	Minimum Post-baseline	09DEC2013	08:35	1.7	ng/ml	29.17	
405-0042/53/M/A7	SCREENING	04OCT2013	08:54	7	ng/mL	.	Rise
	WEEK 4	30OCT2013	10:48	11.7	ng/mL	-67.14	
	Minimum Post-baseline	30OCT2013	10:48	11.7	ng/mL	-67.14	
405-0043/49/M/A7	SCREENING	16SEP2013	11:50	199.9	ng/dl	.	Rise
	WEEK 4	17OCT2013	12:10	1315.2	ng/dl	-557.93	
	WEEK 8	14NOV2013	12:02	6982.4	ng/dl	-3392.95	

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
405-0043/49/M/A7	Minimum Post-baseline	17OCT2013	12:10	1315.2	ng/dl	-557.93	
405-0044/56/M/A7	SCREENING	25SEP2013	13:55	1461.9	ng/dl	.	Rise
	WEEK 4	18OCT2013	11:36	2627.5	ng/dl	-79.73	
	WEEK 8	13NOV2013	11:37	4129.5	ng/dl	-182.47	
	Minimum Post-baseline	18OCT2013	11:36	2627.5	ng/dl	-79.73	
501-0001/59/M/A1	SCREENING	05NOV2013	06:30	24601.01	ug/L	.	Decline
	WEEK 8	01JAN2014	07:00	1205	ug/L	95.1	
	END OF TREATMENT	25JAN2014	06:00	23736.52	ug/L	3.51	
	Minimum Post-baseline	01JAN2014	07:00	1205	ug/L	95.1	
501-0002/36/F/A1	SCREENING	27NOV2013	07:00	113564.16	ug/L	.	Stable

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
501-0002/36/F/A1	WEEK 4	23DEC2013	08:10	121440.03	ug/L	-6.94	
	WEEK 8	20JAN2014	07:42	103325.16	ug/L	9.02	
	END OF TREATMENT	18FEB2014	07:00	152984.72	ug/L	-34.71	
	Minimum Post-baseline	20JAN2014	07:42	103325.16	ug/L	9.02	
501-0005/80/M/A1	SCREENING	14JAN2014	08:59	1.38	ug/L	.	Rise
	WEEK 4	13FEB2014	08:45	3.24	ug/L	-134.78	
	WEEK 8	14MAR2014	07:30	3.67	ug/L	-165.94	
	WEEK 12	10APR2014	09:51	4.2	ug/L	-204.35	
	WEEK 16	09MAY2014	09:50	4.63	ug/L	-235.51	
	WEEK 20	06JUN2014	07:58	4.4	ug/L	-218.84	

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
501-0005/80/M/A1	WEEK 24	03JUL2014	08:30	4.16	ug/L	-201.45	
	WEEK 28	01AUG2014	08:15	5.43	ug/L	-293.48	
	WEEK 32	29AUG2014	07:10	4.06	ug/L	-194.2	
	WEEK 36	24SEP2014	08:30	3.39	ug/L	-145.65	
	WEEK 40	23OCT2014	08:30	3.49	ug/L	-152.9	
	WEEK 44	20NOV2014	08:38	1.6	ug/L	-15.94	
	WEEK 48	18DEC2014	08:45	2.2	ug/L	-59.42	
	WEEK 52	15JAN2015	08:37	2	ug/L	-44.93	
	WEEK 56	10FEB2015	08:46	3.4	ug/L	-146.38	
	WEEK 60	12MAR2015	08:45	3.5	ug/L	-153.62	

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
501-0005/80/M/A1	WEEK 64	10APR2015	08:20	3.7	ug/L	-168.12	
	WEEK 72	04JUN2015	07:45	4.2	ug/L	-204.35	
	END OF TREATMENT	26JUN2015	08:00	2.9	ug/L	-110.14	
	Minimum Post-baseline	20NOV2014	08:38	1.6	ug/L	-15.94	
501-0006/60/M/A1	SCREENING	07FEB2014	09:52	2.73	ug/l	.	Stable
	WEEK 4	06MAR2014	08:30	3.65	ug/l	-33.7	
	WEEK 8	03APR2014	07:30	2.9	ug/l	-6.23	
	WEEK 12	28APR2014	08:00	2.42	ug/l	11.36	
	Minimum Post-baseline	28APR2014	08:00	2.42	ug/l	11.36	
501-0007/43/M/A1	SCREENING	26FEB2014	06:54	2006.14	ug/l	.	Decline

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Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
501-0007/43/M/A1	WEEK 8	21APR2014	07:20	2750.1	ug/l	-37.08	
	UNSCHEDULED	19MAY2014	09:50	5073.73	ug/l	-152.91	
	Minimum Post-baseline	21APR2014	07:20	2750.1	ug/l	-37.08	
501-0008/76/F/A1	SCREENING	09APR2014	07:43	0.6	ug/L	.	Rise
	WEEK 4	06MAY2014	08:03	5.6	ug/L	-833.33	
	WEEK 8	03JUN2014	08:00	7.42	ug/L	-1136.67	
	WEEK 12	01JUL2014	09:05	6.2	ug/L	-933.33	
	Minimum Post-baseline	06MAY2014	08:03	5.6	ug/L	-833.33	
501-0009/62/M/A1	SCREENING	09JUL2014	08:02	35.1	UG/L	.	Rise
	WEEK 4	08AUG2014	08:00	68.93	UG/L	-96.38	

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[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

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Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
501-0009/62/M/A1	WEEK 8	05SEP2014	07:00	62.86	UG/L	-79.09	
	WEEK 12	30SEP2014	06:00	47.45	UG/L	-35.19	
	END OF TREATMENT	18OCT2014	06:00	53.85	UG/L	-53.42	
	Minimum Post-baseline	30SEP2014	06:00	47.45	UG/L	-35.19	
501-0010/65/M/A1	SCREENING	02SEP2014	08:00	7.04	ug/l	.	Stable
	WEEK 4	28SEP2014	07:30	7.7	ug/l	-9.38	
	WEEK 8	28OCT2014	08:30	7.49	ug/l	-6.39	
	WEEK 12	27NOV2014	08:00	7.16	ug/l	-1.7	
	Minimum Post-baseline	27NOV2014	08:00	7.16	ug/l	-1.7	
502-0002/65/M/A1	SCREENING	09JAN2014	07:45	1210	ng/ml	.	Stable

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[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
503-0001/32/M/A1	SCREENING	06DEC2013	08:00	62.24	ng/ml	.	Stable
503-0004/49/M/A1	SCREENING	07MAR2014	09:00	1210	ng/ml	.	Stable
503-0006/54/M/A1	SCREENING	02AUG2014	10:37	1.54	ng/ml	.	Rise
	WEEK 4	27AUG2014	08:20	1	ng/ml	35.06	
	WEEK 8	25SEP2014	08:32	1.31	ng/ml	14.94	
	WEEK 12	22OCT2014	08:45	1.4	ng/ml	9.09	
	WEEK 16	19NOV2014	09:30	1.78	ng/ml	-15.58	
	WEEK 20	17DEC2014	09:15	1.78	ng/ml	-15.58	
	WEEK 24	15JAN2015	15:20	2.14	ng/ml	-38.96	
	WEEK 28	09FEB2015	09:45	3.06	ng/ml	-98.7	

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
503-0006/54/M/A1	Minimum Post-baseline	27AUG2014	08:20	1	ng/ml	35.06	
503-0007/57/M/A1	SCREENING	22OCT2014	08:03	1210	ng/ml	.	Stable
	WEEK 4	18NOV2014	09:40	1210	ng/ml	0	
	WEEK 8	16DEC2014	09:36	1210	ng/ml	0	
	WEEK 12	13JAN2015	09:30	1210	ng/ml	0	
	Minimum Post-baseline	16DEC2014	09:36	1210	ng/ml	0	
503-0008/50/M/A1	SCREENING	17OCT2014	08:02	1210	ng/ml	.	Stable
	WEEK 4	19NOV2014	09:45	1210	ng/ml	0	
	Minimum Post-baseline	19NOV2014	09:45	1210	ng/ml	0	
503-0009/57/M/A1	SCREENING	18NOV2014	09:10	1210	ng/ml	.	Stable

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
504-0001/47/M/A1	SCREENING	13FEB2014	08:49	22932	ng/ml	.	Rise
	WEEK 4	11MAR2014	10:40	31333	ng/ml	-36.63	
	WEEK 8	08APR2014	09:35	37540	ng/ml	-63.7	
	WEEK 16	03JUN2014	09:15	69450	ng/ml	-202.85	
	Minimum Post-baseline	11MAR2014	10:40	31333	ng/ml	-36.63	
504-0007/32/M/A1	SCREENING	07OCT2014	17:34	266.5	ng/ml	.	Stable
505-0001/70/M/A1	SCREENING	13AUG2014	08:06	2000	ng/ml	.	Stable
	WEEK 4	16SEP2014	08:15	2000	ng/ml	0	
	END OF TREATMENT	28OCT2014	07:46	2000	ng/ml	0	
	Minimum Post-baseline	16SEP2014	08:15	2000	ng/ml	0	

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
506-0002/54/M/A1	SCREENING	05MAY2014	09:55	9.4	IU/ml	.	Rise
	WEEK 2	19MAY2014	09:08	9.2	IU/ml	2.13	
	WEEK 4	04JUN2014	09:17	8.4	IU/ml	10.64	
	WEEK 6	16JUN2014	08:56	8	IU/ml	14.89	
	WEEK 8	02JUL2014	09:16	10.9	IU/ml	-15.96	
	WEEK 10	16JUL2014	07:57	10.3	IU/ml	-9.57	
	WEEK 12	30JUL2014	09:19	11.3	IU/ml	-20.21	
	WEEK 14	13AUG2014	08:35	12.9	IU/ml	-37.23	
	WEEK 16	27AUG2014	08:54	11.07	IU/ml	-17.77	
	WEEK 18	10SEP2014	08:06	9.49	IU/ml	-0.96	

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
506-0002/54/M/A1	WEEK 20	24SEP2014	08:55	8.49	IU/ml	9.68	
	WEEK 22	08OCT2014	08:28	9.52	IU/ml	-1.28	
	WEEK 24	22OCT2014	06:00	10.35	IU/ml	-10.11	
	WEEK 26	05NOV2014	08:09	9.01	IU/ml	4.15	
	WEEK 30	03DEC2014	08:25	9.91	IU/ml	-5.43	
	WEEK 32	17DEC2014	08:50	10.45	IU/ml	-11.17	
	WEEK 34	31DEC2014	08:20	9.61	IU/ml	-2.23	
	WEEK 36	14JAN2015	09:10	11.01	IU/ml	-17.13	
	WEEK 38	28JAN2015	08:14	11.6	IU/ml	-23.4	
	WEEK 40	11FEB2015	08:40	10.98	IU/ml	-16.81	

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
506-0002/54/M/A1	WEEK 42	26FEB2015	08:07	13.17	IU/ml	-40.11	
	WEEK 44	11MAR2015	08:40	15.47	IU/ml	-64.57	
	WEEK 46	25MAR2015	07:58	18.18	IU/ml	-93.4	
	END OF TREATMENT	08MAY2015	08:10	24.28	IU/ml	-158.3	
	Minimum Post-baseline	16JUN2014	08:56	8	IU/ml	14.89	
506-0003/66/M/A1	SCREENING	09SEP2014	08:57	418.1	IU/ml	.	Rise
	WEEK 4	30SEP2014	09:20	460.1	IU/ml	-10.05	
	WEEK 6	15OCT2014	08:32	683	IU/ml	-63.36	
	WEEK 7	22OCT2014	08:40	859.6	IU/ml	-105.6	
	END OF TREATMENT	28OCT2014	06:06	1243	IU/ml	-197.3	

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
506-0003/66/M/A1	Minimum Post-baseline	30SEP2014	09:20	460.1	IU/ml	-10.05	
506-0004/49/M/A1	SCREENING	24OCT2014	07:00	40049	IU/ml	.	Rise
	WEEK 2	05NOV2014	08:50	57962	IU/ml	-44.73	
	WEEK 4	19NOV2014	08:35	93658	IU/ml	-133.86	
	WEEK 6	03DEC2014	08:26	119112	IU/ml	-197.42	
	WEEK 8	17DEC2014	08:55	171904	IU/ml	-329.23	
	Minimum Post-baseline	05NOV2014	08:50	57962	IU/ml	-44.73	
508-0001/36/M/A1	SCREENING	31DEC2013	09:00	2310	ng/ml	.	Rise
	WEEK 4	27JAN2014	09:40	4465	ng/ml	-93.29	
	Minimum Post-baseline	27JAN2014	09:40	4465	ng/ml	-93.29	

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
508-0003/49/F/A1	SCREENING	13MAR2014	09:50	121000	ng/ml	.	Stable
	WEEK 4	08APR2014	11:08	121000	ng/ml	0	
	Minimum Post-baseline	08APR2014	11:08	121000	ng/ml	0	
509-0001/45/M/A1	SCREENING	28APR2014	11:00	12100	NG/ML	.	Stable
	WEEK 4	21MAY2014	10:05	12100	NG/ML	0	
	WEEK 8	17JUN2014	10:10	12100	NG/ML	0	
	WEEK 12	15JUL2014	10:45	12100	NG/ML	0	
	Minimum Post-baseline	17JUN2014	10:10	12100	NG/ML	0	
509-0002/51/M/A1	SCREENING	19MAY2014	10:10	5.39	NG/ML	.	Stable
510-0002/50/M/A1	SCREENING	Unknown		.		.	

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Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
510-0002/50/M/A1	WEEK 4	11JUN2014	08:30	2387	ng/ ml	.	
	WEEK 8	09JUL2014	08:20	1210	ng/ ml	.	
	Minimum Post-baseline	09JUL2014	08:20	1210	ng/ ml	.	
510-0004/72/M/A1	SCREENING	30JUL2014	08:30	2513	ng/ml	.	Stable
	WEEK 4	20AUG2014	07:00	3146	ng/ml	-25.19	
	WEEK 8	17SEP2014	07:10	3406	ng/ml	-35.54	
	WEEK 12	15OCT2014	07:30	3659	ng/ml	-45.6	
	Minimum Post-baseline	20AUG2014	07:00	3146	ng/ml	-25.19	
511-0001/35/M/A1	SCREENING	18JAN2014	06:30	2.67	ug/L	.	Rise
	WEEK 2	28JAN2014	07:35	3.36	ug/L	-25.84	

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
511-0001/35/M/A1	WEEK 4	11FEB2014	08:15	3.18	ug/L	-19.1	
	WEEK 6	25FEB2014	08:37	4.4	ug/L	-64.79	
	END OF TREATMENT	28MAR2014	07:10	5.4	ug/L	-102.25	
	Minimum Post-baseline	11FEB2014	08:15	3.18	ug/L	-19.1	
511-0002/49/M/A1	SCREENING	07MAR2014	06:30	2000	ug/L	.	Decline
	WEEK 2	18MAR2014	08:10	2000	ug/L	0	
	WEEK 4	01APR2014	09:20	2000	ug/L	0	
	WEEK 6	15APR2014	09:20	2000	ug/L	0	
	WEEK 8	29APR2014	09:00	2000	ug/L	0	
	WEEK 10	13MAY2014	08:50	2000	ug/L	0	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
511-0002/49/M/A1	WEEK 12	27MAY2014	09:00	2000	ug/L	0	
	WEEK 14	10JUN2014	08:45	2000	ug/L	0	
	WEEK 16	24JUN2014	08:55	2000	ug/L	0	
	WEEK 18	08JUL2014	08:30	2000	ug/L	0	
	WEEK 20	22JUL2014	08:49	2000	ug/L	0	
	WEEK 22	05AUG2014	09:10	2000	ug/L	0	
	WEEK 24	19AUG2014	08:20	2000	ug/L	0	
	END OF TREATMENT	23SEP2014	09:05	337.79	ug/L	83.11	
	Minimum Post-baseline	23SEP2014	09:05	337.79	ug/L	83.11	
512-0001/59/M/A1	SCREENING	25FEB2014	06:30	1001	IU/ml	.	Rise

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
512-0001/59/M/A1	WEEK 4	25MAR2014	08:45	1001	IU/ml	0	
	WEEK 8	22APR2014	08:32	2010	IU/ml	-100.8	
	WEEK 10	07MAY2014	09:01	1467	IU/ml	-46.55	
	WEEK 12	20MAY2014	09:18	1474	IU/ml	-47.25	
	WEEK 16	18JUN2014	09:26	1471	IU/ml	-46.95	
	Minimum Post-baseline	25MAR2014	08:45	1001	IU/ml	0	
513-0001/28/M/A1	SCREENING	07APR2014	18:30	60501	ng/mL	.	Stable
	WEEK 4	04MAY2014	09:41	60501	ng/mL	0	
	Minimum Post-baseline	04MAY2014	09:41	60501	ng/mL	0	
513-0004/46/M/A1	SCREENING	12JUN2014	07:00	11165	ng/ml	.	Rise

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
513-0004/46/M/A1	WEEK 4	08JUL2014	08:58	21928	ng/ml	-96.4	
	Minimum Post-baseline	08JUL2014	08:58	21928	ng/ml	-96.4	
513-0005/61/M/A1	SCREENING	30OCT2014	11:11	668.8	NG/ML	.	Rise
	WEEK 4	20NOV2014	09:10	955.4	NG/ML	-42.85	
	WEEK 8	18DEC2014	09:25	1153	NG/ML	-72.4	
	WEEK 12	14JAN2015	09:40	2459	NG/ML	-267.67	
	Minimum Post-baseline	20NOV2014	09:10	955.4	NG/ML	-42.85	
515-0001/64/M/A1	SCREENING	14FEB2014	09:30	3631	ng/ml	.	Stable
	WEEK 4	12MAR2014	15:15	3630	ng/ml	0.03	
	WEEK 8	09APR2014	15:10	3630	ng/ml	0.03	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
515-0001/64/M/A1	WEEK 12	07MAY2014	15:10	3630	ng/ml	0.03	
	Minimum Post-baseline	09APR2014	15:10	3630	ng/ml	0.03	
515-0003/69/M/A1	SCREENING	08MAY2014	00:00	155.1	ng/ml	.	Rise
	WEEK 4	05JUN2014	10:00	295.2	ng/ml	-90.33	
	WEEK 12	29JUL2014	08:00	828.4	ng/ml	-434.11	
	END OF TREATMENT	27AUG2014	09:50	1532	ng/ml	-887.75	
	Minimum Post-baseline	05JUN2014	10:00	295.2	ng/ml	-90.33	
515-0004/52/M/A1	SCREENING	22MAY2014	08:00	2557	ng/ml	.	Rise
	WEEK 4	16JUN2014	09:30	3631	ng/ml	-42	
	WEEK 8	14JUL2014	09:50	3631	ng/ml	-42	

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
515-0004/52/M/A1	WEEK 12	11AUG2014	10:00	3631	ng/ml	-42	
	WEEK 16	09SEP2014	10:00	300000	ng/ml	-11632.5	
	Minimum Post-baseline	14JUL2014	09:50	3631	ng/ml	-42	
515-0006/47/M/A1	SCREENING	23JUL2014	07:30	40.27	ng/ml	.	Rise
	WEEK 4	26AUG2014	09:03	69.86	ng/ml	-73.48	
	WEEK 8	22SEP2014	08:50	82.02	ng/ml	-103.68	
	WEEK 12	20OCT2014	10:10	134.9	ng/ml	-234.99	
	Minimum Post-baseline	26AUG2014	09:03	69.86	ng/ml	-73.48	
515-0007/39/M/A1	SCREENING	12SEP2014	09:05	300000	ng/ml	.	Stable
	WEEK 4	08OCT2014	10:10	300000	ng/ml	0	

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
515-0007/39/M/A1	Minimum Post-baseline	08OCT2014	10:10	300000	ng/ml	0	
515-0008/60/M/A1	SCREENING	21NOV2014	09:35	300000	ng/ml	.	Stable
	WEEK 4	17DEC2014	10:30	300000	ng/ml	0	
	WEEK 8	14JAN2015	09:40	300000	ng/ml	0	
	WEEK 12	09FEB2015	09:05	300000	ng/ml	0	
	Minimum Post-baseline	14JAN2015	09:40	300000	ng/ml	0	
516-0001/45/M/A1	SCREENING	07AUG2014	09:20	2406	ng/mL	.	Rise
	WEEK 4	29AUG2014	08:48	1210	ng/mL	49.71	
	WEEK 8	26SEP2014	08:40	1210	ng/mL	49.71	
	WEEK 12	24OCT2014	08:10	1210	ng/mL	49.71	

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
516-0001/45/M/A1	WEEK 16	21NOV2014	09:15	4452	ng/mL	-85.04	
	WEEK 20	19DEC2014	08:50	4535	ng/mL	-88.49	
	WEEK 24	16JAN2015	09:00	1210	ng/mL	49.71	
	END OF TREATMENT	16FEB2015	09:00	1210	ng/mL	49.71	
	Minimum Post-baseline	26SEP2014	08:40	1210	ng/mL	49.71	
517-0001/42/M/A1	SCREENING	18DEC2013	09:41	1210	NG/ML	.	Stable
	WEEK 4	13JAN2014	09:05	1210	NG/ML	0	
	Minimum Post-baseline	13JAN2014	09:05	1210	NG/ML	0	
517-0002/43/M/A1	SCREENING	24MAR2014	08:55	1210	ng/ml	.	Stable
	WEEK 4	15APR2014	09:25	1210	ng/ml	0	

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
517-0002/43/M/A1	WEEK 8	13MAY2014	08:43	1210	ng/ml	0	
	WEEK 12	10JUN2014	09:10	1210	ng/ml	0	
	WEEK 16	08JUL2014	09:00	1210	ng/ml	0	
	WEEK 20	05AUG2014	09:00	1210	ng/ml	0	
	WEEK 24	02SEP2014	08:54	1210	ng/ml	0	
	END OF TREATMENT	08OCT2014	09:20	1210	ng/ml	0	
	Minimum Post-baseline	13MAY2014	08:43	1210	ng/ml	0	
517-0005/46/M/MIX	SCREENING	22MAY2014	11:33	1210	ng/ml	.	Stable
517-0006/67/F/A1	SCREENING	12AUG2014	08:40	17.1	ng/ml	.	Rise
	WEEK 4	10SEP2014	09:08	37.59	ng/ml	-119.82	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
517-0006/67/F/A1	WEEK 8	08OCT2014	09:15	48.32	ng/ml	-182.57	
	WEEK 12	05NOV2014	09:30	112	ng/ml	-554.97	
	WEEK 16	03DEC2014	09:15	191.4	ng/ml	-1019.3	
	WEEK 20	30DEC2014	09:17	314.8	ng/ml	-1740.94	
	WEEK 24	28JAN2015	09:30	333.9	ng/ml	-1852.63	
	WEEK 28	25FEB2015	09:35	425.5	ng/ml	-2388.3	
	WEEK 32	25MAR2015	09:05	688.8	ng/ml	-3928.07	
	WEEK 36	22APR2015	09:10	1210	ng/ml	-6976.02	
	Minimum Post-baseline	10SEP2014	09:08	37.59	ng/ml	-119.82	
517-0007/66/M/A1	SCREENING	12AUG2014	09:20	3.52	ng/ml	.	Stable

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
517-0007/66/M/A1	WEEK 4	12SEP2014	09:10	2.46	ng/ml	30.11	
	Minimum Post-baseline	12SEP2014	09:10	2.46	ng/ml	30.11	
517-0008/59/M/A1	SCREENING	15AUG2014	08:40	1210	ng/ml	.	Stable
	WEEK 4	12SEP2014	09:20	1210	ng/ml	0	
	END OF TREATMENT	22OCT2014	09:30	1210	ng/ml	0	
	Minimum Post-baseline	12SEP2014	09:20	1210	ng/ml	0	
517-0009/23/M/A1	SCREENING	11SEP2014	10:05	244.9	ng/ml	.	Rise
	WEEK 4	08OCT2014	10:15	185	ng/ml	24.46	
	WEEK 8	05NOV2014	09:35	298.5	ng/ml	-21.89	
	WEEK 12	03DEC2014	10:10	367.2	ng/ml	-49.94	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
517-0009/23/M/A1	END OF TREATMENT	07JAN2015	10:10	413.4	ng/ml	-68.8	
	Minimum Post-baseline	08OCT2014	10:15	185	ng/ml	24.46	

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
101-0002/70/M/OTH	SCREENING	19JUL2011	11:34	2.2	ng/mL	.	Rise
	WEEK 8	20SEP2011	08:08	2.7	ng/ml	-22.73	
	WEEK 12	18OCT2011	07:52	3.4	ng/ml	-54.55	
	Minimum Post-baseline	20SEP2011	08:08	2.7	ng/ml	-22.73	
101-0004/78/F/A2	SCREENING	02AUG2011	08:40	3.6	ng/ml	.	Stable
	WEEK 8	23SEP2011	11:52	3.7	ng/ml	-2.78	
	WEEK 12	21OCT2011	12:51	3.8	ng/ml	-5.56	
	WEEK 16	18NOV2011	14:50	3.7	ng/ml	-2.78	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
101-0004/78/F/A2	WEEK 20	15DEC2011	16:05	4.1	ng/ml	-13.89	
	WEEK 24	13JAN2012	13:33	4	ng/ml	-11.11	
	WEEK 28	10FEB2012	11:45	4.3	ng/dl	-19.44	
	WEEK 32	09MAR2012	10:23	4.4	ng/ml	-22.22	
	WEEK 36	10APR2012	15:26	3.8	ng/ml	-5.56	
	WEEK 40	11MAY2012	11:51	4.1	ng/ml	-13.89	
	WEEK 44	08JUN2012	12:29	3.4	ng/ml	5.56	
	WEEK 48	06JUL2012	11:15	3.2	ng/ml	11.11	
	WEEK 52	03AUG2012	11:02	3.7	ng/ml	-2.78	
	WEEK 56	31AUG2012	09:57	3.8	ng/ml	-5.56	

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
101-0004/78/F/A2	WEEK 60	28SEP2012	14:31	3.9	ng/ml	-8.33	
	Minimum Post-baseline	06JUL2012	11:15	3.2	ng/ml	11.11	
101-0010/43/M/BL	SCREENING	13SEP2011	07:43	250.6	ng/ml	.	Stable
101-0014/61/M/W2	SCREENING	03JAN2012	15:35	3.1	ng/ml	.	Stable
	WEEK 4	27JAN2012	10:06	2.9	ng/ml	6.45	
	WEEK 8	24FEB2012	11:16	3.8	ng/ml	-22.58	
	WEEK 12	23MAR2012	07:52	4.1	ng/ml	-32.26	
	WEEK 16	20APR2012	08:59	2.7	ng/ml	12.9	
	END OF TREATMENT	03JUL2012	08:57	3.1	ng/ml	0	
	Minimum Post-baseline	20APR2012	08:59	2.7	ng/ml	12.9	

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
101-0015/65/M/A4	SCREENING	28DEC2011	16:38	2582.9	ng/ml	.	Rise
	WEEK 4	31JAN2012	13:00	4287.1	ng/ml	-65.98	
	WEEK 8	28FEB2012	14:55	5484.2	ng/ml	-112.33	
	END OF TREATMENT	24APR2012	10:14	11544.5	ng/ml	-346.96	
	Minimum Post-baseline	31JAN2012	13:00	4287.1	ng/ml	-65.98	
101-0017/60/M/W2	SCREENING	21FEB2012	07:28	6.8	ng/ml	.	Stable
	WEEK 4	13MAR2012	10:10	5.7	ng/ml	16.18	
	WEEK 8	10APR2012	12:28	4.8	ng/ml	29.41	
	WEEK 12	08MAY2012	12:51	3.6	ng/ml	47.06	
	Minimum Post-baseline	08MAY2012	12:51	3.6	ng/ml	47.06	

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
101-0020/86/M/W2	SCREENING	13MAR2012	07:49	3.9	ng/ml	.	Stable
	WEEK 4	03APR2012	08:15	3.3	ng/ml	15.38	
	WEEK 8	01MAY2012	07:48	2.8	ng/ml	28.21	
	WEEK 12	05JUN2012	08:59	2.4	ng/ml	38.46	
	WEEK 16	03JUL2012	07:51	2.6	NG/ML	33.33	
	WEEK 20	31JUL2012	07:28	2.8	ng/ml	28.21	
	WEEK 24	28AUG2012	07:12	2.5	ng/ml	35.9	
	END OF TREATMENT	28SEP2012	07:40	2.7	ng/ml	30.77	
	Minimum Post-baseline	05JUN2012	08:59	2.4	ng/ml	38.46	
101-0027/72/M/W2	SCREENING	22MAY2012	11:16	724.3	ng/ml	.	Rise

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
101-0027/72/M/W2	WEEK 4	15JUN2012	09:07	942.7	ng/ml	-30.15	
	END OF TREATMENT	24JUL2012	10:26	1659.3	ng/ml	-129.09	
	Minimum Post-baseline	15JUN2012	09:07	942.7	ng/ml	-30.15	
101-0031/69/F/W2	SCREENING	17JUL2012	10:00	39.6	ng/ml	.	Rise
	WEEK 4	07AUG2012	10:24	79.3	NG/ML	-100.25	
	WEEK 8	04SEP2012	12:54	159.7	NG/ML	-303.28	
	Minimum Post-baseline	07AUG2012	10:24	79.3	NG/ML	-100.25	
101-0034/44/M/OTH	SCREENING	11SEP2012	12:14	19626.5	ng/ml	.	Rise
	WEEK 4	02OCT2012	17:37	55457.7	ng/ml	-182.57	
	WEEK 8	02NOV2012	11:14	123219.2	ng/ml	-527.82	

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
101-0034/44/M/OTH	Minimum Post-baseline	02OCT2012	17:37	55457.7	ng/ml	-182.57	
101-0035/37/M/A6	SCREENING	07SEP2012	13:22	42412	ng/ml	.	Stable
	UNSCHEDULED	09OCT2012	10:55	39347	NG/ML	7.23	
	END OF TREATMENT	13NOV2012	15:23	61402.7	NG/ML	-44.78	
	Minimum Post-baseline	09OCT2012	10:55	39347	NG/ML	7.23	
101-0043/69/M/W1	SCREENING	08OCT2013	11:15	1636.1	ng/ml	.	Rise
	WEEK 5	19NOV2013	08:57	2207.3	ng/ml	-34.91	
	WEEK 8	10DEC2013	08:55	2730.1	ng/ml	-66.87	
	END OF TREATMENT	14JAN2014	08:00	2556.5	ng/ml	-56.26	
	Minimum Post-baseline	19NOV2013	08:57	2207.3	ng/ml	-34.91	

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
101-0051/70/F/W2	SCREENING	27JAN2014	14:32	3766.2	ng/ml	.	Stable
	WEEK 4	17FEB2014	13:31	4633.1	ng/ml	-23.02	
	Minimum Post-baseline	17FEB2014	13:31	4633.1	ng/ml	-23.02	
102-0006/66/M/BL	SCREENING	05DEC2013	09:45	71	ng/mL	.	Decline
	WEEK 4	02JAN2014	09:53	93.6	ng/mL	-31.83	
	WEEK 8	29JAN2014	09:22	63.9	ng/mL	10	
	WEEK 12	26FEB2014	09:25	34.8	ng/mL	50.99	
	END OF TREATMENT	31MAR2014	11:30	22.9	ng/mL	67.75	
	Minimum Post-baseline	31MAR2014	11:30	22.9	ng/mL	67.75	
102-0007/61/M/W2	SCREENING	23DEC2013	09:25	1486.8	ng/mL	.	Rise

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
102-0007/61/M/W2	WEEK 4	23JAN2014	10:24	2300.5	ng/mL	-54.73	
	WEEK 8	20FEB2014	10:10	2705.9	ng/mL	-81.99	
	UNSCHEDULED	27FEB2014	11:00	2643.9	ng/mL	-77.82	
	WEEK 12	20MAR2014	10:12	4108.5	ng/mL	-176.33	
	Minimum Post-baseline	23JAN2014	10:24	2300.5	ng/mL	-54.73	
103-0002/74/M/W2	SCREENING	05DEC2012	13:35	113.1	ng/mL	.	Rise
	WEEK 4	02JAN2013	10:48	140.4	ng/mL	-24.14	
	WEEK 8	30JAN2013	10:00	207.3	ng/mL	-83.29	
	WEEK 12	27FEB2013	10:15	238.5	ng/mL	-110.88	
	WEEK 16	27MAR2013	10:00	254.7	ng/mL	-125.2	

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
103-0002/74/M/W2	WEEK 20	24APR2013	10:00	137.6	ng/mL	-21.66	
	END OF TREATMENT	14JUN2013	10:45	256.7	ng/mL	-126.97	
	Minimum Post-baseline	24APR2013	10:00	137.6	ng/mL	-21.66	
103-0006/57/M/W2	SCREENING	06NOV2014	10:30	4.8	ng/mL	.	Rise
	WEEK 4	11DEC2014	08:30	8.8	ng/mL	-83.33	
	WEEK 8	06JAN2015	09:25	9.5	ng/mL	-97.92	
	END OF TREATMENT	26FEB2015	12:00	15.2	ng/mL	-216.67	
	Minimum Post-baseline	11DEC2014	08:30	8.8	ng/mL	-83.33	
104-0002/80/M/W2	SCREENING	30APR2012	09:10	499	ng/mL	.	Rise
	WEEK 4	29MAY2012	10:25	470.5	ng/mL	5.71	

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
104-0002/80/M/W2	WEEK 8	25JUN2012	09:05	450.4	ng/mL	9.74	
	WEEK 12	23JUL2012	08:55	587.5	ng/mL	-17.74	
	WEEK 16	20AUG2012	08:55	583.1	ng/mL	-16.85	
	WEEK 20	17SEP2012	09:55	507.9	ng/mL	-1.78	
	WEEK 24	15OCT2012	11:02	611.9	ng/mL	-22.63	
	WEEK 28	12NOV2012	09:50	519.4	ng/mL	-4.09	
	WEEK 32	10DEC2012	10:10	537.3	ng/mL	-7.68	
	WEEK 36	07JAN2013	09:33	843.1	ng/mL	-68.96	
	Minimum Post-baseline	25JUN2012	09:05	450.4	ng/mL	9.74	
104-0007/89/M/A1	SCREENING	30JUL2013	08:20	372	ng/mL	.	Decline

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
104-0007/89/M/A1	WEEK 4	26AUG2013	08:42	117.1	ng/mL	68.52	
	WEEK 8	23SEP2013	09:50	154.4	ng/mL	58.49	
	WEEK 12	21OCT2013	09:40	158.3	ng/mL	57.45	
	WEEK 16	18NOV2013	09:00	139.8	ng/mL	62.42	
	WEEK 20	16DEC2013	09:45	166.3	ng/mL	55.3	
	WEEK 22	02JAN2014	09:05	193.7	ng/mL	47.93	
	WEEK 24	13JAN2014	09:05	267.8	ng/mL	28.01	
	WEEK 28	10FEB2014	09:35	225.9	ng/mL	39.27	
	WEEK 32	10MAR2014	09:05	274.9	ng/mL	26.1	
	WEEK 36	09APR2014	09:25	325.1	ng/mL	12.61	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
104-0007/89/M/A1	WEEK 40	05MAY2014	09:24	390.4	ng/mL	-4.95	
	WEEK 42	19MAY2014	09:33	446.7	ng/mL	-20.08	
	WEEK 44	02JUN2014	09:30	434.7	ng/mL	-16.85	
	WEEK 46	16JUN2014	09:17	460.4	ng/mL	-23.76	
	WEEK 48	02JUL2014	09:50	469.6	ng/mL	-26.24	
	WEEK 50	14JUL2014	09:39	586.1	ng/mL	-57.55	
	WEEK 52	28JUL2014	09:44	650.3	ng/mL	-74.81	
	WEEK 54	13AUG2014	10:00	725.6	ng/mL	-95.05	
	WEEK 56	25AUG2014	09:35	658.9	ng/mL	-77.12	
	WEEK 58	08SEP2014	09:30	411.7	ng/mL	-10.67	

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
104-0007/89/M/A1	WEEK 60	22SEP2014	09:15	295.2	ng/mL	20.65	
	WEEK 62	08OCT2014	09:54	115.9	ng/mL	68.84	
	WEEK 64	20OCT2014	10:05	56.2	ng/mL	84.89	
	WEEK 66	03NOV2014	09:35	28.8	ng/mL	92.26	
	WEEK 68	17NOV2014	09:40	23	ng/mL	93.82	
	WEEK 70	01DEC2014	09:20	29.1	ng/mL	92.18	
	WEEK 72	15DEC2014	09:40	21.4	ng/mL	94.25	
	WEEK 74	29DEC2014	09:33	16.2	ng/mL	95.65	
	WEEK 76	12JAN2015	10:43	11.6	ng/mL	96.88	
	WEEK 78	26JAN2015	09:48	13	ng/mL	96.51	

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
104-0007/89/M/A1	WEEK 80	09FEB2015	09:54	10.5	ng/mL	97.18	
	WEEK 82	26FEB2015	08:43	10.8	ng/mL	97.1	
	WEEK 84	11MAR2015	09:26	12.1	ng/mL	96.75	
	WEEK 86	25MAR2015	10:18	13.1	ng/mL	96.48	
	WEEK 88	06APR2015	09:52	16.9	ng/mL	95.46	
	WEEK 90	20APR2015	09:45	18	ng/mL	95.16	
	WEEK 92	04MAY2015	09:40	22.5	ng/mL	93.95	
	WEEK 94	20MAY2015	09:23	14.7	ng/mL	96.05	
	WEEK 96	03JUN2015	09:12	15.3	ng/mL	95.89	
	WEEK 98	15JUN2015	10:10	16	ng/mL	95.7	

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
104-0007/89/M/A1	WEEK 100	29JUN2015	10:06	17.9	ng/mL	95.19	
	Minimum Post-baseline	09FEB2015	09:54	10.5	ng/mL	97.18	
105-0003/57/M/W2	SCREENING	22OCT2013	13:40	522.3	ng/mL	.	Decline
	WEEK 4	26NOV2013	11:05	406.7	ng/mL	22.13	
	WEEK 8	27DEC2013	11:35	48.3	ng/mL	90.75	
	WEEK 12	24JAN2014	10:15	15.4	ng/mL	97.05	
	WEEK 16	21FEB2014	10:30	53.8	ng/mL	89.7	
	WEEK 20	18MAR2014	10:20	43.8	ng/mL	91.61	
	WEEK 24	15APR2014	10:20	18.5	ng/mL	96.46	
	WEEK 28	16MAY2014	11:34	22.7	ng/mL	95.65	

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
105-0003/57/M/W2	WEEK 32	12JUN2014	10:40	23.5	ng/mL	95.5	
	WEEK 36	08JUL2014	12:00	4.9	ng/mL	99.06	
	WEEK 40	08AUG2014	11:00	3	ng/mL	99.43	
	WEEK 42	22AUG2014	11:00	3.2	ng/mL	99.39	
	WEEK 44	05SEP2014	09:50	2.7	ng/mL	99.48	
	WEEK 48	30SEP2014	13:10	3.3	ng/mL	99.37	
	END OF TREATMENT	31OCT2014	11:00	3.1	ng/mL	99.41	
	Minimum Post-baseline	05SEP2014	09:50	2.7	ng/mL	99.48	
105-0006/60/F/BL	SCREENING	17DEC2014	09:40	1278.3	ng/mL	.	Rise
	WEEK 4	20JAN2015	10:45	1633.3	ng/mL	-27.77	

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
105-0006/60/F/BL	WEEK 8	19FEB2015	11:35	1883.3	ng/mL	-47.33	
	WEEK 12	17MAR2015	08:30	2567.1	ng/mL	-100.82	
	WEEK 16	15APR2015	10:30	3278	ng/mL	-156.43	
	WEEK 24	09JUN2015	10:30	3873.8	ng/mL	-203.04	
	Minimum Post-baseline	20JAN2015	10:45	1633.3	ng/mL	-27.77	
108-0003/85/M/W2	SCREENING	14NOV2012	15:00	76.5	ng/mL	.	Stable
	WEEK 4	10DEC2012	09:35	82.1	ng/mL	-7.32	
	Minimum Post-baseline	10DEC2012	09:35	82.1	ng/mL	-7.32	
109-0002/63/M/W2	SCREENING	20MAR2013	13:10	2220.3	ng/mL	.	Stable
	WEEK 4	12APR2013	08:30	1849.7	ng/mL	16.69	

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
109-0002/63/M/W2	WEEK 8	10MAY2013	09:00	1997.5	ng/mL	10.03	
	WEEK 12	07JUN2013	09:10	2142.2	ng/mL	3.52	
	WEEK 16	05JUL2013	10:28	2017.2	ng/mL	9.15	
	WEEK 20	02AUG2013	08:40	1653.1	ng/mL	25.55	
	WEEK 24	30AUG2013	08:35	1793.7	ng/mL	19.21	
	END OF TREATMENT	30SEP2013	16:30	1825.2	ng/mL	17.79	
	Minimum Post-baseline	02AUG2013	08:40	1653.1	ng/mL	25.55	
109-0005/64/F/W2	SCREENING	24JUL2013	12:25	105284.6	ng/mL	.	Stable
	WEEK 4	21AUG2013	13:15	105323.2	ng/mL	-0.04	
	Minimum Post-baseline	21AUG2013	13:15	105323.2	ng/mL	-0.04	

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
109-0012/21/F/W2	SCREENING	18SEP2014	14:36	258.6	ng/mL	.	Rise
	WEEK 4	14OCT2014	11:45	482.8	ng/mL	-86.7	
	WEEK 8	11NOV2014	12:25	802.5	ng/mL	-210.32	
	Minimum Post-baseline	14OCT2014	11:45	482.8	ng/mL	-86.7	
109-0014/50/F/W2	SCREENING	12JAN2015	16:00	1648.8	ng/mL	.	Rise
	WEEK 4	18FEB2015	15:25	1632.4	ng/mL	0.99	
	WEEK 6	04MAR2015	14:25	2525.9	ng/mL	-53.2	
	Minimum Post-baseline	18FEB2015	15:25	1632.4	ng/mL	0.99	
111-0003/37/M/A1	SCREENING	02JAN2013	10:40	6800.5	ng/mL	.	Rise
	WEEK 4	31JAN2013	13:20	24416.3	ng/mL	-259.04	

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
111-0003/37/M/A1	WEEK 8	28FEB2013	10:35	300000	ng/mL	-4311.44	
	Minimum Post-baseline	31JAN2013	13:20	24416.3	ng/mL	-259.04	
112-0010/56/F/W2	SCREENING	27NOV2013	11:15	541.9	ng/mL	.	Rise
	WEEK 4	27DEC2013	07:28	840.2	ng/mL	-55.05	
	WEEK 8	24JAN2014	10:55	496.9	ng/mL	8.3	
	WEEK 12	21FEB2014	11:10	284.7	ng/mL	47.46	
	END OF TREATMENT	26MAR2014	15:10	323.6	ng/mL	40.28	
	Minimum Post-baseline	21FEB2014	11:10	284.7	ng/mL	47.46	
113-0007/74/M/W2	SCREENING	21JAN2014	12:44	206.1	ng/mL	.	Stable
	WEEK 4	20FEB2014	09:20	193.1	ng/mL	6.31	

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
113-0007/74/M/W2	WEEK 8	19MAR2014	08:58	212.4	ng/mL	-3.06	
	WEEK 12	18APR2014	08:30	229.4	ng/mL	-11.31	
	WEEK 16	16MAY2014	08:17	191.7	ng/mL	6.99	
	WEEK 20	10JUN2014	12:35	169.8	ng/mL	17.61	
	Minimum Post-baseline	10JUN2014	12:35	169.8	ng/mL	17.61	
113-0015/58/F/BL	SCREENING	20NOV2014	14:54	5.9	ng/mL	.	Stable
114-0001/25/F/OTH	SCREENING	24JUL2012	15:20	3.5	ng/mL	.	Stable
	END OF TREATMENT	28SEP2012	14:18	3.9	ng/mL	-11.43	
	Minimum Post-baseline	28SEP2012	14:18	3.9	ng/mL	-11.43	
114-0004/54/F/A1	SCREENING	30JAN2013	11:35	3277.1	ng/mL	.	Decline

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Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
114-0004/54/F/A1	WEEK 4	27FEB2013	11:10	3773.5	ng/mL	-15.15	
	WEEK 8	27MAR2013	09:35	4767.7	ng/mL	-45.49	
	END OF TREATMENT	03APR2013	10:33	445.8	ng/mL	86.4	
	Minimum Post-baseline	03APR2013	10:33	445.8	ng/mL	86.4	
115-0005/60/M/W2	SCREENING	08MAR2013	11:31	62.3	ng/mL	.	Stable
115-0006/62/M/W2	SCREENING	04APR2013	13:02	13.8	ng/mL	.	Decline
	WEEK 4	02MAY2013	10:25	9.2	ng/mL	33.33	
	WEEK 8	30MAY2013	13:10	7	ng/mL	49.28	
	WEEK 12	27JUN2013	07:38	6.4	ng/mL	53.62	
	Minimum Post-baseline	27JUN2013	07:38	6.4	ng/mL	53.62	

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Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
115-0007/57/M/W2	SCREENING	10APR2013	13:20	1541.5	ng/mL	.	Rise
	WEEK 4	09MAY2013	08:20	2990.1	ng/mL	-93.97	
	Minimum Post-baseline	09MAY2013	08:20	2990.1	ng/mL	-93.97	
115-0010/54/M/A4	SCREENING	10APR2014	13:47	126.3	ng/mL	.	Rise
	WEEK 4	05MAY2014	08:47	177.2	ng/mL	-40.3	
	WEEK 8	02JUN2014	10:38	321.8	ng/mL	-154.79	
	END OF TREATMENT	22JUL2014	13:55	618.2	ng/mL	-389.47	
	Minimum Post-baseline	05MAY2014	08:47	177.2	ng/mL	-40.3	
121-0003/65/M/BL	SCREENING	18JUN2014	14:35	11173.9	ng/mL	.	Rise
	WEEK 4	23JUL2014	08:00	26892.9	ng/mL	-140.68	

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Serum Alpha Fetoprotein Response
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Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
121-0003/65/M/BL	WEEK 8	20AUG2014	08:35	34024	ng/mL	-204.5	
	END OF TREATMENT	24SEP2014	07:37	63049	ng/mL	-464.25	
	Minimum Post-baseline	23JUL2014	08:00	26892.9	ng/mL	-140.68	
201-0002/76/M/W2	SCREENING	06MAR2012	08:15	5.2	ng/mL	.	Rise
	WEEK 4	05APR2012	08:00	6.8	ng/mL	-30.77	
	WEEK 12	31MAY2012	08:00	7.6	ng/mL	-46.15	
	WEEK 16	28JUN2012	08:30	11.7	ng/mL	-125	
	WEEK 20	26JUL2012	08:30	13.4	ng/mL	-157.69	
	WEEK 24	23AUG2012	08:15	12.7	ng/mL	-144.23	
	WEEK 28	20SEP2012	08:30	13.7	ng/mL	-163.46	

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Serum Alpha Fetoprotein Response
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201-0002/76/M/W2	WEEK 32	18OCT2012	08:30	18.2	ng/mL	-250	
	WEEK 36	15NOV2012	08:00	21.9	ng/mL	-321.15	
	WEEK 40	12DEC2012	08:00	32.9	ng/mL	-532.69	
	WEEK 44	10JAN2013	08:00	36.2	ng/mL	-596.15	
	WEEK 48	07FEB2013	08:00	56.6	ng/mL	-988.46	
	END OF TREATMENT	12MAR2013	08:00	64.6	ng/mL	-1142.31	
	Minimum Post-baseline	05APR2012	08:00	6.8	ng/mL	-30.77	
201-0006/71/M/W2	SCREENING	05JUL2012	08:10	4103.4	ng/mL	.	Rise
	WEEK 4	02AUG2012	08:30	5379.1	ng/mL	-31.09	
	WEEK 8	30AUG2012	08:30	7404.6	ng/mL	-80.45	

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Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
201-0006/71/M/W2	WEEK 12	27SEP2012	08:30	6135.1	ng/mL	-49.51	
	WEEK 16	25OCT2012	08:30	8807.9	ng/mL	-114.65	
	WEEK 20	22NOV2012	08:05	9939	ng/mL	-142.21	
	WEEK 24	18DEC2012	08:10	10411.5	ng/mL	-153.73	
	END OF TREATMENT	17JAN2013	07:45	10860.5	ng/mL	-164.67	
	Minimum Post-baseline	02AUG2012	08:30	5379.1	ng/mL	-31.09	
201-0007/71/M/W2	SCREENING	16JUL2012	08:00	1991.9	ng/mL	.	Decline
	WEEK 8	12SEP2012	08:30	2006.7	ng/mL	-0.74	
	WEEK 12	11OCT2012	08:00	1811.3	ng/mL	9.07	
	WEEK 16	08NOV2012	08:00	1465.1	ng/mL	26.45	

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201-0007/71/M/W2	WEEK 20	06DEC2012	07:50	1878.3	ng/mL	5.7	
	WEEK 24	03JAN2013	08:00	1791.5	ng/mL	10.06	
	WEEK 32	28FEB2013	08:00	1359	ng/mL	31.77	
	WEEK 36	28MAR2013	07:50	1148.8	ng/mL	42.33	
	END OF TREATMENT	29APR2013	08:00	993.9	ng/mL	50.1	
	Minimum Post-baseline	29APR2013	08:00	993.9	ng/mL	50.1	
201-0009/64/M/W2	SCREENING	13JUN2013	08:30	3.1	ng/mL	.	Stable
	WEEK 4	11JUL2013	08:30	3.5	ng/mL	-12.9	
	WEEK 8	08AUG2013	07:50	3	ng/mL	3.23	
	WEEK 12	05SEP2013	09:05	3	ng/mL	3.23	

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201-0009/64/M/W2	WEEK 16	03OCT2013	08:00	2.4	ng/mL	22.58	
	WEEK 20	31OCT2013	08:10	2.7	ng/mL	12.9	
	WEEK 24	28NOV2013	07:45	2.5	ng/mL	19.35	
	WEEK 34	06FEB2014	08:00	3.1	ng/mL	0	
	WEEK 36	20FEB2014	08:30	3.2	ng/mL	-3.23	
	WEEK 40	20MAR2014	08:15	2.7	ng/mL	12.9	
	WEEK 44	17APR2014	08:40	2.9	ng/mL	6.45	
	WEEK 48	15MAY2014	08:00	2.5	ng/mL	19.35	
	WEEK 52	12JUN2014	08:15	2.2	ng/mL	29.03	
	WEEK 56	11JUL2014	08:00	2.8	ng/mL	9.68	

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201-0009/64/M/W2	WEEK 60	07AUG2014	08:00	2	ng/mL	35.48	
	WEEK 64	04SEP2014	08:00	3.5	ng/mL	-12.9	
	WEEK 66	18SEP2014	08:00	2.3	ng/mL	25.81	
	WEEK 68	01OCT2014	08:00	2.2	ng/mL	29.03	
	WEEK 72	30OCT2014	08:00	2.6	ng/mL	16.13	
	WEEK 76	27NOV2014	08:00	2.2	ng/mL	29.03	
	WEEK 84	21JAN2015	08:30	2.4	ng/mL	22.58	
	WEEK 88	19FEB2015	08:10	2.6	ng/mL	16.13	
	WEEK 92	19MAR2015	07:50	2.5	ng/mL	19.35	
	WEEK 96	16APR2015	07:50	2.6	ng/mL	16.13	

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201-0009/64/M/W2	WEEK 100	14MAY2015	07:50	2.3	ng/mL	25.81	
	WEEK 104	11JUN2015	08:00	2.8	ng/mL	9.68	
	WEEK 106	24JUN2015	08:15	2	ng/mL	35.48	
	Minimum Post-baseline	07AUG2014	08:00	2	ng/mL	35.48	
201-0010/81/F/W2	SCREENING	20JUN2013	08:00	36.4	ng/mL	.	Rise
	WEEK 4	17JUL2013	08:40	99.1	ng/mL	-172.25	
	WEEK 12	12SEP2013	07:50	508.1	ng/mL	-1295.88	
	END OF TREATMENT	05NOV2013	08:00	1343.6	ng/mL	-3591.21	
	Minimum Post-baseline	17JUL2013	08:40	99.1	ng/mL	-172.25	
201-0014/73/M/W2	SCREENING	11JUL2013	08:50	54.7	ng/mL	.	Rise

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Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
201-0014/73/M/W2	WEEK 4	08AUG2013	08:25	81.9	ng/mL	-49.73	
	WEEK 8	05SEP2013	08:50	100.4	ng/mL	-83.55	
	WEEK 12	03OCT2013	08:15	73.3	ng/mL	-34	
	END OF TREATMENT	05NOV2013	08:30	113.5	ng/mL	-107.5	
	Minimum Post-baseline	03OCT2013	08:15	73.3	ng/mL	-34	
201-0015/49/M/W2	SCREENING	01AUG2013	09:05	22.8	ng/mL	.	Rise
	WEEK 4	29AUG2013	09:05	23.6	ng/mL	-3.51	
	WEEK 8	26SEP2013	08:35	26	ng/mL	-14.04	
	WEEK 12	24OCT2013	08:00	37.7	ng/mL	-65.35	
	WEEK 16	21NOV2013	08:15	79.4	ng/mL	-248.25	

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
201-0015/49/M/W2	WEEK 20	19DEC2013	08:20	189.3	ng/mL	-730.26	
	WEEK 24	16JAN2014	08:30	469.5	ng/mL	-1959.21	
	WEEK 28	13FEB2014	08:30	1584.8	ng/mL	-6850.88	
	WEEK 32	13MAR2014	08:00	4463.4	ng/mL	-19476.32	
	END OF TREATMENT	17APR2014	08:00	5791.4	ng/mL	-25300.88	
	Minimum Post-baseline	29AUG2013	09:05	23.6	ng/mL	-3.51	
201-0022/80/F/W2	SCREENING	09MAY2014	09:30	5.8	ng/mL	.	Stable
	WEEK 4	05JUN2014	08:00	6.4	ng/mL	-10.34	
	WEEK 8	03JUL2014	08:30	5.4	ng/mL	6.9	
	WEEK 12	31JUL2014	08:20	6.9	ng/mL	-18.97	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
201-0022/80/F/W2	WEEK 16	28AUG2014	08:30	5.7	ng/mL	1.72	
	WEEK 20	25SEP2014	08:00	6.1	ng/mL	-5.17	
	WEEK 24	23OCT2014	08:00	5.9	ng/mL	-1.72	
	END OF TREATMENT	25NOV2014	08:00	6.4	ng/mL	-10.34	
	Minimum Post-baseline	03JUL2014	08:30	5.4	ng/mL	6.9	
203-0004/81/M/W2	SCREENING	22MAR2012	08:00	21.8	ng/mL	.	Rise
	WEEK 4	19APR2012	08:00	27.1	ng/mL	-24.31	
	WEEK 8	22MAY2012	08:00	22.4	ng/mL	-2.75	
	WEEK 12	28JUN2012	08:00	25.4	ng/mL	-16.51	
	WEEK 16	26JUL2012	08:00	29.1	ng/mL	-33.49	

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
203-0004/81/M/W2	WEEK 24	20SEP2012	08:30	54.1	ng/mL	-148.17	
	WEEK 28	18OCT2012	08:00	54.9	ng/mL	-151.83	
	WEEK 32	15NOV2012	08:00	78.7	ng/mL	-261.01	
	WEEK 36	13DEC2012	08:00	145.2	ng/mL	-566.06	
	WEEK 38	28DEC2012	08:00	160.8	ng/mL	-637.61	
	WEEK 40	17JAN2013	08:00	379.1	ng/mL	-1638.99	
	Minimum Post-baseline	22MAY2012	08:00	22.4	ng/mL	-2.75	
203-0006/76/M/W2	SCREENING	30MAR2012	08:00	18.4	ng/mL	.	Stable
	WEEK 4	04MAY2012	06:00	17.5	ng/mL	4.89	
	WEEK 8	30MAY2012	08:30	18.7	ng/mL	-1.63	

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
203-0006/76/M/W2	Minimum Post-baseline	04MAY2012	06:00	17.5	ng/mL	4.89	
203-0007/59/M/W2	SCREENING	28MAY2012	08:30	3639.5	ng/mL	.	Stable
	WEEK 4	06JUL2012	08:00	3583.4	ng/mL	1.54	
	WEEK 8	01AUG2012	08:00	2191.2	ng/mL	39.79	
	TERMINATION	14SEP2012	08:00	2137.8	ng/mL	41.26	
	Minimum Post-baseline	14SEP2012	08:00	2137.8	ng/mL	41.26	
203-0009/73/M/W2	SCREENING	30AUG2012	08:00	352.1	ng/mL	.	Rise
	WEEK 4	08OCT2012	08:00	315.9	ng/mL	10.28	
	WEEK 8	15NOV2012	08:00	474.1	ng/mL	-34.65	
	WEEK 12	20DEC2012	08:00	533.6	ng/mL	-51.55	

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
203-0009/73/M/W2	WEEK 16	25JAN2013	08:00	587.3	ng/mL	-66.8	
	WEEK 20	27FEB2013	08:00	626.5	ng/mL	-77.93	
	WEEK 24	04APR2013	08:00	769.8	ng/mL	-118.63	
	WEEK 28	13MAY2013	08:00	611	ng/mL	-73.53	
	WEEK 32	27JUN2013	08:00	906.6	ng/mL	-157.48	
	WEEK 36	01AUG2013	08:00	1044.8	ng/mL	-196.73	
	WEEK 38	22AUG2013	08:00	1262.3	ng/mL	-258.51	
	WEEK 40	12SEP2013	08:00	1227.7	ng/mL	-248.68	
	WEEK 42	27SEP2013	09:00	902	ng/mL	-156.18	
	WEEK 44	14OCT2013	08:00	921.1	ng/mL	-161.6	

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
203-0009/73/M/W2	WEEK 46	31OCT2013	09:00	1138.7	ng/mL	-223.4	
	END OF TREATMENT	20NOV2013	08:00	1296.6	ng/mL	-268.25	
	Minimum Post-baseline	08OCT2012	08:00	315.9	ng/mL	10.28	
203-0010/74/M/W2	SCREENING	26SEP2012	08:00	2.1	ng/mL	.	Rise
	WEEK 4	18OCT2012	08:00	2	ng/mL	4.76	
	WEEK 8	15NOV2012	08:00	2.1	ng/mL	0	
	WEEK 12	13DEC2012	08:00	2.8	ng/mL	-33.33	
	WEEK 16	17JAN2013	08:00	2.3	ng/mL	-9.52	
	WEEK 20	15FEB2013	08:00	2.6	ng/mL	-23.81	
	WEEK 24	21MAR2013	08:00	3.3	ng/mL	-57.14	

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
203-0010/74/M/W2	WEEK 28	17APR2013	08:00	3.4	ng/mL	-61.9	
	WEEK 32	17MAY2013	08:00	3.5	ng/mL	-66.67	
	WEEK 36	20JUN2013	08:00	4.4	ng/mL	-109.52	
	WEEK 38	11JUL2013	08:00	4.7	ng/mL	-123.81	
	WEEK 40	25JUL2013	08:00	4.2	ng/mL	-100	
	WEEK 44	29AUG2013	08:30	4.9	ng/mL	-133.33	
	WEEK 46	12SEP2013	08:00	4.9	ng/mL	-133.33	
	WEEK 48	26SEP2013	09:00	5.3	ng/mL	-152.38	
	WEEK 50	17OCT2013	09:00	5.5	ng/mL	-161.9	
	WEEK 52	30OCT2013	09:00	3.9	ng/mL	-85.71	

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
203-0010/74/M/W2	WEEK 54	15NOV2013	08:00	5.3	ng/mL	-152.38	
	WEEK 56	02DEC2013	09:00	5.9	ng/mL	-180.95	
	WEEK 58	20DEC2013	08:00	7.1	ng/mL	-238.1	
	WEEK 60	09JAN2014	08:00	6.9	ng/mL	-228.57	
	WEEK 62	24JAN2014	09:00	7.8	ng/mL	-271.43	
	WEEK 64	10FEB2014	09:00	8.1	ng/mL	-285.71	
	WEEK 66	12MAR2014	09:00	9.2	ng/mL	-338.1	
	WEEK 70	28MAR2014	09:00	10.3	ng/mL	-390.48	
	WEEK 72	17APR2014	08:30	13.8	ng/mL	-557.14	
	WEEK 74	02MAY2014	09:00	14.5	ng/mL	-590.48	

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
203-0010/74/M/W2	WEEK 76	19MAY2014	08:00	18.9	ng/mL	-800	
	WEEK 78	05JUN2014	09:00	22.8	ng/mL	-985.71	
	WEEK 80	19JUN2014	09:00	27.8	ng/mL	-1223.81	
	WEEK 82	04JUL2014	08:30	44.6	ng/mL	-2023.81	
	WEEK 84	17JUL2014	09:00	49.5	ng/mL	-2257.14	
	WEEK 86	31JUL2014	09:00	59	ng/mL	-2709.52	
	WEEK 88	13AUG2014	09:00	71	ng/mL	-3280.95	
	WEEK 90	04SEP2014	09:00	116.6	ng/mL	-5452.38	
	WEEK 92	22SEP2014	09:00	102.3	ng/mL	-4771.43	
	WEEK 94	10OCT2014	09:00	134.1	ng/mL	-6285.71	

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
203-0010/74/M/W2	WEEK 96	24OCT2014	09:00	188.1	ng/mL	-8857.14	
	END OF TREATMENT	15DEC2014	09:00	1.4	ng/mL	33.33	
	Minimum Post-baseline	15DEC2014	09:00	1.4	ng/mL	33.33	
203-0014/73/M/W2	SCREENING	10JAN2014	08:00	5273.8	ng/mL	.	Rise
	WEEK 4	13FEB2014	09:00	6243.2	ng/mL	-18.38	
	END OF TREATMENT	13MAR2014	09:00	8390.5	ng/mL	-59.1	
	Minimum Post-baseline	13FEB2014	09:00	6243.2	ng/mL	-18.38	
203-0016/57/M/W2	SCREENING	28JAN2014	09:00	3.8	ng/mL	.	Rise
	WEEK 4	27FEB2014	09:00	4.5	ng/mL	-18.42	
	WEEK 7	24MAR2014	09:00	4.8	ng/mL	-26.32	

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Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
203-0016/57/M/W2	WEEK 8	31MAR2014	08:30	4	ng/mL	-5.26	
	WEEK 12	02MAY2014	09:00	5.7	ng/mL	-50	
	WEEK 16	03JUN2014	09:00	6.9	ng/mL	-81.58	
	WEEK 20	03JUL2014	09:00	6.2	ng/mL	-63.16	
	WEEK 24	31JUL2014	09:00	5.6	ng/mL	-47.37	
	Minimum Post-baseline	31MAR2014	08:30	4	ng/mL	-5.26	
203-0019/68/M/W2	SCREENING	12MAY2014	09:00	42.8	ng/mL	.	Rise
	UNSCHEDULED	22MAY2014	08:00	60.9	ng/mL	-42.29	
	WEEK 4	13JUN2014	09:00	121.6	ng/mL	-184.11	
	END OF TREATMENT	10JUL2014	09:00	296.3	ng/mL	-592.29	

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
203-0019/68/M/W2	Minimum Post-baseline	22MAY2014	08:00	60.9	ng/mL	-42.29	
204-0003/64/M/W2	SCREENING	27JUN2013	13:50	2.4	ng/mL	.	Rise
	WEEK 4	29JUL2013	09:30	3.1	ng/mL	-29.17	
	WEEK 8	26AUG2013	09:55	3.9	ng/mL	-62.5	
	WEEK 12	26SEP2013	08:20	3.5	ng/mL	-45.83	
	TERMINATION	24OCT2013	09:00	4.3	ng/mL	-79.17	
	Minimum Post-baseline	29JUL2013	09:30	3.1	ng/mL	-29.17	
204-0004/76/F/W2	SCREENING	04SEP2013	10:20	9501.7	ng/mL	.	Rise
	WEEK 4	11OCT2013	09:58	12434	ng/mL	-30.86	
	WEEK 8	14NOV2013	08:30	15069.2	ng/mL	-58.59	

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[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
204-0004/76/F/W2	WEEK 12	12DEC2013	09:25	23757.5	ng/mL	-150.03	
	TERMINATION	30JAN2014	09:15	27789.4	ng/mL	-192.47	
	Minimum Post-baseline	11OCT2013	09:58	12434	ng/mL	-30.86	
205-0002/71/M/W2	SCREENING	14FEB2012	09:00	6352.7	ng/mL	.	Rise
	WEEK 8	13APR2012	09:00	19473.8	ng/mL	-206.54	
	UNSCHEDULED	20APR2012	09:00	22876	ng/mL	-260.1	
	WEEK 12	08MAY2012	09:00	28633.5	ng/mL	-350.73	
	Minimum Post-baseline	13APR2012	09:00	19473.8	ng/mL	-206.54	
205-0003/79/M/W2	SCREENING	Unknown		.		.	
	UNSCHEDULED	30MAR2012	11:30	14.5	ng/mL	.	

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
205-0003/79/M/W2	WEEK 4	17APR2012	09:00	18.5	ng/mL	.	
	WEEK 8	15MAY2012	09:00	26.1	ng/mL	.	
	WEEK 12	12JUN2012	09:00	22.1	ng/mL	.	
	WEEK 16	10JUL2012	09:00	15.1	ng/mL	.	
	WEEK 20	14AUG2012	09:00	21.4	ng/mL	.	
	WEEK 24	11SEP2012	09:00	23.7	ng/mL	.	
	WEEK 28	09OCT2012	09:00	35.8	ng/mL	.	
	WEEK 33	13NOV2012	12:17	72.2	ng/ml	.	
	WEEK 36	04DEC2012	09:00	68.3	ng/mL	.	
	END OF TREATMENT	03JAN2013	09:00	114.5	ng/mL	.	

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
205-0003/79/M/W2	Minimum Post-baseline	30MAR2012	11:30	14.5	ng/mL	.	
205-0005/71/M/W2	SCREENING	12MAR2012	09:00	35.8	ng/mL	.	Rise
	WEEK 4	12APR2012	09:00	76	ng/mL	-112.29	
	WEEK 8	10MAY2012	09:00	104	ng/mL	-190.5	
	WEEK 12	05JUN2012	09:00	124.2	ng/mL	-246.93	
	END OF TREATMENT	05JUL2012	09:00	85.4	ng/mL	-138.55	
	Minimum Post-baseline	12APR2012	09:00	76	ng/mL	-112.29	
205-0014/70/M/W2	SCREENING	07JUN2013	07:30	20969.7	ng/mL	.	Rise
	WEEK 4	26JUL2013	10:30	44258.3	ng/mL	-111.06	
	Minimum Post-baseline	26JUL2013	10:30	44258.3	ng/mL	-111.06	

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
205-0023/72/M/W2	SCREENING	29OCT2013	13:30	5.4	ng/mL	.	Stable
	WEEK 4	29NOV2013	08:30	5.2	ng/mL	3.7	
	WEEK 8	23DEC2013	09:30	6.1	ng/mL	-12.96	
	WEEK 12	21JAN2014	08:45	4	ng/mL	25.93	
	END OF TREATMENT	27FEB2014	12:00	5.1	ng/mL	5.56	
	Minimum Post-baseline	21JAN2014	08:45	4	ng/mL	25.93	
205-0026/61/F/W2	SCREENING	02FEB2015	11:00	61.3	ng/mL	.	Stable
	WEEK 4	03MAR2015	10:30	79.9	ng/mL	-30.34	
	WEEK 8	31MAR2015	10:00	61.7	ng/mL	-0.65	
	WEEK 12	28APR2015	11:00	71	ng/mL	-15.82	

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
205-0026/61/F/W2	Minimum Post-baseline	31MAR2015	10:00	61.7	ng/mL	-0.65	
205-0028/73/F/W2	SCREENING	19JAN2015	12:00	1412.3	ng/mL	.	Stable
207-0002/71/M/W2	SCREENING	08MAR2012	12:30	399.5	ng/mL	.	Decline
	WEEK 4	12APR2012	09:40	191.1	ng/mL	52.17	
	WEEK 8	10MAY2012	09:40	294.3	ng/mL	26.33	
	WEEK 12	07JUN2012	09:30	340.5	ng/mL	14.77	
	TERMINATION	20JUN2012	13:40	552.2	ng/mL	-38.22	
	Minimum Post-baseline	12APR2012	09:40	191.1	ng/mL	52.17	
207-0007/71/M/W2	SCREENING	18JUN2012	10:30	90.1	ng/mL	.	Rise
	WEEK 4	23JUL2012	10:00	109.2	ng/mL	-21.2	

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[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
207-0007/71/M/W2	WEEK 8	20AUG2012	10:55	184.2	ng/mL	-104.44	
	END OF TREATMENT	15OCT2012	10:45	216	ng/mL	-139.73	
	Minimum Post-baseline	23JUL2012	10:00	109.2	ng/mL	-21.2	
207-0012/66/M/W2	SCREENING	12MAR2013	08:30	17215.6	ng/mL	.	Rise
	WEEK 4	11APR2013	09:50	15078.9	ng/mL	12.41	
	WEEK 8	09MAY2013	08:30	13057.6	ng/mL	24.15	
	WEEK 12	06JUN2013	08:45	13819.4	ng/mL	19.73	
	WEEK 16	04JUL2013	08:45	13499.5	ng/mL	21.59	
	WEEK 20	01AUG2013	09:15	14808	ng/mL	13.98	
	WEEK 24	30AUG2013	08:30	12216.2	ng/mL	29.04	

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
207-0012/66/M/W2	WEEK 28	04OCT2013	08:50	12831.1	ng/mL	25.47	
	WEEK 32	31OCT2013	08:50	13889.5	ng/mL	19.32	
	WEEK 36	29NOV2013	09:30	13794.6	ng/mL	19.87	
	WEEK 40	27DEC2013	08:45	27447.3	ng/mL	-59.43	
	WEEK 42	10JAN2014	11:30	25335.4	ng/mL	-47.17	
	WEEK 44	24JAN2014	09:45	29861.8	ng/mL	-73.46	
	WEEK 46	06FEB2014	10:30	36127.7	ng/mL	-109.85	
	END OF TREATMENT	27FEB2014	10:45	50175.1	ng/mL	-191.45	
	Minimum Post-baseline	30AUG2013	08:30	12216.2	ng/mL	29.04	
207-0016/82/F/W2	SCREENING	30SEP2013	10:00	1524.5	ng/mL	.	Rise

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
207-0016/82/F/W2	WEEK 4	31OCT2013	10:40	2318.1	ng/mL	-52.06	
	WEEK 8	28NOV2013	09:40	2928.5	ng/mL	-92.1	
	WEEK 12	27DEC2013	09:30	4404.5	ng/mL	-188.91	
	END OF TREATMENT	12FEB2014	09:30	5656.4	ng/mL	-271.03	
	Minimum Post-baseline	31OCT2013	10:40	2318.1	ng/mL	-52.06	
207-0017/81/F/W2	SCREENING	22NOV2013	10:00	39.5	ng/mL	.	Rise
	WEEK 4	19DEC2013	10:00	104.2	ng/mL	-163.8	
	WEEK 8	17JAN2014	10:50	227.2	ng/mL	-475.19	
	WEEK 12	13FEB2014	12:30	233.1	ng/mL	-490.13	
	Minimum Post-baseline	19DEC2013	10:00	104.2	ng/mL	-163.8	

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
207-0019/55/M/W2	SCREENING	27MAY2014	13:15	4187.6	ng/mL	.	Stable
209-0006/68/M/W2	SCREENING	18APR2013	09:45	11.4	ng/mL	.	Stable
	WEEK 4	21MAY2013	09:30	11.2	ng/mL	1.75	
	WEEK 8	18JUN2013	10:45	10.3	ng/mL	9.65	
	WEEK 12	24JUL2013	08:00	9.3	ng/mL	18.42	
	WEEK 16	20AUG2013	10:00	9.4	ng/mL	17.54	
	WEEK 20	20SEP2013	09:30	9.5	ng/mL	16.67	
	WEEK 24	15OCT2013	10:30	12.9	ng/mL	-13.16	
	WEEK 28	14NOV2013	11:00	9.2	ng/mL	19.3	
	WEEK 32	10DEC2013	09:30	13.2	ng/mL	-15.79	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
209-0006/68/M/W2	WEEK 36	07JAN2014	09:15	13.6	ng/mL	-19.3	
	TERMINATION	18FEB2014	11:00	11	ng/mL	3.51	
	Minimum Post-baseline	14NOV2013	11:00	9.2	ng/mL	19.3	
209-0011/69/M/W2	SCREENING	21NOV2013	10:50	197.1	ng/mL	.	Stable
	WEEK 4	23DEC2013	09:00	244.1	ng/mL	-23.85	
	WEEK 8	22JAN2014	09:50	234.5	ng/mL	-18.98	
	WEEK 12	19FEB2014	09:30	183.5	ng/mL	6.9	
	TERMINATION	19MAR2014	10:40	174.2	ng/mL	11.62	
	Minimum Post-baseline	19MAR2014	10:40	174.2	ng/mL	11.62	
209-0014/79/M/W2	SCREENING	04MAR2014	10:05	942.1	ng/mL	.	Rise

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
209-0014/79/M/W2	WEEK 4	08APR2014	11:00	1446.6	ng/mL	-53.55	
	WEEK 8	07MAY2014	10:20	1964.5	ng/mL	-108.52	
	WEEK 12	04JUN2014	10:30	2629.8	ng/mL	-179.14	
	WEEK 16	02JUL2014	09:00	2816.7	ng/mL	-198.98	
	WEEK 20	29JUL2014	10:00	3097.8	ng/mL	-228.82	
	WEEK 24	26AUG2014	10:10	3372.5	ng/mL	-257.98	
	END OF TREATMENT	23SEP2014	09:00	4148.3	ng/mL	-340.32	
	Minimum Post-baseline	08APR2014	11:00	1446.6	ng/mL	-53.55	
210-0003/74/M/W2	SCREENING	30OCT2013	10:00	74.4	ng/mL	.	Stable
	WEEK 4	28NOV2013	11:15	62.7	ng/mL	15.73	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
210-0003/74/M/W2	Minimum Post-baseline	28NOV2013	11:15	62.7	ng/mL	15.73	
210-0004/71/M/W2	SCREENING	02JAN2014	09:45	2623.3	ng/mL	.	Rise
	WEEK 4	29JAN2014	09:30	6053.1	ng/mL	-130.74	
	WEEK 8	26FEB2014	09:35	2810.6	ng/mL	-7.14	
	WEEK 12	26MAR2014	10:00	4031	ng/mL	-53.66	
	END OF TREATMENT	21MAY2014	09:45	5209.7	ng/mL	-98.59	
	Minimum Post-baseline	26FEB2014	09:35	2810.6	ng/mL	-7.14	
210-0005/53/M/W2	SCREENING	13FEB2014	09:20	488.6	ng/mL	.	Rise
	WEEK 4	13MAR2014	11:30	551.2	ng/mL	-12.81	
	WEEK 8	10APR2014	09:15	734.6	ng/mL	-50.35	

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
210-0005/53/M/W2	WEEK 12	07MAY2014	09:10	967.4	ng/mL	-97.99	
	END OF TREATMENT	29MAY2014	09:30	956.2	ng/mL	-95.7	
	Minimum Post-baseline	13MAR2014	11:30	551.2	ng/mL	-12.81	
210-0006/45/M/W2	SCREENING	18JUN2014	10:45	7	ng/mL	.	Stable
	WEEK 4	16JUL2014	10:15	5.1	ng/mL	27.14	
	WEEK 8	14AUG2014	09:30	4.7	ng/mL	32.86	
	WEEK 12	10SEP2014	10:20	4.5	ng/mL	35.71	
	Minimum Post-baseline	10SEP2014	10:20	4.5	ng/mL	35.71	
251-0002/69/M/W2	SCREENING	06AUG2013	11:00	3070.3	ng/mL	.	Rise
	WEEK 3	27AUG2013	11:20	3481.4	ng/mL	-13.39	

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
251-0002/69/M/W2	WEEK 4	03SEP2013	11:45	3421.1	ng/mL	-11.43	
	WEEK 8	01OCT2013	11:30	5474.7	ng/mL	-78.31	
	Minimum Post-baseline	03SEP2013	11:45	3421.1	ng/mL	-11.43	
251-0003/68/M/W2	SCREENING	29OCT2013	09:36	2.4	ng/mL	.	Rise
	WEEK 4	26NOV2013	09:15	4	ng/mL	-66.67	
	WEEK 8	24DEC2013	10:00	3.3	ng/mL	-37.5	
	WEEK 12	21JAN2014	10:00	2.3	ng/mL	4.17	
	WEEK 16	18FEB2014	10:00	2.5	ng/mL	-4.17	
	WEEK 20	18MAR2014	10:30	2.1	ng/mL	12.5	
	WEEK 24	15APR2014	11:00	1.8	ng/mL	25	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
251-0003/68/M/W2	Minimum Post-baseline	15APR2014	11:00	1.8	ng/mL	25	
252-0001/65/M/A3	SCREENING	01MAY2012	10:30	133.1	ng/mL	.	Rise
	WEEK 4	29MAY2012	11:25	162.9	ng/mL	-22.39	
	WEEK 8	26JUN2012	11:35	408.9	ng/mL	-207.21	
	Minimum Post-baseline	29MAY2012	11:25	162.9	ng/mL	-22.39	
252-0004/50/M/A1	SCREENING	21MAY2013	11:20	14419.6	ng/mL	.	Rise
	WEEK 4	18JUN2013	11:30	21085.3	ng/mL	-46.23	
	WEEK 8	16JUL2013	10:35	30451.1	ng/mL	-111.18	
	END OF TREATMENT	20AUG2013	12:00	184255.6	ng/mL	-1177.81	
	Minimum Post-baseline	18JUN2013	11:30	21085.3	ng/mL	-46.23	

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
252-0006/64/M/W2	SCREENING	17SEP2013	08:35	46.1	ng/mL	.	Rise
	WEEK 4	22OCT2013	08:30	59.6	ng/mL	-29.28	
	WEEK 8	19NOV2013	08:30	156.8	ng/mL	-240.13	
	WEEK 12	17DEC2013	08:30	274.8	ng/mL	-496.1	
	WEEK 16	14JAN2014	08:20	282.6	ng/mL	-513.02	
	WEEK 20	11FEB2014	08:00	297.8	ng/mL	-545.99	
	WEEK 24	11MAR2014	08:00	442.1	ng/mL	-859	
	END OF TREATMENT	22APR2014	10:05	733	ng/mL	-1490.02	
	Minimum Post-baseline	22OCT2013	08:30	59.6	ng/mL	-29.28	
252-0008/76/M/W2	SCREENING	20MAY2014	11:30	1415	ng/mL	.	Rise

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
252-0008/76/M/W2	WEEK 4	17JUN2014	11:25	2682.1	ng/mL	-89.55	
	WEEK 8	15JUL2014	11:15	3812.1	ng/mL	-169.41	
	WEEK 12	12AUG2014	12:40	4671.3	ng/mL	-230.13	
	END OF TREATMENT	23SEP2014	11:55	7577.1	ng/mL	-435.48	
	Minimum Post-baseline	17JUN2014	11:25	2682.1	ng/mL	-89.55	
252-0010/56/F/W2	SCREENING	28OCT2014	10:40	4.1	ng/mL	.	Stable
	WEEK 4	25NOV2014	10:10	4.8	ng/mL	-17.07	
	WEEK 8	23DEC2014	10:03	4.9	ng/mL	-19.51	
	WEEK 12	20JAN2015	10:45	5.4	ng/mL	-31.71	
	Minimum Post-baseline	25NOV2014	10:10	4.8	ng/mL	-17.07	

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
253-0003/75/M/W2	SCREENING	25MAY2012	11:30	9.5	ng/mL	.	Rise
	WEEK 4	06JUL2012	11:44	10.7	ng/mL	-12.63	
	WEEK 8	03AUG2012	11:35	11.4	ng/mL	-20	
	WEEK 12	31AUG2012	11:20	12.1	ng/mL	-27.37	
	WEEK 16	28SEP2012	11:20	10.6	ng/mL	-11.58	
	WEEK 24	23NOV2012	11:30	13.1	ng/mL	-37.89	
	WEEK 28	21DEC2012	11:30	15.7	ng/mL	-65.26	
	WEEK 32	18JAN2013	12:00	19.8	ng/mL	-108.42	
	WEEK 36	15FEB2013	11:20	23.7	ng/mL	-149.47	
	END OF TREATMENT	08MAR2013	11:30	24.6	ng/mL	-158.95	

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[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
253-0003/75/M/W2	Minimum Post-baseline	28SEP2012	11:20	10.6	ng/mL	-11.58	
253-0004/79/M/W2	SCREENING	04SEP2012	14:30	32.7	ng/mL	.	Rise
	WEEK 4	28SEP2012	10:20	44.4	ng/mL	-35.78	
	WEEK 12	23NOV2012	10:00	156.8	ng/mL	-379.51	
	END OF TREATMENT	21DEC2012	12:00	153.6	ng/mL	-369.72	
	Minimum Post-baseline	28SEP2012	10:20	44.4	ng/mL	-35.78	
253-0005/74/F/W2	SCREENING	26OCT2012	14:30	958.5	ng/mL	.	Stable
253-0006/63/M/A3	SCREENING	21DEC2012	11:30	240.3	ng/mL	.	Rise
	WEEK 4	18JAN2013	12:00	261.3	ng/mL	-8.74	
	WEEK 8	15FEB2013	11:45	296.9	ng/mL	-23.55	

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
253-0006/63/M/A3	WEEK 12	15MAR2013	11:30	609.6	ng/mL	-153.68	
	WEEK 16	12APR2013	11:05	2763.2	ng/mL	-1049.9	
	WEEK 20	10MAY2013	10:00	29181.3	ng/mL	-12043.7	
	TERMINATION	28JUN2013	10:00	152327.4	ng/mL	-63290.51	
	Minimum Post-baseline	18JAN2013	12:00	261.3	ng/mL	-8.74	
253-0011/67/M/W2	SCREENING	25SEP2014	10:00	2274.2	ng/mL	.	Decline
	WEEK 4	27OCT2014	10:30	1548.7	ng/mL	31.9	
	WEEK 8	24NOV2014	10:20	863	ng/mL	62.05	
	WEEK 12	22DEC2014	10:00	283.5	ng/mL	87.53	
	WEEK 16	19JAN2015	11:00	52	ng/mL	97.71	

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
253-0011/67/M/W2	WEEK 20	16FEB2015	09:50	28.6	ng/mL	98.74	
	WEEK 24	16MAR2015	10:50	14.8	ng/mL	99.35	
	WEEK 28	13APR2015	09:40	24.4	ng/mL	98.93	
	WEEK 32	11MAY2015	09:58	24.4	ng/mL	98.93	
	WEEK 36	08JUN2015	10:30	25.1	ng/mL	98.9	
	Minimum Post-baseline	16MAR2015	10:50	14.8	ng/mL	99.35	
253-0012/67/M/W2	SCREENING	24NOV2014	12:10	9988.4	ng/mL	.	Rise
	WEEK 4	29DEC2014	09:30	15695.6	ng/mL	-57.14	
	WEEK 5	05JAN2015	00:00	16306	KU/L	-63.25	
	Minimum Post-baseline	29DEC2014	09:30	15695.6	ng/mL	-57.14	

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
257-0005/66/M/W2	SCREENING	13DEC2012	11:15	7.8	ng/mL	.	Stable
	WEEK 4	24JAN2013	11:56	5.8	ng/mL	25.64	
	UNSCHEDULED	28FEB2013	10:10	4.6	ng/mL	41.03	
	WEEK 12	21MAR2013	10:35	5.6	ng/mL	28.21	
	Minimum Post-baseline	28FEB2013	10:10	4.6	ng/mL	41.03	
257-0013/63/M/W2	SCREENING	23MAY2013	12:10	103	ng/mL	.	Stable
	WEEK 4	20JUN2013	11:45	140.8	ng/mL	-36.7	
	Minimum Post-baseline	20JUN2013	11:45	140.8	ng/mL	-36.7	
257-0020/72/M/A1	SCREENING	20OCT2014	14:10	8.4	ng/mL	.	Rise
	WEEK 4	17NOV2014	13:43	22.2	ng/mL	-164.29	

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
257-0020/72/M/A1	END OF TREATMENT	22DEC2014	14:25	64.9	ng/mL	-672.62	
	Minimum Post-baseline	17NOV2014	13:43	22.2	ng/mL	-164.29	
258-0002/69/F/W2	SCREENING	08APR2013	10:00	242284	ng/mL	.	Decline
	WEEK 4	01MAY2013	11:00	230392.6	ng/mL	4.91	
	WEEK 8	29MAY2013	11:08	230495.8	ng/mL	4.87	
	WEEK 12	26JUN2013	11:30	153104.8	ng/mL	36.81	
	WEEK 16	24JUL2013	09:45	165511.8	ng/mL	31.69	
	WEEK 20	21AUG2013	10:26	148041.9	ng/mL	38.9	
	WEEK 24	18SEP2013	10:34	126932.9	ng/mL	47.61	
	WEEK 28	16OCT2013	10:46	108474.5	ng/mL	55.23	

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
258-0002/69/F/W2	WEEK 36	11DEC2013	12:13	228557	ng/mL	5.67	
	END OF TREATMENT	15JAN2014	10:45	157174.8	ng/mL	35.13	
	Minimum Post-baseline	16OCT2013	10:46	108474.5	ng/mL	55.23	
258-0003/67/F/W2	SCREENING	09MAY2013	11:30	12.3	ng/mL	.	Stable
	WEEK 4	05JUN2013	11:25	13.9	ng/mL	-13.01	
	WEEK 8	03JUL2013	11:05	13.9	ng/mL	-13.01	
	WEEK 12	31JUL2013	11:24	13.9	ng/mL	-13.01	
	WEEK 16	30AUG2013	10:07	15.4	ng/mL	-25.2	
	WEEK 24	23OCT2013	10:25	10.3	ng/mL	16.26	
	END OF TREATMENT	27NOV2013	11:32	11.7	ng/mL	4.88	

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
258-0003/67/F/W2	Minimum Post-baseline	23OCT2013	10:25	10.3	ng/mL	16.26	
258-0004/65/M/W2	SCREENING	09MAY2013	12:33	4.8	ng/mL	.	Stable
	END OF TREATMENT	21JUN2013	09:45	6	ng/mL	-25	
	Minimum Post-baseline	21JUN2013	09:45	6	ng/mL	-25	
258-0006/69/M/W2	SCREENING	02OCT2013	10:50	1862.3	ng/mL	.	Stable
	WEEK 4	08NOV2013	10:45	2194.6	ng/mL	-17.84	
	Minimum Post-baseline	08NOV2013	10:45	2194.6	ng/mL	-17.84	
258-0013/59/M/W2	SCREENING	05NOV2014	10:05	203.9	ng/mL	.	Rise
	WEEK 4	03DEC2014	10:40	5021.7	ng/mL	-2362.82	
	WEEK 8	29DEC2014	11:25	18025.1	ng/mL	-8740.17	

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
258-0013/59/M/W2	WEEK 12	28JAN2015	12:00	33335.5	ng/mL	-16248.95	
	END OF TREATMENT	04MAR2015	10:55	137028.5	ng/mL	-67103.78	
	Minimum Post-baseline	03DEC2014	10:40	5021.7	ng/mL	-2362.82	
259-0003/73/M/W2	SCREENING	09JUN2014	13:50	2	ng/mL	.	Rise
	WEEK 4	02JUL2014	11:15	2.3	ng/mL	-15	
	WEEK 8	30JUL2014	12:15	2.4	ng/mL	-20	
	WEEK 12	27AUG2014	11:40	2.3	ng/mL	-15	
	WEEK 16	24SEP2014	11:55	2.1	ng/mL	-5	
	WEEK 20	22OCT2014	11:10	2.2	ng/mL	-10	
	WEEK 24	19NOV2014	11:00	2.7	ng/mL	-35	

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
259-0003/73/M/W2	WEEK 28	17DEC2014	11:30	3.4	ng/mL	-70	
	WEEK 32	14JAN2015	11:10	3.1	ng/mL	-55	
	WEEK 36	11FEB2015	11:10	3.9	ng/mL	-95	
	WEEK 40	11MAR2015	11:14	5.2	ng/mL	-160	
	WEEK 44	08APR2015	11:40	8.7	ng/mL	-335	
	WEEK 48	06MAY2015	10:50	10.2	ng/mL	-410	
	Minimum Post-baseline	24SEP2014	11:55	2.1	ng/mL	-5	
259-0004/52/M/W2	SCREENING	16JUL2014	10:45	378.2	ng/mL	.	Stable
	UNSCHEDULED	23JUL2014	11:30	426.9	ng/mL	-12.88	
	WEEK 4	13AUG2014	11:25	412.9	ng/mL	-9.18	

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
259-0004/52/M/W2	Minimum Post-baseline	13AUG2014	11:25	412.9	ng/mL	-9.18	
260-0002/66/M/W2	SCREENING	18SEP2013	15:15	4.1	ng/mL	.	Stable
	WEEK 4	23OCT2013	14:15	5	ng/mL	-21.95	
	END OF TREATMENT	11DEC2013	14:30	5.3	ng/mL	-29.27	
	Minimum Post-baseline	23OCT2013	14:15	5	ng/mL	-21.95	
301-0001/47/F/A2	SCREENING	27OCT2011	10:05	5204.37	ng/mL	.	Rise
	WEEK 4	22NOV2011	09:25	9842.03	ng/mL	-89.11	
	WEEK 8	20DEC2011	09:25	10518.07	ng/mL	-102.1	
	WEEK 12	17JAN2012	11:50	12549.73	ng/mL	-141.14	
	Minimum Post-baseline	22NOV2011	09:25	9842.03	ng/mL	-89.11	

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
301-0003/61/F/A2	SCREENING	23FEB2012	11:40	394965	ng/mL	.	Decline
	WEEK 4	22MAR2012	10:40	362503.5	ng/mL	8.22	
	WEEK 8	19APR2012	11:10	168076.77	ng/mL	57.45	
	WEEK 12	17MAY2012	11:10	178890	ng/mL	54.71	
	END OF TREATMENT	19JUN2012	10:30	130368.6	ng/mL	66.99	
	Minimum Post-baseline	19JUN2012	10:30	130368.6	ng/mL	66.99	
301-0008/53/M/A2	SCREENING	26DEC2012	09:50	600.49	ng/mL	.	Rise
	WEEK 4	25JAN2013	09:50	1605.45	ng/mL	-167.36	
	WEEK 8	22FEB2013	09:50	2177.03	ng/mL	-262.54	
	WEEK 12	22MAR2013	10:35	4699.83	ng/mL	-682.67	

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Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
301-0008/53/M/A2	Minimum Post-baseline	25JAN2013	09:50	1605.45	ng/mL	-167.36	
302-0006/49/M/A2	SCREENING	04JAN2012	09:30	386121	ng/mL	.	Rise
	WEEK 4	31JAN2012	09:45	807618	ng/mL	-109.16	
	WEEK 8	28FEB2012	09:40	1343886	ng/mL	-248.05	
	Minimum Post-baseline	31JAN2012	09:45	807618	ng/mL	-109.16	
302-0009/73/M/A2	SCREENING	11APR2012	09:02	47271.42	ng/mL	.	Rise
	WEEK 4	08MAY2012	09:03	93121.29	ng/mL	-96.99	
	WEEK 8	05JUN2012	09:12	135634.8	ng/mL	-186.93	
	Minimum Post-baseline	08MAY2012	09:03	93121.29	ng/mL	-96.99	
302-0012/62/M/A2	SCREENING	18APR2012	08:30	828.72	ng/mL	.	Rise

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[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
302-0012/62/M/A2	WEEK 4	15MAY2012	08:15	1458.33	ng/mL	-75.97	
	WEEK 8	12JUN2012	10:22	2750.89	ng/mL	-231.94	
	WEEK 12	10JUL2012	08:23	3086.96	ng/mL	-272.5	
	END OF TREATMENT	14AUG2012	09:15	4341.87	ng/mL	-423.92	
	Minimum Post-baseline	15MAY2012	08:15	1458.33	ng/mL	-75.97	
302-0013/62/M/A2	SCREENING	21MAR2013	09:55	2.5	ng/mL	.	Stable
	WEEK 4	16APR2013	08:05	2.11	ng/mL	15.6	
	WEEK 8	14MAY2013	08:10	2.26	ng/mL	9.6	
	END OF TREATMENT	02JUL2013	11:05	2.54	ng/mL	-1.6	
	Minimum Post-baseline	16APR2013	08:05	2.11	ng/mL	15.6	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
302-0020/52/M/A2	SCREENING	16MAY2013	09:00	92.1	ng/mL	.	Rise
	WEEK 4	11JUN2013	09:00	377.7	ng/mL	-310.1	
	END OF TREATMENT	15JUL2013	10:05	673.24	ng/mL	-630.99	
	Minimum Post-baseline	11JUN2013	09:00	377.7	ng/mL	-310.1	
302-0021/75/F/A2	SCREENING	06JUN2013	10:25	1756.65	ng/mL	.	Rise
	WEEK 4	02JUL2013	09:30	1841.85	ng/mL	-4.85	
	WEEK 8	30JUL2013	09:45	1860.57	ng/mL	-5.92	
	WEEK 12	27AUG2013	09:10	2662.48	ng/mL	-51.57	
	WEEK 16	24SEP2013	09:45	4763.4	ng/mL	-171.16	
	WEEK 20	22OCT2013	10:15	8506.96	ng/mL	-384.27	

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
302-0021/75/F/A2	WEEK 24	19NOV2013	09:20	12046.8	ng/mL	-585.78	
	Minimum Post-baseline	02JUL2013	09:30	1841.85	ng/mL	-4.85	
304-0003/56/F/A2	SCREENING	11MAR2013	11:50	3.82	ng/mL	.	Stable
	WEEK 4	03APR2013	10:00	3.22	ng/mL	15.71	
	WEEK 8	02MAY2013	10:00	3.11	ng/mL	18.59	
	WEEK 12	30MAY2013	09:02	3.38	ng/mL	11.52	
	END OF TREATMENT	03JUL2013	08:50	5.12	ng/mL	-34.03	
	Minimum Post-baseline	02MAY2013	10:00	3.11	ng/mL	18.59	
304-0004/69/M/A2	SCREENING	30MAY2013	13:00	2.21	ng/mL	.	Stable
	WEEK 4	25JUN2013	08:02	1.72	ng/mL	22.17	

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
304-0004/69/M/A2	Minimum Post-baseline	25JUN2013	08:02	1.72	ng/mL	22.17	
304-0007/72/M/A2	SCREENING	07NOV2013	11:20	1.09	ng/mL	.	Stable
	WEEK 4	04DEC2013	10:00	1.38	ng/mL	-26.61	
	WEEK 8	02JAN2014	10:00	1.43	ng/mL	-31.19	
	WEEK 12	28JAN2014	09:48	1.35	ng/mL	-23.85	
	END OF TREATMENT	26FEB2014	10:45	1.41	ng/mL	-29.36	
	Minimum Post-baseline	28JAN2014	09:48	1.35	ng/mL	-23.85	
305-0004/79/M/A2	SCREENING	14FEB2012	16:50	18.06	ng/mL	.	Rise
	WEEK 4	15MAR2012	08:07	26.7	ng/mL	-47.84	
	WEEK 8	12APR2012	09:00	36.22	ng/mL	-100.55	

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
305-0004/79/M/A2	WEEK 12	10MAY2012	08:16	45.78	ng/mL	-153.49	
	WEEK 13	17MAY2012	10:00	59.2	ng/mL	-227.8	
	Minimum Post-baseline	15MAR2012	08:07	26.7	ng/mL	-47.84	
305-0007/67/M/A2	SCREENING	08MAR2012	09:50	9483.71	ng/mL	.	Decline
	WEEK 4	30MAR2012	08:00	4744.55	ng/mL	49.97	
	WEEK 8	27APR2012	08:00	376.72	ng/mL	96.03	
	WEEK 12	25MAY2012	07:40	15.25	ng/mL	99.84	
	WEEK 16	22JUN2012	07:32	4.11	ng/mL	99.96	
	WEEK 20	20JUL2012	07:55	3.84	ng/mL	99.96	
	WEEK 24	17AUG2012	07:38	3.66	ng/mL	99.96	

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
305-0007/67/M/A2	END OF TREATMENT	14SEP2012	10:07	3.13	ng/mL	99.97	
	Minimum Post-baseline	14SEP2012	10:07	3.13	ng/mL	99.97	
305-0015/84/M/A2	SCREENING	04JUL2012	11:50	18455.82	ng/mL	.	Rise
	WEEK 4	26JUL2012	07:13	41414.96	ng/mL	-124.4	
	WEEK 8	21AUG2012	12:47	101153.25	ng/mL	-448.08	
	WEEK 12	20SEP2012	08:14	104017.5	ng/mL	-463.6	
	UNSCHEDULED	29SEP2012	05:22	90170.8	ng/mL	-388.58	
	END OF TREATMENT	24OCT2012	15:00	112509.75	ng/mL	-509.62	
	Minimum Post-baseline	26JUL2012	07:13	41414.96	ng/mL	-124.4	
305-0016/78/M/A2	SCREENING	04JUL2012	16:10	197.26	ng/mL	.	Rise

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
305-0016/78/M/A2	WEEK 4	01AUG2012	12:40	340.49	ng/mL	-72.61	
	WEEK 8	28AUG2012	09:05	174.65	ng/mL	11.46	
	WEEK 12	25SEP2012	12:40	248.1	ng/mL	-25.77	
	Minimum Post-baseline	28AUG2012	09:05	174.65	ng/mL	11.46	
305-0021/83/F/A2	SCREENING	16NOV2012	16:34	29.2	ng/mL	.	Rise
	WEEK 4	11DEC2012	12:58	39.67	ng/mL	-35.86	
	WEEK 8	08JAN2013	13:10	47.13	ng/mL	-61.4	
	WEEK 12	05FEB2013	13:00	54.38	ng/mL	-86.23	
	Minimum Post-baseline	11DEC2012	12:58	39.67	ng/mL	-35.86	
305-0024/68/M/A2	SCREENING	14JAN2013	10:30	10	ng/mL	.	Stable

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
305-0024/68/M/A2	WEEK 4	08FEB2013	08:00	11.66	ng/mL	-16.6	
	WEEK 8	05MAR2013	13:15	9.04	ng/mL	9.6	
	WEEK 12	03APR2013	13:10	7.63	ng/mL	23.7	
	Minimum Post-baseline	03APR2013	13:10	7.63	ng/mL	23.7	
305-0033/37/F/A2	SCREENING	25JUN2013	15:20	903.24	ng/mL	.	Stable
	WEEK 4	23JUL2013	15:00	723.69	ng/mL	19.88	
	WEEK 8	20AUG2013	15:25	713.57	ng/mL	21	
	WEEK 12	17SEP2013	16:00	876.35	ng/mL	2.98	
	Minimum Post-baseline	20AUG2013	15:25	713.57	ng/mL	21	
305-0035/60/M/A2	SCREENING	27AUG2013	15:30	540.43	ng/mL	.	Rise

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
305-0035/60/M/A2	WEEK 4	18SEP2013	11:40	520.6	ng/mL	3.67	
	WEEK 8	16OCT2013	12:00	809.43	ng/mL	-49.78	
	WEEK 12	13NOV2013	12:25	1568.19	ng/mL	-190.17	
	WEEK 16	11DEC2013	12:50	1559.37	ng/mL	-188.54	
	WEEK 20	08JAN2014	12:53	2102.09	ng/mL	-288.97	
	WEEK 24	05FEB2014	12:20	3673.39	ng/mL	-579.72	
	Minimum Post-baseline	18SEP2013	11:40	520.6	ng/mL	3.67	
305-0046/60/M/A2	SCREENING	03NOV2014	12:20	4058.53	ng/mL	.	Rise
	WEEK 4	28NOV2014	13:21	2710.16	ng/mL	33.22	
	WEEK 8	26DEC2014	13:15	2867.48	ng/mL	29.35	

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Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
305-0046/60/M/A2	WEEK 12	23JAN2015	12:50	3261.21	ng/mL	19.65	
	WEEK 16	17FEB2015	13:05	4310.23	ng/mL	-6.2	
	WEEK 20	20MAR2015	12:40	5449	ng/mL	-34.26	
	WEEK 24	14APR2015	12:50	7061	ng/mL	-73.98	
	END OF TREATMENT	19MAY2015	15:20	8411	ng/mL	-107.24	
	Minimum Post-baseline	28NOV2014	13:21	2710.16	ng/mL	33.22	
306-0004/46/M/A2	SCREENING	15FEB2012	09:30	644908.5	ng/mL	.	Stable
	WEEK 4	13MAR2012	09:00	946710	ng/mL	-46.8	
	Minimum Post-baseline	13MAR2012	09:00	946710	ng/mL	-46.8	
306-0010/69/M/A2	SCREENING	09MAR2012	15:00	3.79	ng/mL	.	Stable

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
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Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
306-0010/69/M/A2	WEEK 4	11APR2012	11:00	3.73	ng/mL	1.58	
	WEEK 8	09MAY2012	10:30	4.49	ng/mL	-18.47	
	WEEK 12	06JUN2012	10:00	5.44	ng/mL	-43.54	
	Minimum Post-baseline	11APR2012	11:00	3.73	ng/mL	1.58	
306-0013/42/M/A2	SCREENING	09APR2012	09:30	47774.4	ng/mL	.	Rise
	WEEK 4	07MAY2012	10:00	106809.39	ng/mL	-123.57	
	WEEK 8	04JUN2012	09:00	274264.5	ng/mL	-474.08	
	Minimum Post-baseline	07MAY2012	10:00	106809.39	ng/mL	-123.57	
306-0015/73/M/A2	SCREENING	15MAY2012	10:30	69.06	ng/mL	.	Rise
	WEEK 4	07JUN2012	09:00	367.72	ng/mL	-432.46	

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[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
306-0015/73/M/A2	Minimum Post-baseline	07JUN2012	09:00	367.72	ng/mL	-432.46	
306-0016/58/M/A2	SCREENING	21JUN2012	09:00	7.01	ng/mL	.	Stable
	WEEK 4	16JUL2012	09:20	5.08	ng/mL	27.53	
	WEEK 8	13AUG2012	09:05	4.83	ng/mL	31.1	
	WEEK 12	11SEP2012	08:20	3.94	ng/mL	43.79	
	END OF TREATMENT	15OCT2012	09:20	4.87	ng/mL	30.53	
	Minimum Post-baseline	11SEP2012	08:20	3.94	ng/mL	43.79	
306-0022/56/M/A2	SCREENING	06NOV2012	09:10	70.03	ng/mL	.	Rise
	WEEK 4	04DEC2012	09:00	52.23	ng/mL	25.42	
	WEEK 8	02JAN2013	08:50	45.04	ng/mL	35.68	

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
306-0022/56/M/A2	WEEK 12	29JAN2013	08:50	57.89	ng/mL	17.34	
	WEEK 16	26FEB2013	08:20	97.88	ng/mL	-39.77	
	WEEK 20	26MAR2013	08:30	151.29	ng/mL	-116.04	
	WEEK 24	23APR2013	08:20	143.59	ng/mL	-105.04	
	END OF TREATMENT	28MAY2013	08:20	172.97	ng/mL	-146.99	
	Minimum Post-baseline	02JAN2013	08:50	45.04	ng/mL	35.68	
306-0028/53/M/A2	SCREENING	18MAR2013	13:30	8025.93	ng/mL	.	Rise
	WEEK 4	18APR2013	09:00	5788.57	ng/mL	27.88	
	WEEK 8	16MAY2013	09:30	18761.41	ng/mL	-133.76	
	WEEK 12	13JUN2013	09:30	13674.15	ng/mL	-70.37	

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
306-0028/53/M/A2	END OF TREATMENT	04JUL2013	09:30	17612.41	ng/mL	-119.44	
	Minimum Post-baseline	18APR2013	09:00	5788.57	ng/mL	27.88	
306-0045/60/F/A1	SCREENING	11JUN2014	12:30	387.06	ng/mL	.	Rise
	WEEK 4	08JUL2014	13:00	584.77	ng/mL	-51.08	
	WEEK 8	05AUG2014	13:00	708.8	ng/mL	-83.12	
	WEEK 12	02SEP2014	13:00	929.45	ng/mL	-140.13	
	END OF TREATMENT	03OCT2014	13:00	863.96	ng/mL	-123.21	
	Minimum Post-baseline	08JUL2014	13:00	584.77	ng/mL	-51.08	
307-0006/72/M/A2	SCREENING	25NOV2011	09:09	23.39	ng/mL	.	Stable
307-0009/53/M/A2	SCREENING	28DEC2011	09:45	193	ng/mL	.	Stable

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
307-0009/53/M/A2	WEEK 4	27JAN2012	09:15	172.06	ng/mL	10.85	
	Minimum Post-baseline	27JAN2012	09:15	172.06	ng/mL	10.85	
307-0012/42/M/A2	SCREENING	31JAN2012	09:00	36171.99	ng/mL	.	Stable
307-0015/75/M/A2	SCREENING	18APR2012	08:43	47.66	ng/mL	.	Rise
	WEEK 4	16MAY2012	08:45	37.74	ng/mL	20.81	
	WEEK 8	13JUN2012	09:25	36.6	ng/mL	23.21	
	WEEK 12	11JUL2012	10:50	34.69	ng/mL	27.21	
	WEEK 16	08AUG2012	09:57	49.44	ng/mL	-3.73	
	WEEK 20	05SEP2012	09:30	62.44	ng/mL	-31.01	
	WEEK 24	04OCT2012	10:50	83.17	ng/mL	-74.51	

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
307-0015/75/M/A2	END OF TREATMENT	08NOV2012	09:35	172.99	ng/mL	-262.97	
	Minimum Post-baseline	11JUL2012	10:50	34.69	ng/mL	27.21	
307-0021/68/M/A2	SCREENING	14AUG2012	09:30	66.19	ng/mL	.	Rise
	WEEK 4	13SEP2012	08:57	97.94	ng/mL	-47.97	
	WEEK 8	09OCT2012	08:35	209.81	ng/mL	-216.98	
	WEEK 12	08NOV2012	09:18	300.04	ng/mL	-353.3	
	WEEK 16	06DEC2012	09:20	384.92	ng/mL	-481.54	
	Minimum Post-baseline	13SEP2012	08:57	97.94	ng/mL	-47.97	
307-0028/69/F/A2	SCREENING	09JAN2013	09:49	3606.34	ng/mL	.	Rise
	WEEK 4	04FEB2013	09:35	8532.98	ng/mL	-136.61	

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
307-0028/69/F/A2	WEEK 8	04MAR2013	09:34	54935.45	ng/mL	-1423.3	
	WEEK 12	01APR2013	09:32	32389.02	ng/mL	-798.11	
	Minimum Post-baseline	04FEB2013	09:35	8532.98	ng/mL	-136.61	
307-0034/48/M/A2	SCREENING	08AUG2013	11:48	65.82	ng/mL	.	Rise
	WEEK 4	03SEP2013	10:24	75.52	ng/mL	-14.74	
	WEEK 8	01OCT2013	09:10	93.01	ng/mL	-41.31	
	WEEK 12	29OCT2013	09:35	117.89	ng/mL	-79.11	
	Minimum Post-baseline	03SEP2013	10:24	75.52	ng/mL	-14.74	
307-0036/76/M/A2	SCREENING	27SEP2013	08:06	36322.67	ng/mL	.	Rise
	WEEK 4	24OCT2013	08:33	38000.14	ng/mL	-4.62	

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Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
307-0036/76/M/A2	WEEK 8	21NOV2013	09:20	56433.88	ng/mL	-55.37	
	WEEK 12	18DEC2013	09:09	98109.28	ng/mL	-170.1	
	END OF TREATMENT	21JAN2014	08:10	122050.31	ng/mL	-236.02	
	Minimum Post-baseline	24OCT2013	08:33	38000.14	ng/mL	-4.62	
307-0042/55/M/A2	SCREENING	10JUN2014	10:35	26.1	ng/mL	.	Decline
	WEEK 4	10JUL2014	09:22	10.41	ng/mL	60.11	
	WEEK 8	07AUG2014	09:40	11.92	ng/mL	54.33	
	WEEK 12	04SEP2014	10:50	15.57	ng/mL	40.34	
	WEEK 16	02OCT2014	09:37	20.32	ng/mL	22.15	
	WEEK 20	30OCT2014	09:28	26.01	ng/mL	0.34	

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Serum Alpha Fetoprotein Response
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Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
307-0042/55/M/A2	WEEK 24	27NOV2014	10:37	33.01	ng/mL	-26.48	
	END OF TREATMENT	18DEC2014	10:50	49.25	ng/mL	-88.7	
	Minimum Post-baseline	10JUL2014	09:22	10.41	ng/mL	60.11	
308-0002/36/F/A2	SCREENING	27DEC2012	09:15	15696.09	ng/mL	.	Rise
	WEEK 4	22JAN2013	11:30	27855.31	ng/mL	-77.47	
	WEEK 8	19FEB2013	12:30	50871.09	ng/mL	-224.1	
	WEEK 12	19MAR2013	12:30	105474.75	ng/mL	-571.98	
	Minimum Post-baseline	22JAN2013	11:30	27855.31	ng/mL	-77.47	
308-0004/52/M/A2	SCREENING	31JAN2013	11:10	9.09	ng/mL	.	Stable
	WEEK 4	26FEB2013	12:30	9.32	ng/mL	-2.53	

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Serum Alpha Fetoprotein Response
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Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
308-0004/52/M/A2	WEEK 8	26MAR2013	12:30	8.97	ng/mL	1.32	
	WEEK 12	23APR2013	12:10	9.84	ng/mL	-8.25	
	Minimum Post-baseline	26MAR2013	12:30	8.97	ng/mL	1.32	
308-0006/64/M/A2	SCREENING	09MAY2013	15:10	550.44	ng/mL	.	Decline
	WEEK 4	04JUN2013	13:20	539.14	ng/mL	2.05	
	WEEK 8	02JUL2013	13:05	289.58	ng/mL	47.39	
	END OF TREATMENT	30JUL2013	10:02	214.26	ng/mL	61.07	
	Minimum Post-baseline	30JUL2013	10:02	214.26	ng/mL	61.07	
308-0008/47/M/A2	SCREENING	11JUL2013	14:10	2294.79	ng/mL	.	Rise
	WEEK 4	13AUG2013	09:15	6790.2	ng/mL	-195.9	

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Serum Alpha Fetoprotein Response
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Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
308-0008/47/M/A2	WEEK 8	10SEP2013	09:10	14362.74	ng/mL	-525.88	
	WEEK 12	08OCT2013	09:00	31655.92	ng/mL	-1279.47	
	END OF TREATMENT	05NOV2013	11:00	44870.26	ng/mL	-1855.31	
	UNSCHEDULED	15NOV2013	10:32	37495	ng/mL	-1533.92	
	Minimum Post-baseline	13AUG2013	09:15	6790.2	ng/mL	-195.9	
308-0009/61/M/A2	SCREENING	11JUL2013	13:40	12423.22	ng/mL	.	Rise
	WEEK 4	08AUG2013	11:10	12568.58	ng/mL	-1.17	
	WEEK 8	05SEP2013	13:30	24320.13	ng/mL	-95.76	
	Minimum Post-baseline	08AUG2013	11:10	12568.58	ng/mL	-1.17	
309-0006/56/M/A2	SCREENING	19NOV2012	12:15	40.73	ng/mL	.	Decline

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
309-0006/56/M/A2	WEEK 4	17DEC2012	10:45	12.57	ng/mL	69.14	
	WEEK 8	14JAN2013	11:20	14.48	ng/mL	64.45	
	WEEK 12	08FEB2013	10:00	36.51	ng/mL	10.36	
	WEEK 16	11MAR2013	09:40	10.08	ng/mL	75.25	
	WEEK 20	08APR2013	10:50	16.88	ng/mL	58.56	
	WEEK 24	06MAY2013	09:20	18.15	ng/mL	55.44	
	WEEK 28	03JUN2013	10:20	20.25	ng/mL	50.28	
	WEEK 32	01JUL2013	09:10	16.47	ng/mL	59.56	
	WEEK 36	29JUL2013	09:50	5.74	ng/mL	85.91	
	END OF TREATMENT	22AUG2013	10:34	4.84	ng/mL	88.12	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
309-0006/56/M/A2	Minimum Post-baseline	22AUG2013	10:34	4.84	ng/mL	88.12	
309-0007/58/M/A2	SCREENING	04DEC2012	16:30	68.63	ng/mL	.	Rise
	WEEK 4	07JAN2013	11:30	71.52	ng/mL	-4.21	
	WEEK 8	04FEB2013	09:40	107.19	ng/mL	-56.19	
	WEEK 12	04MAR2013	09:20	280.6	ng/mL	-308.86	
	END OF TREATMENT	28MAR2013	15:40	162.11	ng/mL	-136.21	
	Minimum Post-baseline	07JAN2013	11:30	71.52	ng/mL	-4.21	
309-0013/45/M/A2	SCREENING	11JUN2013	13:50	1069.36	ng/mL	.	Rise
	WEEK 4	11JUL2013	09:35	1476.81	ng/mL	-38.1	
	WEEK 8	08AUG2013	09:30	2082.23	ng/mL	-94.72	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
309-0013/45/M/A2	WEEK 12	05SEP2013	09:15	1579.1	ng/mL	-47.67	
	END OF TREATMENT	30SEP2013	09:55	2041.02	ng/mL	-90.86	
	Minimum Post-baseline	11JUL2013	09:35	1476.81	ng/mL	-38.1	
309-0014/39/M/A2	SCREENING	14JUN2013	12:30	1626.16	ng/mL	.	Rise
	WEEK 4	11JUL2013	09:51	2537.91	ng/mL	-56.07	
	WEEK 8	08AUG2013	09:35	2717.47	ng/mL	-67.11	
	WEEK 12	05SEP2013	10:05	2912.9	ng/mL	-79.13	
	END OF TREATMENT	03OCT2013	10:30	5004.43	ng/mL	-207.75	
	Minimum Post-baseline	11JUL2013	09:51	2537.91	ng/mL	-56.07	
309-0019/68/M/A2	SCREENING	17JUN2014	12:30	14.74	ng/mL	.	Rise

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
309-0019/68/M/A2	WEEK 4	15JUL2014	10:50	15.72	ng/mL	-6.65	
	WEEK 8	12AUG2014	13:10	17.25	ng/mL	-17.03	
	WEEK 12	09SEP2014	11:20	19.96	ng/mL	-35.41	
	WEEK 16	07OCT2014	11:15	18.05	ng/mL	-22.46	
	WEEK 20	04NOV2014	11:20	26.91	ng/mL	-82.56	
	WEEK 24	01DEC2014	11:20	28.42	ng/mL	-92.81	
	WEEK 28	29DEC2014	10:40	25.07	ng/mL	-70.08	
	WEEK 32	28JAN2015	09:10	21.22	ng/mL	-43.96	
	WEEK 36	24FEB2015	11:00	25.64	ng/mL	-73.95	
	WEEK 40	24MAR2015	11:25	33.87	ng/mL	-129.78	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
309-0019/68/M/A2	WEEK 44	22APR2015	09:30	36.56	ng/mL	-148.03	
	WEEK 48	19MAY2015	11:20	34.46	ng/mL	-133.79	
	WEEK 52	16JUN2015	10:30	44.45	ng/mL	-201.56	
	Minimum Post-baseline	15JUL2014	10:50	15.72	ng/mL	-6.65	
309-0027/49/M/A2	SCREENING	22OCT2014	12:20	849.75	ng/mL	.	Stable
	WEEK 4	24NOV2014	10:55	907.64	ng/mL	-6.81	
	WEEK 8	22DEC2014	10:16	898.05	ng/mL	-5.68	
	WEEK 12	19JAN2015	10:14	542.61	ng/mL	36.14	
	END OF TREATMENT	16FEB2015	08:54	659.92	ng/mL	22.34	
	Minimum Post-baseline	19JAN2015	10:14	542.61	ng/mL	36.14	

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[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
309-0029/50/M/A2	SCREENING	18NOV2014	13:00	34875.94	ng/mL	.	Rise
	WEEK 4	22DEC2014	10:25	93445.2	ng/mL	-167.94	
	WEEK 8	19JAN2015	09:35	174603.24	ng/mL	-400.64	
	Minimum Post-baseline	22DEC2014	10:25	93445.2	ng/mL	-167.94	
310-0004/50/F/A2	SCREENING	25JAN2013	09:40	36307.65	ng/mL	.	Stable
	WEEK 4	27FEB2013	09:00	33363.33	ng/mL	8.11	
	WEEK 8	27MAR2013	08:50	27541.02	ng/mL	24.15	
	WEEK 12	24APR2013	11:10	32190.9	ng/mL	11.34	
	Minimum Post-baseline	27MAR2013	08:50	27541.02	ng/mL	24.15	
310-0005/58/M/A2	SCREENING	13MAR2013	14:00	3.15	ng/mL	.	Decline

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
310-0005/58/M/A2	WEEK 4	17APR2013	11:00	2.79	ng/mL	11.43	
	WEEK 8	15MAY2013	09:40	2.41	ng/mL	23.49	
	WEEK 12	10JUN2013	09:30	1.45	ng/mL	53.97	
	END OF TREATMENT	03JUL2013	08:00	1.46	ng/mL	53.65	
	Minimum Post-baseline	10JUN2013	09:30	1.45	ng/mL	53.97	
310-0006/50/F/A2	SCREENING	24APR2013	08:50	9885.15	ng/mL	.	Rise
	WEEK 4	22MAY2013	09:20	12334.5	ng/mL	-24.78	
	WEEK 8	19JUN2013	08:30	9404.98	ng/mL	4.86	
	WEEK 12	17JUL2013	11:25	10922.72	ng/mL	-10.5	
	WEEK 16	14AUG2013	09:00	13003.29	ng/mL	-31.54	

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
310-0006/50/F/A2	WEEK 20	11SEP2013	10:00	15286.94	ng/mL	-54.65	
	WEEK 24	09OCT2013	09:50	18414.19	ng/mL	-86.28	
	WEEK 28	06NOV2013	10:50	18057.34	ng/mL	-82.67	
	WEEK 32	02DEC2013	11:00	25219.76	ng/mL	-155.13	
	Minimum Post-baseline	19JUN2013	08:30	9404.98	ng/mL	4.86	
310-0007/74/M/A2	SCREENING	03JUN2013	14:30	32322.61	ng/mL	.	Stable
	WEEK 4	04JUL2013	11:00	27525.53	ng/mL	14.84	
	WEEK 8	01AUG2013	10:45	25083.35	ng/mL	22.4	
	WEEK 12	30AUG2013	11:00	22459.57	ng/mL	30.51	
	WEEK 16	26SEP2013	10:45	21192.79	ng/mL	34.43	

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[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
310-0007/74/M/A2	WEEK 20	24OCT2013	11:00	23700.7	ng/mL	26.67	
	WEEK 24	21NOV2013	10:50	19920.3	ng/mL	38.37	
	WEEK 28	19DEC2013	10:55	21779.29	ng/mL	32.62	
	WEEK 32	16JAN2014	09:40	19279.18	ng/mL	40.35	
	WEEK 36	13FEB2014	11:00	18288.84	ng/mL	43.42	
	WEEK 40	11MAR2014	11:00	18856.18	ng/mL	41.66	
	WEEK 44	08APR2014	11:10	17403.75	ng/mL	46.16	
	Minimum Post-baseline	08APR2014	11:10	17403.75	ng/mL	46.16	
310-0009/46/M/A2	SCREENING	31JUL2013	09:30	5480.92	ng/mL	.	Rise
	WEEK 4	28AUG2013	10:45	10689.22	ng/mL	-95.03	

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
310-0009/46/M/A2	WEEK 8	25SEP2013	10:30	31379.72	ng/mL	-472.53	
	Minimum Post-baseline	28AUG2013	10:45	10689.22	ng/mL	-95.03	
310-0010/34/F/A2	SCREENING	15AUG2013	14:20	151582.82	ng/mL	.	Rise
	WEEK 4	16SEP2013	08:20	361196.2	ng/mL	-138.28	
	Minimum Post-baseline	16SEP2013	08:20	361196.2	ng/mL	-138.28	
310-0011/52/M/A2	SCREENING	17OCT2013	12:40	249.53	ng/mL	.	Rise
	WEEK 4	14NOV2013	12:15	282.36	ng/mL	-13.16	
	WEEK 8	09DEC2013	08:40	381.67	ng/mL	-52.96	
	Minimum Post-baseline	14NOV2013	12:15	282.36	ng/mL	-13.16	
310-0014/64/M/A2	SCREENING	17SEP2014	08:37	4.64	ng/mL	.	Stable

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
310-0014/64/M/A2	WEEK 4	15OCT2014	07:05	4.03	ng/mL	13.15	
	WEEK 8	10NOV2014	07:01	4.56	ng/mL	1.72	
	END OF TREATMENT	29DEC2014	07:03	4.39	ng/mL	5.39	
	Minimum Post-baseline	15OCT2014	07:05	4.03	ng/mL	13.15	
311-0003/44/M/A2	SCREENING	18SEP2013	10:10	1950.95	ng/mL	.	Rise
	WEEK 4	16OCT2013	09:00	2362.26	ng/mL	-21.08	
	WEEK 8	13NOV2013	10:10	2666.48	ng/mL	-36.68	
	WEEK 12	10DEC2013	08:00	3283.66	ng/mL	-68.31	
	END OF TREATMENT	08JAN2014	10:30	4427.97	ng/mL	-126.96	
	Minimum Post-baseline	16OCT2013	09:00	2362.26	ng/mL	-21.08	

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[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
311-0004/68/M/A2	SCREENING	26SEP2013	09:00	104668.14	ng/mL	.	Stable
311-0005/58/M/A2	SCREENING	07OCT2013	14:00	1.76	ng/mL	.	Stable
	WEEK 4	11NOV2013	14:00	1.85	ng/mL	-5.11	
	WEEK 8	09DEC2013	13:30	2.07	ng/mL	-17.61	
	END OF TREATMENT	22JAN2014	14:30	1.81	ng/mL	-2.84	
	Minimum Post-baseline	22JAN2014	14:30	1.81	ng/mL	-2.84	
311-0006/73/F/A2	SCREENING	04NOV2013	15:00	625.17	ng/mL	.	Stable
	WEEK 4	26NOV2013	09:45	824.48	ng/mL	-31.88	
	WEEK 8	24DEC2013	08:30	924.69	ng/mL	-47.91	
	Minimum Post-baseline	26NOV2013	09:45	824.48	ng/mL	-31.88	

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
311-0009/51/F/A2	SCREENING	01JUL2014	16:10	50313.65	ng/mL	.	Stable
	WEEK 4	05AUG2014	14:40	55779.79	ng/mL	-10.86	
	WEEK 8	02SEP2014	12:00	61714.18	ng/mL	-22.66	
	WEEK 12	30SEP2014	09:47	69205.79	ng/mL	-37.55	
	END OF TREATMENT	04NOV2014	14:30	49692.52	ng/mL	1.23	
	Minimum Post-baseline	04NOV2014	14:30	49692.52	ng/mL	1.23	
311-0010/47/M/A2	SCREENING	26AUG2014	08:55	1709.9	ng/mL	.	Decline
	WEEK 4	23SEP2014	14:30	68.48	ng/mL	96	
	WEEK 8	21OCT2014	13:25	8.79	ng/mL	99.49	
	WEEK 12	18NOV2014	09:45	9.05	ng/mL	99.47	

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
311-0010/47/M/A2	WEEK 16	17DEC2014	11:00	11.69	ng/mL	99.32	
	WEEK 20	14JAN2015	10:50	13.42	ng/mL	99.22	
	WEEK 24	12FEB2015	13:10	2	ng/mL	99.88	
	WEEK 28	11MAR2015	13:32	0.605	ng/mL	99.96	
	WEEK 32	09APR2015	13:30	0.605	ng/mL	99.96	
	WEEK 36	07MAY2015	13:20	0.605	ng/mL	99.96	
	WEEK 40	04JUN2015	13:20	0.605	ng/mL	99.96	
	Minimum Post-baseline	04JUN2015	13:20	0.605	ng/mL	99.96	
311-0011/46/M/A2	SCREENING	28OCT2014	09:20	29639.36	ng/mL	.	Rise
	WEEK 4	19NOV2014	09:15	30038.74	ng/mL	-1.35	

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
311-0011/46/M/A2	WEEK 8	17DEC2014	12:10	75681.63	ng/mL	-155.34	
	END OF TREATMENT	28JAN2015	14:00	102032.34	ng/mL	-244.25	
	Minimum Post-baseline	19NOV2014	09:15	30038.74	ng/mL	-1.35	
311-0012/55/M/A2	SCREENING	20JAN2015	09:56	2	ng/mL	.	Stable
	WEEK 4	17FEB2015	14:49	2.31	ng/mL	-15.5	
	WEEK 8	19MAR2015	13:57	2.65	ng/mL	-32.5	
	WEEK 12	16APR2015	11:27	1.89	ng/mL	5.5	
	WEEK 16	14MAY2015	14:00	1.68	ng/mL	16	
	WEEK 20	11JUN2015	12:44	2.22	ng/mL	-11	
	Minimum Post-baseline	14MAY2015	14:00	1.68	ng/mL	16	

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
401-0001/70/M/A7	SCREENING	03JUN2013	09:30	233.3	ng/ml	.	Stable
	END OF TREATMENT	07JUL2013	17:21	301.4	ng/ml	-29.19	
	Minimum Post-baseline	07JUL2013	17:21	301.4	ng/ml	-29.19	
401-0002/55/M/A7	SCREENING	12JUN2013	11:23	24.7	ng/ml	.	Stable
402-0001/35/M/A7	SCREENING	15APR2013	14:31	378350	ng/mL	.	Stable
	UNSCHEDULED	20MAY2013	12:58	460110	ng/mL	-21.61	
	WEEK 8	10JUN2013	12:10	492750	ng/mL	-30.24	
	Minimum Post-baseline	20MAY2013	12:58	460110	ng/mL	-21.61	
402-0002/58/M/A7	SCREENING	15APR2013	10:16	7	ng/ml	.	Decline
	WEEK 8	11JUN2013	12:20	3.2	ng/ml	54.29	

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
402-0002/58/M/A7	WEEK 12	09JUL2013	11:50	6.4	ng/ml	8.57	
	END OF TREATMENT	12AUG2013	11:32	12.1	ng/ml	-72.86	
	Minimum Post-baseline	11JUN2013	12:20	3.2	ng/ml	54.29	
402-0005/70/M/A7	SCREENING	30APR2013	08:19	90.2	ng/ml	.	Rise
	WEEK 2	16MAY2013	09:18	86.1	ng/ml	4.55	
	WEEK 4	28MAY2013	08:28	139.1	ng/ml	-54.21	
	WEEK 6	13JUN2013	07:20	232.7	ng/ml	-157.98	
	WEEK 8	27JUN2013	08:47	397.6	ng/ml	-340.8	
	WEEK 12	23JUL2013	06:57	676.5	ng/ml	-650	
	Minimum Post-baseline	16MAY2013	09:18	86.1	ng/ml	4.55	

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[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
402-0010/50/M/A7	SCREENING	10MAY2013	11:30	1.6	ng/ml	.	Decline
	WEEK 4	10JUN2013	12:50	1	ng/ml	37.5	
	END OF TREATMENT	08JUL2013	10:59	0.8	ng/ml	50	
	Minimum Post-baseline	08JUL2013	10:59	0.8	ng/ml	50	
402-0022/60/F/A7	SCREENING	Unknown		.		.	
402-0023/57/M/A7	SCREENING	22AUG2013	14:54	5300.6	ng/ml	.	Rise
	WEEK 4	24SEP2013	12:35	5924.3	ng/ml	-11.77	
	WEEK 8	22OCT2013	12:17	32855	ng/ml	-519.84	
	WEEK 12	19NOV2013	11:59	160621	ng/ml	-2930.24	
	Minimum Post-baseline	24SEP2013	12:35	5924.3	ng/ml	-11.77	

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
402-0029/49/M/A7	SCREENING	06NOV2013	14:59	750000	ng/ml	.	Stable
402-0032/49/F/A7	SCREENING	28NOV2013	14:10	18994	ng/ml	.	Stable
402-0034/43/F/A7	SCREENING	11DEC2013	11:34	1618.1	ng/ml	.	Rise
	WEEK 4	09JAN2014	09:51	3011.5	ng/ml	-86.11	
	WEEK 8	07FEB2014	10:09	2440.3	ng/ml	-50.81	
	WEEK 12	06MAR2014	09:58	2058.7	ng/ml	-27.23	
	WEEK 16	03APR2014	10:04	2279	ng/ml	-40.84	
	WEEK 18	17APR2014	09:56	2065.3	ng/ml	-27.64	
	WEEK 20	02MAY2014	10:15	2671.5	ng/ml	-65.1	
	WEEK 22	15MAY2014	09:58	3190.6	ng/ml	-97.18	

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
402-0034/43/F/A7	WEEK 24	29MAY2014	09:57	4349.9	ng/ml	-168.83	
	Minimum Post-baseline	06MAR2014	09:58	2058.7	ng/ml	-27.23	
403-0004/37/M/A7	SCREENING	03JUL2013	08:55	11019.97	ng/mL	.	Rise
	WEEK 4	31JUL2013	09:01	15914.14	ng/mL	-44.41	
	WEEK 8	28AUG2013	12:24	23978.95	ng/mL	-117.6	
	WEEK 12	25SEP2013	09:21	32202.01	ng/mL	-192.22	
	END OF TREATMENT	31OCT2013	11:19	18697.44	ng/mL	-69.67	
	Minimum Post-baseline	31JUL2013	09:01	15914.14	ng/mL	-44.41	
404-0003/53/M/A7	SCREENING	02SEP2013	08:56	11011	ng/mL	.	Stable
404-0004/61/F/A7	SCREENING	08OCT2013	09:24	5614	ng/mL	.	Rise

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
404-0004/61/F/A7	WEEK 4	04NOV2013	11:52	6477	ng/mL	-15.37	
	WEEK 8	02DEC2013	11:53	10836	ng/mL	-93.02	
	Minimum Post-baseline	04NOV2013	11:52	6477	ng/mL	-15.37	
405-0001/55/M/A7	SCREENING	22APR2013	09:25	2	ng/mL	.	Stable
	WEEK 4	15MAY2013	13:30	2.3	ng/mL	-15	
	WEEK 8	10JUN2013	08:33	2.1	ng/mL	-5	
	WEEK 12	10JUL2013	10:17	2.5	ng/mL	-25	
	Minimum Post-baseline	10JUN2013	08:33	2.1	ng/mL	-5	
405-0005/35/M/A6	SCREENING	19APR2013	13:50	26697	ng/mL	.	Rise
	WEEK 4	15MAY2013	11:03	23769	ng/mL	10.97	

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[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
405-0005/35/M/A6	WEEK 8	10JUN2013	09:00	27166	ng/mL	-1.76	
	WEEK 12	10JUL2013	09:19	34483	ng/mL	-29.16	
	WEEK 16	07AUG2013	09:29	34717	ng/mL	-30.04	
	WEEK 20	04SEP2013	09:19	35865	ng/mL	-34.34	
	WEEK 24	02OCT2013	09:01	46186	ng/mL	-73	
	WEEK 28	30OCT2013	09:17	49602	ng/mL	-85.8	
	WEEK 32	27NOV2013	09:20	52010	ng/mL	-94.82	
	WEEK 36	23DEC2013	08:53	63141	ng/mL	-136.51	
	END OF TREATMENT	22JAN2014	11:28	94407	ng/mL	-253.62	
	Minimum Post-baseline	15MAY2013	11:03	23769	ng/mL	10.97	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
405-0012/72/M/A7	SCREENING	09MAY2013	16:48	18349.1	ng/mL	.	Rise
	WEEK 4	05JUN2013	10:35	17233.4	ng/mL	6.08	
	WEEK 8	01JUL2013	09:05	19959.5	ng/mL	-8.78	
	WEEK 12	29JUL2013	09:59	24671	ng/mL	-34.45	
	WEEK 16	26AUG2013	09:06	29619	ng/mL	-61.42	
	WEEK 20	23SEP2013	08:44	26804	ng/mL	-46.08	
	WEEK 24	21OCT2013	09:11	26603	ng/mL	-44.98	
	Minimum Post-baseline	05JUN2013	10:35	17233.4	ng/mL	6.08	
405-0019/61/M/A7	SCREENING	17JUN2013	11:01	5413.8	ng/ml	.	Stable
	WEEK 4	15JUL2013	09:20	7809.1	ng/ml	-44.24	

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
405-0019/61/M/A7	Minimum Post-baseline	15JUL2013	09:20	7809.1	ng/ml	-44.24	
405-0024/69/M/A7	SCREENING	19JUN2013	17:23	3507.9	ng/mL	.	Stable
405-0026/67/M/A7	SCREENING	27JUN2013	15:27	3086.6	ng/mL	.	Rise
	WEEK 4	31JUL2013	12:36	7460	ng/mL	-141.69	
	WEEK 8	28AUG2013	11:26	9050	ng/mL	-193.2	
	WEEK 12	25SEP2013	11:45	13486	ng/mL	-336.92	
	END OF TREATMENT	22OCT2013	14:26	11400	ng/mL	-269.34	
	Minimum Post-baseline	31JUL2013	12:36	7460	ng/mL	-141.69	
405-0036/70/M/A7	SCREENING	16AUG2013	08:40	12796.7	ng/ml	.	Rise
	WEEK 4	13SEP2013	09:18	18459.5	ng/ml	-44.25	

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
405-0036/70/M/A7	WEEK 8	14OCT2013	08:43	49117	ng/ml	-283.83	
	WEEK 12	11NOV2013	08:36	75473	ng/ml	-489.78	
	Minimum Post-baseline	13SEP2013	09:18	18459.5	ng/ml	-44.25	
405-0041/57/M/A7	SCREENING	11SEP2013	14:40	249.1	ng/dl	.	Rise
	WEEK 4	02OCT2013	14:38	315.2	ng/dl	-26.54	
	WEEK 8	28OCT2013	08:32	362	ng/dl	-45.32	
	WEEK 12	25NOV2013	08:31	527.1	ng/dl	-111.6	
	WEEK 16	23DEC2013	08:28	664.2	ng/dl	-166.64	
	WEEK 20	22JAN2014	12:41	918	ng/dl	-268.53	
	WEEK 24	17FEB2014	08:43	852.9	ng/dl	-242.39	

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
405-0041/57/M/A7	WEEK 28	12MAR2014	14:13	997.6	ng/dl	-300.48	
	WEEK 32	11APR2014	10:48	1028.2	ng/dl	-312.77	
	END OF TREATMENT	02JUN2014	09:48	1299.6	ng/dl	-421.72	
	Minimum Post-baseline	02OCT2013	14:38	315.2	ng/dl	-26.54	
501-0003/22/M/A1	SCREENING	03DEC2013	08:00	46549.41	ug/l	.	Stable
	WEEK 4	31DEC2013	08:00	42938.56	ug/l	7.76	
	WEEK 8	28JAN2014	08:17	57570	ug/l	-23.68	
	END OF TREATMENT	25FEB2014	08:20	60292.88	ug/l	-29.52	
	Minimum Post-baseline	31DEC2013	08:00	42938.56	ug/l	7.76	
501-0004/26/M/A1	SCREENING	17DEC2013	06:00	16.86	ug/L	.	Rise

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
501-0004/26/M/A1	WEEK 4	09JAN2014	08:00	26.77	ug/L	-58.78	
	WEEK 8	07FEB2014	08:35	70.82	ug/L	-320.05	
	WEEK 12	05MAR2014	08:00	155.54	ug/L	-822.54	
	Minimum Post-baseline	09JAN2014	08:00	26.77	ug/L	-58.78	
501-0011/61/M/A1	SCREENING	19SEP2014	07:00	106208.77	ug/L	.	Rise
	WEEK 4	15OCT2014	08:00	133983.33	ug/L	-26.15	
	WEEK 8	12NOV2014	08:30	275401.53	ug/L	-159.3	
	WEEK 10	26NOV2014	08:00	120612.51	ug/L	-13.56	
	WEEK 12	10DEC2014	08:30	226704	ug/L	-113.45	
	END OF TREATMENT	16DEC2014	08:00	275126.2	ug/L	-159.04	

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
501-0011/61/M/A1	Minimum Post-baseline	26NOV2014	08:00	120612.51	ug/L	-13.56	
502-0001/70/M/A1	SCREENING	13DEC2013	08:30	58.31	ng/ml	.	Stable
	WEEK 4	03JAN2014	08:20	82.58	ng/ml	-41.62	
	Minimum Post-baseline	03JAN2014	08:20	82.58	ng/ml	-41.62	
502-0003/48/M/A1	SCREENING	13JAN2014	08:00	1210	ng/ml	.	Rise
	WEEK 4	07FEB2014	08:30	1211	ng/ml	-0.08	
	WEEK 8	07MAR2014	09:30	2001	ng/ml	-65.37	
	WEEK 12	04APR2014	08:40	2001	ng/ml	-65.37	
	END OF TREATMENT	05MAY2014	08:24	1211	ng/ml	-0.08	
	Minimum Post-baseline	07FEB2014	08:30	1211	ng/ml	-0.08	

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
503-0002/71/F/A1	SCREENING	19FEB2014	09:01	1.94	ng/ml	.	Stable
	WEEK 8	10APR2014	10:00	1.61	ng/ml	17.01	
	WEEK 12	08MAY2014	08:50	2.05	ng/ml	-5.67	
	WEEK 16	03JUN2014	08:50	2.22	ng/ml	-14.43	
	WEEK 20	01JUL2014	08:30	1.85	ng/ml	4.64	
	WEEK 24	29JUL2014	08:40	1.76	ng/ml	9.28	
	WEEK 26	12AUG2014	09:00	1.8	ng/ml	7.22	
	WEEK 28	26AUG2014	09:10	1.87	ng/ml	3.61	
	WEEK 32	23SEP2014	08:20	1.83	ng/ml	5.67	
	WEEK 36	21OCT2014	09:10	2.18	ng/ml	-12.37	

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
503-0002/71/F/A1	Minimum Post-baseline	10APR2014	10:00	1.61	ng/ml	17.01	
503-0003/47/F/A1	SCREENING	06MAR2014	08:00	1210	ng/ml	.	Stable
503-0005/72/M/A1	SCREENING	20MAR2014	09:00	6.15	ng/ml	.	Rise
	WEEK 8	13MAY2014	08:30	5.81	ng/ml	5.53	
	WEEK 12	10JUN2014	08:35	6.62	ng/ml	-7.64	
	WEEK 16	08JUL2014	09:15	6.91	ng/ml	-12.36	
	WEEK 20	05AUG2014	09:15	7.31	ng/ml	-18.86	
	WEEK 24	02SEP2014	08:10	6.69	ng/ml	-8.78	
	WEEK 28	29SEP2014	08:36	8.79	ng/ml	-42.93	
	WEEK 32	28OCT2014	08:35	7.73	ng/ml	-25.69	

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
503-0005/72/M/A1	WEEK 36	25NOV2014	10:05	12.39	ng/ml	-101.46	
	WEEK 40	23DEC2014	09:30	12.19	ng/ml	-98.21	
	WEEK 44	21JAN2015	09:15	17.74	ng/ml	-188.46	
	WEEK 48	15FEB2015	10:10	15.95	ng/ml	-159.35	
	Minimum Post-baseline	13MAY2014	08:30	5.81	ng/ml	5.53	
504-0003/53/M/A1	SCREENING	11MAR2014	08:15	4.1	ng/ml	.	Stable
504-0005/41/F/A1	SCREENING	02SEP2014	14:15	510.8	ng/ml	.	Stable
	WEEK 4	24SEP2014	09:35	653.3	ng/ml	-27.9	
	Minimum Post-baseline	24SEP2014	09:35	653.3	ng/ml	-27.9	
504-0006/51/M/A1	SCREENING	30AUG2014	07:45	1210	ng/ml	.	Stable

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Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
506-0001/43/M/A1	SCREENING	14APR2014	07:00	2859	IU/mL	.	Rise
	WEEK 4	06MAY2014	08:51	5991	IU/mL	-109.55	
	WEEK 6	21MAY2014	10:34	12112	IU/mL	-323.64	
	Minimum Post-baseline	06MAY2014	08:51	5991	IU/mL	-109.55	
506-0005/24/M/A1	SCREENING	21DEC2014	09:45	488.7	IU/ml	.	Stable
	WEEK 2	31DEC2014	07:15	647.7	IU/ml	-32.54	
	Minimum Post-baseline	31DEC2014	07:15	647.7	IU/ml	-32.54	
507-0001/51/M/A1	SCREENING	18JUL2014		11	ng/mL	.	Rise
	WEEK 4	14AUG2014		26	ng/mL	-136.36	
	WEEK 8	11SEP2014		14	ng/mL	-27.27	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
507-0001/51/M/A1	WEEK 12	09OCT2014		18.4	ng/mL	-67.27	
	END OF TREATMENT	11NOV2014		28.1	ng/mL	-155.45	
	Minimum Post-baseline	11SEP2014		14	ng/mL	-27.27	
507-0002/44/M/A1	SCREENING	27JUL2014		200000	ng/mL	.	Stable
	WEEK 4	20AUG2014		200000	ng/mL	0	
	WEEK 8	16SEP2014		200000	ng/mL	0	
	UNSCHEDULED	14OCT2014		200001	ng/mL	0	
	Minimum Post-baseline	16SEP2014		200000	ng/mL	0	
508-0002/64/M/A1	SCREENING	13FEB2014	08:28	4656	ng/ml	.	Stable
	WEEK 4	10MAR2014	10:43	3349	ng/ml	28.07	

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
508-0002/64/M/A1	WEEK 8	11APR2014	10:35	2868	ng/ml	38.4	
	Minimum Post-baseline	11APR2014	10:35	2868	ng/ml	38.4	
508-0004/58/M/A1	SCREENING	25AUG2014	10:05	19444	ng/ml	.	Stable
509-0003/39/M/A1	SCREENING	22JUL2014	10:00	2.42	ng/ml	.	Stable
	WEEK 4	14AUG2014	10:30	1.78	ng/ml	26.45	
	WEEK 8	11SEP2014	10:56	1.54	ng/ml	36.36	
	WEEK 12	09OCT2014	10:45	2.55	ng/ml	-5.37	
	END OF TREATMENT	12NOV2014	11:00	2.89	ng/ml	-19.42	
	Minimum Post-baseline	11SEP2014	10:56	1.54	ng/ml	36.36	
510-0001/67/M/A1	SCREENING	25FEB2014	08:05	1210	ng/ml	.	Rise

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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
510-0001/67/M/A1	WEEK 4	19MAR2014	08:40	1210	ng/ml	0	
	WEEK 8	16APR2014	08:05	1210	ng/ml	0	
	WEEK 12	14MAY2014	07:55	3408	ng/ml	-181.65	
	WEEK 16	11JUN2014	08:20	1454	ng/ml	-20.17	
	WEEK 20	09JUL2014	08:30	1179	ng/ml	2.56	
	WEEK 24	06AUG2014	08:30	1307	ng/ml	-8.02	
	WEEK 28	04SEP2014	08:00	2027	ng/ml	-67.52	
	WEEK 32	30SEP2014	07:30	2571	ng/ml	-112.48	
	WEEK 36	29OCT2014	07:30	4312	ng/ml	-256.36	
	WEEK 40	26NOV2014	07:30	5326	ng/ml	-340.17	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
510-0001/67/M/A1	END OF TREATMENT	10DEC2014	07:30	5868	ng/ml	-384.96	
	Minimum Post-baseline	09JUL2014	08:30	1179	ng/ml	2.56	
510-0003/43/M/A1	SCREENING	30MAY2014	08:30	20879	ng/ml	.	Rise
	WEEK 4	25JUN2014	08:30	23146	ng/ml	-10.86	
	WEEK 10	06AUG2014	08:25	36173	ng/ml	-73.25	
	Minimum Post-baseline	25JUN2014	08:30	23146	ng/ml	-10.86	
513-0003/46/M/A1	SCREENING	23APR2014	09:00	54218	ng/ml	.	Stable
515-0005/45/M/A1	SCREENING	16JUN2014	08:00	300000	ng/ml	.	Stable
	WEEK 4	14JUL2014	09:55	300000	ng/ml	0	
	WEEK 8	11AUG2014	09:20	300000	ng/ml	0	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
515-0005/45/M/A1	WEEK 12	09SEP2014	06:00	300000	ng/ml	0	
	Minimum Post-baseline	11AUG2014	09:20	300000	ng/ml	0	
517-0003/45/M/A1	SCREENING	12MAY2014	09:30	9.67	ng/ml	.	Rise
	WEEK 4	04JUN2014	09:30	13.35	ng/ml	-38.06	
	WEEK 8	02JUL2014	09:01	18.05	ng/ml	-86.66	
	WEEK 12	30JUL2014	10:04	72.12	ng/ml	-645.81	
	END OF TREATMENT	29AUG2014	09:30	193.5	ng/ml	-1901.03	
	Minimum Post-baseline	04JUN2014	09:30	13.35	ng/ml	-38.06	
517-0010/67/M/A1	SCREENING	04NOV2014	09:04	38.6	ng/ml	.	Rise
	WEEK 4	03DEC2014	09:10	72.54	ng/ml	-87.93	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
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[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.7
Serum Alpha Fetoprotein Response
(Intent-to-Treat Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/Race [2]	Visit	Collection Date	Collection Time	AFP Result	Unit	Percent Change from Baseline [%] [3]	AFP Best Change Category [4]
517-0010/67/M/A1	WEEK 8	30DEC2014	08:54	102	ng/ml	-164.25	
	WEEK 12	28JAN2015	09:26	121.8	ng/ml	-215.54	
	Minimum Post-baseline	03DEC2014	09:10	72.54	ng/ml	-87.93	

[1] Age is calculated to be the integer part of (Date of Informed Consent-Date of Birth + 1)/365.25.
[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.
[3] Percent change from baseline is calculated as ((baseline AFP - post-treatment AFP) / baseline AFP)*100.
[4] AFP change category will be calculated for each subject by comparing AFP maximal percent change during the course of study to AFP at baseline. AFP Change Category: 50% or greater decrease from baseline = Decline, between 50% decrease and 50% increase from baseline = Stable, 50% or greater increase from baseline = Rise.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
101-0001/59/M/A2	Screening	20JAN2009	Unknown	0		
	Week 4	16AUG2011	14:39	0		
	Week 8	16SEP2011	10:34	1		
	Week 12	14OCT2011	12:44	1		
	Week 16	11NOV2011	15:22	2		
	Week 24	06JAN2012	15:39	3		
101-0005/77/M/W2	Screening	02AUG2011	09:45	0		
	Week 4	30AUG2011	12:40	1		
	Week 8	27SEP2011	12:23	0		
	Week 12	25OCT2011	14:11	0		
101-0006/62/M/W2	Screening	05AUG2011	08:25	1		
	Week 4	02SEP2011	07:48	1		
	Week 8	30SEP2011	Unknown	3		
101-0007/77/M/A1	Screening	10DEC2009	Unknown	2		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
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[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
101-0007/77/M/A1	Week 4	13SEP2011	10:31	0		
	Week 8	11OCT2011	11:14	0		
	Week 12	08NOV2011	15:26	0		
101-0008/83/M/BL	Screening	22FEB2008	Unknown	0		
	Week 4	20SEP2011	08:38	1		
	Week 8	18OCT2011	15:22	3		
	Week 12	15NOV2011	14:51	4		
101-0009/82/M/A1	Week 4	25OCT2011	15:53	1		
	Week 8	15NOV2011	17:53	2		
	Week 12	20DEC2011	14:42	4		
101-0011/75/F/W2	Screening	27JUN2011	Unknown	0		
101-0012/68/M/W2	Screening	01SEP2010	Unknown	0		
	Week 4	20DEC2011	11:16	0		
	Week 8	17JAN2012	09:34	3		

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[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
101-0013/66/F/A5	Screening	29NOV2011	10:38	0	0	Collected on 29Nov2011
	Screening	02JAN2012	10:38	0		Collected on 02Jan2012
	Week 4	31JAN2012	09:57	0		
	Week 8	28FEB2012	11:09	2		
	Week 12	27MAR2012	10:18	3		
	Week 16	24APR2012	14:55	4		
	Week 20	Unknown	Unknown	4		
101-0016/61/M/A4	Screening	05JUN2007	Unknown	0		
	Week 4	07FEB2012	10:23	1		
	Week 8	06MAR2012	15:24	3		
	Week 12	06APR2012	15:45	3		
	Week 16	04MAY2012	07:37	3		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
	Week 20	29MAY2012	12:57	3		
	Week 24	26JUN2012	09:43	3		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
101-0016/61/M/A4	Week 28	24JUL2012	12:01	3		
	Week 32	21AUG2012	07:54	3		
	Week 36	18SEP2012	11:45	3		
	Week 40	19OCT2012	09:35	3		Uns Continuation
	Week 44	16NOV2012	12:59	3		Uns Continuation
	Week 48	11DEC2012	13:01	3		Uns Continuation
	Week 52	08JAN2013	13:09	3		Uns Continuation
	Week 56	08FEB2013	07:49	3		Uns Continuation
	Week 60	08MAR2013	12:37	2		Uns Continuation
101-0018/51/M/A1	Screening	21FEB2012	16:28	0		Back up sample, no primary sample was received
101-0019/68/M/W2	Screening	28FEB2012	09:11	0		Week 4 in sample list from CLS
	Week 8	17APR2012	11:39	3		

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[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
	Week 12	15MAY2012	15:26	4		
101-0021/74/M/W2	Screening	20MAR2012	11:57	0		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
101-0021/74/M/W2	Week 4	10APR2012	14:24	5		
	Week 8	08MAY2012	10:43	5		
	Week 12	05JUN2012	08:58	4		
101-0022/55/M/BL	Screening	26NOV2008	Unknown	0		
	Week 4	10APR2012	18:21	0		
101-0023/70/M/W2	Screening	30MAR2012	16:40	0		
	Week 4	20APR2012	07:52	0		
	Week 8	18MAY2012	08:20	0		
	Week 12	15JUN2012	08:13	0	1	
	Week 12	15JUN2012	08:13	2		
101-0024/35/F/A4	Screening	19MAR2012	Unknown	0		
	Week 4	22MAY2012	11:59	0		
	Week 8	19JUN2012	15:19	3		
	Week 12	17JUL2012	14:58	5		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
101-0025/57/F/W2	Screening	01MAR2012	Unknown	0		
	Week 4	11MAY2012	08:36	0		
	Week 8	08JUN2012	12:48	4		
101-0026/82/M/W2	Screening	17NOV2003	Unknown	0		
	Week 4	05JUN2012	15:39	0		
	Week 8	05JUL2012	11:09	1		
	Week 12	03AUG2012	14:54	0		
	Week 16	31AUG2012	14:19	1		
	Week 20	28SEP2012	15:54	3		
	Week 24	23OCT2012	11:22	3		
	Week 28	23NOV2012	13:02	3		
	Week 32	18DEC2012	09:39	3		
	Week 36	Unknown	Unknown	3		
101-0028/60/M/W2	Screening	14DEC2011	Unknown	0		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
101-0028/60/M/W2	Week 4	03JUL2012	07:58	0		
	Week 8	31JUL2012	07:37	2		
	Week 12	28AUG2012	07:41	3		
101-0029/70/M/A1	Screening	15JUN2012	10:31	0		
	Week 4	10JUL2012	10:23	0		
	Week 8	07AUG2012	10:35	3		
	Week 12	Unknown	Unknown	3		
101-0030/51/M/W2	Screening	04APR2011	Unknown	0		
	Week 4	24JUL2012	08:03	0		
	Week 8	21AUG2012	07:38	3		
101-0032/84/M/W2	Screening	04DEC2006	Unknown	1		
	Week 4	21AUG2012	11:52	2		
	Week 8	21SEP2012	09:30	4		
101-0033/66/F/W2	Screening	03AUG2012	11:57	0		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
101-0033/66/F/W2	Week 4	24AUG2012	10:20	0		
	Week 8	21SEP2012	10:22	3		
	Week 12	16OCT2012	11:29	3		
	Week 16	16NOV2012	10:55	3		
	Week 20	14DEC2012	07:04	3		
	Week 24	11JAN2013	Unknown	3		
101-0036/67/M/A4	Screening	23OCT2012	15:02	0		
	Week 4	27NOV2012	14:30	0		
101-0037/57/M/A1	Screening	11JUN2008	Unknown	0		
	Week 4	28DEC2012	09:26	0		
101-0038/56/M/W2	Screening	27JUN2012	Unknown	0		
	Week 2	12FEB2013	14:28	0		
	Week 4	01MAR2013	11:10	0		
101-0039/77/F/W2	Screening	05APR2013	12:07	0		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
101-0039/77/F/W2	Week 2	12APR2013	08:57	0		
	Week 4	26APR2013	08:38	2		
	Week 8	24MAY2013	11:21	4		
	Week 12	21JUN2013	08:44	4		
	Week 16	16JUL2013	08:41	4		
	Week 20	13AUG2013	10:51	4		
	Week 24	10SEP2013	07:36	5		
	Week 28	08OCT2013	07:15	5		
	Week 32	04NOV2013	07:43	5		
	Week 36	02DEC2013	07:33	5		
101-0040/60/M/W2	Screening	18OCT2013	Unknown	0		
	Week 2	08JUL2013	08:04	0		
	Week 4	22JUL2013	08:40	0		
101-0041/54/M/W2	Screening	21DEC2012	Unknown	0		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
101-0041/54/M/W2	Week 2	06AUG2013	12:33	0		
101-0042/64/M/W2	Screening	22MAY2012	Unknown	0		
	Week 2	13AUG2013	09:42	0		
	Week 4	27AUG2013	16:02	0		
	Week 8	23SEP2013	14:50	1		
101-0044/78/M/W2	Screening	18OCT2013	07:26	0		
	Week 4	08NOV2013	07:16	1		
	Week 8	06DEC2013	07:30	3		
	Week 12	03JAN2014	08:58	4		
101-0045/74/F/W2	Screening	22OCT2013	08:26	0		
	Week 2	12NOV2013	07:21	0		
	Week 4	26NOV2013	07:40	3		
	Week 8	23DEC2013	07:51	4		
	Week 12	21JAN2014	10:49	4		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
101-0046/70/M/OTH	Screening	17DEC2012	Unknown	2		
	Week 2	29OCT2013	10:39	1		
	Week 4	12NOV2013	08:03	2		
	Week 8	10DEC2013	07:30	2		
	Week 12	07JAN2014	07:28	3		
101-0047/52/M/W2	Screening	10JAN2012	Unknown	0		
	Week 2	28OCT2013	10:50	0		
	Week 4	11NOV2013	08:29	0		
	Week 8	09DEC2013	07:43	2		
101-0048/66/F/W2	Screening	22OCT2013	09:35	0		
	Week 2	29OCT2013	09:30	0		
	Week 4	19NOV2013	09:19	0		
	Week 8	10DEC2013	10:05	3		
	Week 12	06JAN2014	10:15	4		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
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[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
101-0049/71/M/A8	Screening	28OCT2013	11:03	0		
	Week 2	04NOV2013	10:02	0		
	Week 4	18NOV2013	10:01	0		
	Week 8	16DEC2013	12:06	3		
	Week 12	13JAN2014	08:36	5		
101-0050/59/M/W2	Screening	29OCT2013	17:51	0		
	Week 2	04NOV2013	12:37	0		
	Week 4	18NOV2013	08:46	0		
102-0001/53/M/BL	Screening	19APR2012	09:09	1		
	Week 4	15MAY2012	08:45	3		
	Week 8	12JUN2012	08:57	4		
102-0003/63/M/BL	Screening	29AUG2012	09:28	0		
	Week 4	02OCT2012	08:18	1		
	Week 8	31OCT2012	07:22	4		

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[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
102-0003/63/M/BL	Week 12	28NOV2012	08:36	4		
102-0008/64/M/BL	Screening	02JAN2013	13:23	0	0	
	Screening	02JAN2013	13:23	0		
	Week 2	15JAN2014	09:20	0		
	Week 4	28JAN2014	08:16	0		
102-0009/58/M/W2	Screening	23OCT2014	09:35	0		
	Week 2	05NOV2014	10:25	1		
	Week 4	19NOV2014	11:25	1		
103-0001/56/M/W2	Screening	07MAY2012	11:15	0		
	Week 4	01JUN2012	10:10	0		
	Week 8	29JUN2012	10:30	3		
103-0003/66/M/W2	Screening	04FEB2013	12:30	0		
	Week 4	06MAR2013	11:00	0		
	Week 8	03APR2013	11:45	1		

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[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
103-0003/66/M/W2	Week 12	01MAY2013	14:45	3		
	Week 16	29MAY2013	14:45	3		
	Week 20	24JUN2013	10:40	4		
103-0004/40/F/A1	Screening	19NOV2012	Unknown	0		
	Week 2	28APR2014	10:00	0		
	Week 4	13MAY2014	13:00	0		
	End of Treatment	09JUN2014	10:00	0		Week 8
104-0003/56/F/W2	Screening	11JUL2012	09:55	1		
	Week 4	08AUG2012	09:50	1		
	Week 8	Unknown	Unknown	4		
104-0004/74/M/W2	Screening	15JUN2012	Unknown	0		
	Week 4	13NOV2012	10:35	0		
104-0008/55/M/PI	Screening	29AUG2013	13:32	1		
	Week 2	13SEP2013	12:55	1		

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[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
104-0008/55/M/PI	Week 4	26SEP2013	07:41	1		
	Week 8	24OCT2013	07:52	2		
	Week 12	21NOV2013	08:00	4		
104-0010/71/F/A8	Screening	02JAN2014	10:20	0		
	Week 2	15JAN2014	09:20	0		
	Week 4	29JAN2014	10:15	0		
	Week 8	26FEB2014	10:21	3		
	Week 12	27MAR2014	09:20	4		
	Week 16	23APR2014	09:25	3		
	Week 20	21MAY2014	09:24	3		
	Week 24	18JUN2014	09:00	3		Back up sample
	Week 28	16JUL2014	09:05	3		
	Week 32	13AUG2014	09:06	4		
	Week 36	10SEP2014	08:56	4		Uns Continuation

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
104-0012/78/F/A2	Screening	23SEP2014	11:15	0		
	Week 2	07OCT2014	11:14	0		
	Week 4	22OCT2014	11:04	0		
	Week 8	18NOV2014	11:00	3		
106-0001/42/F/W2	Screening	20FEB2012	Unknown	0	0	Collected on 20Feb2012
	Screening	20FEB2012	Unknown	0		Collected on 20Feb2012
	Week 4	26MAR2012	09:30	0		
	Week 8	23APR2012	10:20	3		
	Week 12	21MAY2012	10:35	3		
	Week 16	18JUN2012	11:40	4		
107-0002/71/M/W2	Screening	21JUL2010	Unknown	0		
	Week 4	21SEP2012	13:10	2		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
	Week 8	15OCT2012	12:15	0		
	Week 12	12NOV2012	10:00	0		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
107-0003/73/M/BL	Screening	18FEB2013	12:05	0		
	Week 4	18MAR2013	09:49	0		
	Week 8	16APR2013	13:45	2		
107-0004/63/M/W2	Screening	26FEB2013	13:16	0		
	Week 2	12MAR2013	10:14	0		
	Week 4	26MAR2013	10:20	0		
	Week 8	23APR2013	07:45	0		
	Week 12	21MAY2013	10:30	1		
107-0006/60/M/W2	Screening	06MAY2013	09:15	0		
	Week 2	20MAY2013	09:26	1		
	Week 4	04JUN2013	13:05	1		
	Week 8	01JUL2013	10:00	1		
	Week 12	29JUL2013	09:00	3		
108-0001/60/F/W2	Screening	07MAR2012	15:00	0		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
108-0001/60/F/W2	Week 4	11APR2012	10:45	0		
108-0002/78/M/BL	Screening	25MAY2012	09:55	0		
	Week 4	21JUN2012	10:00	0		
108-0004/61/M/W2	Screening	04APR2013	10:31	0		
	Week 3	02MAY2013	09:07	0		
	Week 4	09MAY2013	07:35	0		
108-0005/68/M/W2	Screening	26APR2013	08:40	1		
	Week 2	15MAY2013	14:40	0		
	Week 4	29MAY2013	13:30	0		
	Week 8	26JUN2013	09:30	1		
	Week 12	24JUL2013	09:20	3		
108-0008/77/M/W2	Screening	01OCT2014	08:05	0		
	Week 2	16OCT2014	09:10	0		
	Week 4	30OCT2014	09:20	0		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
108-0008/77/M/W2	Week 8	26NOV2014	12:06	2		
	Week 12	23DEC2014	08:54	3		
	Week 16	22JAN2015	09:15	4		
	Week 20	19FEB2015	08:15	4		
	End of Treatment	16APR2015	Unknown	4		Week 24 in sample list from CLS
109-0003/68/M/W2	Screening	30APR2013	11:33	0		
	Week 2	13MAY2013	13:38	0		
	Week 4	28MAY2013	16:00	1		
109-0004/57/M/W2	Screening	13FEB2012	Unknown	0		
	Week 2	26JUL2013	09:20	0		
	Week 4	12AUG2013	13:45	0		
	Week 8	11SEP2013	13:55	0		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
	Week 12	09OCT2013	09:10	0		
109-0006/62/M/PI	Screening	14AUG2013	12:25	1		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
109-0006/62/M/PI	Week 2	30AUG2013	11:40	1		
	Week 4	12SEP2013	11:40	1		
	Week 8	09OCT2013	13:15	3		
	Week 12	06NOV2013	11:45	4		
109-0007/55/M/W2	Screening	02DEC2013	15:40	1		
	Unscheduled	10DEC2013	Unknown	1	1	Week 1 (backup sample)
	Unscheduled	10DEC2013	Unknown	1		Week 1
	Week 2	18DEC2013	11:20	1		
	Week 4	03JAN2014	12:40	1		
	Week 8	30JAN2014	13:20	3		
	Week 12	26FEB2014	12:40	5		
	Week 16	25MAR2014	13:52	5		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
	Week 20	23APR2014	11:25	4		
109-0008/70/F/W2	Screening	21MAY2014	11:35	0		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
109-0008/70/F/W2	Week 2	12JUN2014	13:30	0		
	Week 4	25JUN2014	12:20	1		
	Week 8	23JUL2014	12:40	3		
	Week 12	20AUG2014	13:10	4		
	Week 16	17SEP2014	12:45	4		
	Week 20	14OCT2014	08:39	4		
	Week 24	13NOV2014	09:20	4		
109-0009/57/M/W2	Screening	25JUN2014	11:45	0		
	Week 2	15JUL2014	14:55	1		
	Week 4	30JUL2014	12:15	2		
	Week 8	26AUG2014	11:19	3		
	Week 12	23SEP2014	13:30	3		
109-0010/65/M/W2	Screening	25JUN2014	14:45	1		
	Week 2	16JUL2014	15:19	1		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
109-0010/65/M/W2	Week 4	30JUL2014	14:10	1		
	Week 8	27AUG2014	12:25	2		
	Week 12	24SEP2014	11:30	3		
109-0011/64/M/A4	Screening	23JAN2013	Unknown	1		
	Week 2	01OCT2014	15:25	0		
	Week 4	15OCT2014	15:05	0		
	Week 8	11NOV2014	15:20	2		
	Week 12	10DEC2014	14:50	3		
109-0013/64/F/W2	Screening	30OCT2014	14:30	0		
	Week 2	11NOV2014	12:31	0		
	Week 4	Unknown	Unknown	0		
	Week 8	22DEC2014	14:55	0		
	Week 12	20JAN2015	11:45	1		
	Unscheduled	24FEB2015	Unknown	2		Week 17

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
109-0013/64/F/W2	Week 24	13APR2015	12:30	4		
110-0003/63/M/OTH	Screening	25JUN2012	16:00	0		
	Week 4	30JUL2012	12:15	0		
	Week 8	27AUG2012	11:30	1		
	Week 12	25SEP2012	12:30	3		
	Week 16	22OCT2012	11:55	3		
	Week 20	19NOV2012	11:35	4		
110-0004/53/M/A4	Screening	11OCT2012	13:05	1		
	Week 8	13DEC2012	11:15	2		
110-0005/77/M/W2	Screening	22SEP2010	Unknown	0		
	Week 4	02APR2013	14:30	0		
	Week 8	30APR2013	13:58	0		
	Week 12	28MAY2013	12:30	3		
110-0007/62/M/A4	Screening	03MAY2013	11:58	0		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
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[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
110-0007/62/M/A4	Week 4	07JUN2013	13:05	3		
	Week 12	02AUG2013	12:00	4		
	Week 16	30AUG2013	11:15	5		
	Week 24	25OCT2013	12:05	5		
	Week 28	22NOV2013	11:35	6		
110-0008/63/F/BL	Screening	26JUN2013	12:18	0		
	Week 4	29JUL2013	12:05	2		
110-0011/77/M/A1	Screening	26JUL2013	Unknown	0		
	Week 2	29JAN2015	11:33	0		
	Week 4	12FEB2015	11:55	1		
	Week 8	12MAR2015	11:31	2		
	Week 12	10APR2015	15:35	3		
111-0001/37/M/A4	Screening	02JUL2012	11:05	0		
	Week 4	02AUG2012	13:00	0		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
111-0004/64/M/W2	Screening	10MAY2013	11:25	0		
	Week 2	30MAY2013	09:54	0		
	Week 4	13JUN2013	09:52	0		
	Week 8	11JUL2013	09:25	0		
111-0006/59/M/W2	Screening	03OCT2013	08:25	0		
	Week 2	17OCT2013	08:28	1		
	Week 4	30OCT2013	07:15	1		
	Week 8	27NOV2013	08:24	3	3	
	Week 8	27NOV2013	08:24	3		
	Week 12	02JAN2014	09:15	4		
	Week 16	29JAN2014	11:20	4		
	Week 20	26FEB2014	10:40	4		
	Week 24	26MAR2014	07:25	4		
	Week 28	23APR2014	07:55	4		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
111-0007/55/M/W2	Screening	23JAN2014	15:46	0		
	Week 2	13FEB2014	15:10	1		
	Week 4	27FEB2014	11:12	2		
	Week 8	27MAR2014	11:35	1		
	Week 12	25APR2014	07:50	2		
112-0006/58/M/W2	Screening	15MAR2013	10:23	0		
	Week 2	01APR2013	07:09	1		
	Week 4	15APR2013	11:53	2		
	Week 8	13MAY2013	12:09	4		
112-0009/50/M/A8	Screening	05JUN2013	Unknown	0		
	Week 2	26JUN2013	07:12	1		
	Week 8	07AUG2013	09:27	1		
	Week 12	04SEP2013	07:53	2		
112-0011/56/M/A4	Screening	03JAN2014	10:10	0		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
112-0011/56/M/A4	Week 2	17JAN2014	11:38	0		
	Week 4	31JAN2014	08:44	0		
	Week 8	28FEB2014	09:02	2		
112-0012/71/M/W2	Screening	16MAY2014	08:05	0		
	Week 2	30MAY2014	08:00	0		
	Week 4	13JUN2014	07:42	1		
	Week 8	11JUL2014	08:00	2		
	Week 12	08AUG2014	07:24	3		
112-0013/28/F/W2	Screening	16MAY2014	11:25	0		
	Week 2	30MAY2014	09:00	0		
	Week 4	13JUN2014	08:00	0		
	Week 8	11JUL2014	08:21	2		
112-0014/79/M/A8	Screening	30MAY2014	13:10	1		
	Week 2	13JUN2014	13:20	0		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
112-0014/79/M/A8	Week 4	27JUN2014	11:38	0		
	Week 8	25JUL2014	09:20	0		
	Week 12	22AUG2014	07:56	0		
112-0015/66/M/A8	Screening	17OCT2014	09:31	0		
	Week 2	31OCT2014	08:20	0		
	Week 4	14NOV2014	08:41	0		
	Week 8	12DEC2014	10:20	2		
113-0001/60/M/W2	Screening	09AUG2012	15:45	0		
	Week 4	17SEP2012	14:10	0		
	Week 8	15OCT2012	12:30	3		
	Week 12	15NOV2012	14:35	3		
	Week 16	10DEC2012	11:49	4		
	Week 20	07JAN2013	13:10	4		
	Week 24	06FEB2013	13:00	4		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
113-0002/64/F/W2	Screening	08OCT2012	15:27	2	1.5	
	Unscheduled	08OCT2012	15:27	1		Screening (collection date not found on visit report, date is between screening and week 1)
	Week 4	05NOV2012	11:00	1		
	Week 8	26NOV2012	11:45	1		
	Week 20	20FEB2013	09:05	2		
	Week 24	25MAR2013	09:50	1		
	Week 28	22APR2013	08:45	1		
	Week 32	20MAY2013	08:04	1		
113-0005/58/M/W2	Screening	08JAN2014	09:50	1		
	Week 2	30JAN2014	09:13	0		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
	Week 4	13FEB2014	09:27	0		
	Week 8	12MAR2014	14:26	3		
113-0008/78/M/A8	Screening	07FEB2014	13:25	1		
113-0010/59/M/W2	Screening	30APR2014	14:17	0		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
113-0010/59/M/W2	Week 2	07MAY2014	08:59	0		
	Week 4	23MAY2014	08:40	0		
113-0013/56/M/W2	Screening	03MAR2011	Unknown	0		
	Week 2	14NOV2014	08:08	0		
	Week 4	24NOV2014	08:24	0		
	Week 8	22DEC2014	08:35	0		
113-0016/72/M/A8	Screening	22JAN2015	14:27	1		
	Week 2	10FEB2015	14:25	0		
	Week 4	25FEB2015	13:34	0		
	Week 8	23MAR2015	08:37	1		
114-0003/59/M/W2	Screening	19NOV2012	11:15	2		
	Week 4	19DEC2012	11:40	1		
	Week 8	16JAN2013	11:45	1		
	Week 12	13FEB2013	11:34	0		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
114-0003/59/M/W2	Week 16	13MAR2013	11:32	3		
	Week 20	10APR2013	12:12	5		
114-0005/73/M/W2	Screening	11SEP2012	Unknown	0		
	Week 2	18DEC2013	08:37	0		
	Week 4	31DEC2013	08:39	0		
	Week 8	29JAN2014	08:08	0		
114-0007/60/F/W2	Screening	14NOV2014	11:46	1		
	Week 2	26NOV2014	11:17	0		
	Week 4	09DEC2014	11:49	0		
	Week 8	06JAN2014	10:11	1		
	Week 12	04FEB2015	10:20	3		
	Week 20	31MAR2015	10:27	3		
	Week 24	28APR2015	10:29	4		
	Week 28	26MAY2015	10:41	4		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
115-0001/59/F/A4	Screening	15JUN2011	Unknown	1		
	Week 4	18DEC2012	09:30	1		
	Week 8	15JAN2013	08:45	4		
	Week 12	14FEB2013	07:25	4		
115-0002/45/F/W2	Screening	26NOV2012	12:44	1		
	Week 4	18DEC2012	13:26	2		
115-0003/63/M/W2	Screening	17DEC2008	Unknown	0		
	Week 4	07FEB2013	08:12	0		
	Week 8	07MAR2013	08:14	0		
	Week 12	04APR2013	07:16	2		
	Week 16	02MAY2013	07:50	2		
	Week 20	30MAY2013	07:25	3		
115-0008/51/M/A8	Screening	13JUN2013	13:50	0		
	Week 2	25JUN2013	09:54	0		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
115-0009/85/M/W2	Screening	03DEC2013	15:25	2		
	Week 2	19DEC2013	13:54	2		
	Week 4	02JAN2014	08:25	2		
	Week 8	28JAN2014	09:55	3		
	Week 16	27MAR2014	09:17	3		
	Week 20	22APR2014	13:07	3		
	Week 24	21MAY2014	08:54	4		
115-0011/56/M/W2	Screening	30MAY2014	07:08	1		
	Week 2	13JUN2014	08:00	1		
	Week 4	26JUN2014	08:45	2		
	Week 12	22AUG2014	07:34	4		
115-0014/72/M/W2	Week 2	18FEB2015	11:40	0		
	Week 4	03MAR2015	08:45	0		
	Week 8	01APR2015	12:30	2		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
116-0002/67/F/W2	Screening	11MAR2013	16:44	0		
	Week 2	25MAR2013	16:02	0		
	Week 4	08APR2013	14:02	1		
	Week 8	06MAY2013	13:54	4		
	Week 12	03JUN2013	14:00	4		
	Week 16	01JUL2013	13:35	4		
	Week 20	29JUL2013	13:52	5		
	Week 24	26AUG2013	14:09	4		
	Week 28	23SEP2013	13:52	5		
	Week 32	21OCT2013	13:41	5		
	Week 36	18NOV2013	14:00	5		
116-0003/66/M/BL	Screening	18MAR2013	16:20	0		
	Week 2	04APR2013	09:12	0		
	Week 4	18APR2013	10:34	2		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
117-0001/69/M/W2	Screening	19MAR2013	13:35	3		
	Week 2	09APR2013	13:00	1		
	Week 4	23APR2013	13:45	1		
	Week 8	21MAY2013	13:00	0		
118-0001/67/F/A8	Screening	06AUG2013	13:20	0	0	
	Unscheduled	06AUG2013	13:20	0		Screening
	Unscheduled	06AUG2013	13:20	0		Screening
	Unscheduled	06AUG2013	13:20	0		Screening
	Week 2	20AUG2013	14:15	1		
	Week 4	03SEP2013	13:00	1		
	Week 8	03OCT2013	13:15	3		
	Week 12	29OCT2013	09:35	4		
119-0001/80/M/A8	Screening	07JAN2014	15:58	0		
	Week 2	28JAN2014	13:32	0		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
121-0001/62/M/W2	Screening	12MAR2012	Unknown	0		
	Week 2	25FEB2014	07:50	0		
	Week 4	11MAR2014	09:00	0		
	Week 8	08APR2014	09:40	2		
	Week 12	06MAY2014	09:05	3		
121-0004/64/F/W2	Screening	18DEC2014	14:33	0		
	Unscheduled	05JAN2015	Unknown	0		Week 1 (3 days after week 1 visit)
201-0001/68/F/W2	Screening	20JAN2012	08:00	0		
	Week 4	16FEB2012	08:00	1		
	Week 8	15MAR2012	09:20	0		
	Week 12	11APR2012	08:10	0		
201-0005/73/M/W2	Screening	05JUL2012	08:00	1		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
	Week 4	09AUG2012	07:50	1		
	Week 8	06SEP2012	08:00	3		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
201-0005/73/M/W2	Week 12	04OCT2012	08:00	3		
201-0008/79/M/W2	Screening	10MAY2013	08:30	0		
	Week 2	23MAY2013	08:00	0		
	Week 4	06JUN2013	08:00	0		
	Week 8	04JUL2013	08:15	1		
201-0011/73/M/W2	Screening	16MAR2011	Unknown	0		
	Week 2	11JUL2013	08:15	0		
	Week 4	24JUL2013	08:40	0		
	Week 8	22AUG2013	08:10	0		
	Week 12	18SEP2013	07:50	0		
201-0012/79/M/W2	Screening	11JUL2013	08:40	0	0	

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
	Unscheduled	11JUL2013	08:40	0		Screening (collection date not found on visit report, date is between screening and week 1)
	Week 2	01AUG2013	08:25	0		
	Week 8	12SEP2013	08:05	0		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
201-0012/79/M/W2	Week 12	10OCT2013	08:00	0		
	Week 16	07NOV2013	08:40	0		
	Week 20	06DEC2013	07:50	1		
	Week 24	03JAN2014	07:50	1		
	Week 28	30JAN2014	08:30	1		
	Week 32	27FEB2014	08:20	0		
	Week 36	27MAR2014	08:30	1		
	Week 38	09APR2014	08:10	1		Uns Continuation
	Week 40	24APR2014	08:00	1		Uns Continuation
	Week 42	08MAY2014	08:00	1		Uns Continuation
	Week 44	21MAY2014	08:25	2		Uns Continuation
	Week 46	05JUN2014	08:20	2		Uns Continuation
	Week 48	19JUN2014	08:15	2		Uns Continuation
	Week 50	03JUL2014	08:00	2		Uns Continuation

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
201-0012/79/M/W2	Week 52	16JUL2014	08:00	2		Uns Continuation
	Week 54	31JUL2014	08:00	2		Uns Continuation
	Week 58	28AUG2014	08:10	1		Uns Continuation
	Week 60	11SEP2014	08:30	2		Uns Continuation
201-0013/67/F/W2	Screening	11JUL2013	09:05	0	0	
	Unscheduled	11JUL2013	09:05	0		Screening (collection date not found on visit report, date is between screening and week 1)
	Week 2	01AUG2013	08:40	0		
	Week 8	12SEP2013	08:20	0		
	Week 12	10OCT2013	08:30	2	1	
	Week 12	10OCT2013	08:30	0		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
201-0016/72/M/W2	Screening	31OCT2013	08:30	0	0	
	Unscheduled	31OCT2013	08:30	0		Screening (collection date not found on visit report, date is between screening and week 1)
	Week 2	21NOV2013	08:30	0		
	Week 4	06DEC2013	08:20	0		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
201-0016/72/M/W2	Week 8	03JAN2014	08:10	0		
	Week 12	30JAN2014	08:10	0		
	Week 16	27FEB2014	08:00	0		
	Week 20	27MAR2014	08:15	0		
201-0017/82/M/W2	Screening	18NOV2013	08:00	1		
	Week 2	06DEC2013	08:40	0		
201-0018/78/F/W2	Screening	28NOV2013	08:20	0		
	Week 2	12DEC2013	08:25	0		
201-0019/68/M/W2	Screening	12DEC2013	09:00	0		
	Week 2	27DEC2013	08:25	0		
	Week 4	09JAN2014	08:15	0		
	Week 8	06FEB2014	08:20	3		
	Week 12	06MAR2014	08:10	4		
201-0020/67/M/W2	Screening	17JAN2014	09:30	0		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
201-0020/67/M/W2	Week 2	30JAN2014	09:00	0		
201-0021/54/M/W2	Screening	04FEB2014	08:00	0		
	Week 2	20FEB2014	08:00	0		
	Week 4	06MAR2014	07:50	0		
	Week 8	03APR2014	08:00	0		
	Week 12	30APR2014	08:00	2		
201-0024/74/M/W2	Screening	16JAN2015	09:30	0		
	Week 2	05FEB2015	08:00	0		
	Week 4	19FEB2015	07:50	2		
201-0025/75/M/W2	Screening	21JAN2015	08:00	1		
	Week 2	05FEB2015	07:45	1		
203-0001/61/F/W2	Screening	29FEB2012	08:00	1		
	Week 4	29MAR2012	08:00	2		
203-0002/72/M/W2	Screening	02MAR2012	08:00	0		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
203-0002/72/M/W2	Week 4	27MAR2012	08:00	0		
203-0005/53/M/W2	Screening	29MAR2012	08:00	0		
	Week 4	27APR2012	08:00	2		
	Week 8	31MAY2012	09:00	4		
203-0013/68/M/W2	Screening	23DEC2013	09:00	1		
	Week 2	08JAN2014	08:00	0		
	Week 4	22JAN2014	08:00	0		
	End of Treatment	31JAN2014	09:00	0		Week 6 (9 days after week 4 visit)
203-0015/85/M/W2	Screening	17JAN2014	09:00	0		
	Week 2	07FEB2014	08:00	0		
	Week 4	24FEB2014	09:00	1		
	Week 8	28MAR2014	09:00	3		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
203-0017/58/M/W2	Screening	18FEB2014	09:00	0		
	Week 2	12MAR2014	09:00	1		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
203-0018/58/F/W2	Screening	26MAR2014	08:00	0		
	Week 2	14APR2014	09:00	0		
	Week 8	04JUN2014	09:00	4		
205-0001/77/M/W2	Screening	14FEB2012	09:00	0		
	Week 4	14MAR2012	09:00	0		
	Week 8	13APR2012	09:00	3		
	Week 12	08MAY2012	09:00	4		
	Week 16	08JUN2012	09:00	4		
	Week 20	06JUL2012	09:00	4		
	Week 24	06AUG2012	09:00	5		
	Week 28	31AUG2012	09:00	5		
	Week 32	28SEP2012	09:00	5		
	Week 36	23OCT2012	09:00	5		
	Week 40	20NOV2012	09:00	5		Uns Continuation

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
205-0001/77/M/W2	Week 44	20DEC2012	09:00	5		Uns Continuation
	Week 52	13FEB2013	09:00	5		Uns Continuation
	Week 56	13MAR2013	09:00	5		Uns Continuation
	Week 68	13JUN2013	09:00	5		Uns Continuation
	Week 70	25JUN2013	09:30	5		Uns Continuation
	Week 72	09JUL2013	08:30	5		Uns Continuation
	Week 74	19JUL2013	09:30	5		Uns Continuation
	Week 78	26AUG2013	09:40	5		Uns Continuation
	Week 80	10SEP2013	09:00	5		Uns Continuation
	Week 82	24SEP2013	09:30	5		Uns Continuation
205-0004/77/F/W2	Screening	12MAR2012	09:00	0		
	Week 4	12APR2012	09:00	2		Back up sample, no primary sample was received

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
	Week 8	10MAY2012	09:00	4		
	Week 12	05JUN2012	09:00	4		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
205-0008/76/M/W2	Screening	20APR2012	09:00	0		
	Unscheduled	27APR2012	Unknown	0		Week 1
	Week 4	17MAY2012	09:00	0		
205-0012/73/F/W2	Screening	27NOV2012	09:00	2		
	Week 4	27DEC2012	09:00	3		
205-0015/71/M/W2	Screening	07JUN2013	07:30	0		
	Week 2	27JUN2013	09:30	0		
	Week 4	12JUL2013	08:30	0		
	Week 7	02AUG2013	08:00	1		
	Week 8	09AUG2013	10:30	0		
205-0016/70/M/W2	Screening	11JUN2013	08:30	0		
	Week 2	02JUL2013	09:30	0		
	Week 4	19JUL2013	09:30	1		
	Week 12	20SEP2013	10:00	0		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
205-0016/70/M/W2	Week 16	17OCT2013	11:00	0		
	Week 20	14NOV2013	14:00	0		
	Week 24	10DEC2013	10:45	1		
	Week 28	10JAN2014	11:00	1		
	Week 32	07FEB2014	11:15	1		
	Week 36	07MAR2014	10:30	0		
	Week 38	21MAR2014	10:30	1		Uns Continuation
	Week 40	03APR2014	10:00	0		Uns Continuation
	Week 44	29APR2014	09:30	0		Uns Continuation
	Week 48	27MAY2014	10:15	0		Uns Continuation
	Week 50	10JUN2014	10:30	0		Uns Continuation
	Week 52	24JUN2014	10:00	0		Uns Continuation
	Week 56	22JUL2014	11:30	0		Uns Continuation
	Week 60	11AUG2014	10:15	0		Uns Continuation

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
205-0016/70/M/W2	Week 64	11SEP2014	10:00	0		Uns Continuation
	Week 68	09OCT2014	10:30	0		Uns Continuation
	Week 72	06NOV2014	11:00	0		Uns Continuation
	Week 76	04DEC2014	11:00	0		Uns Continuation
	Week 78	18DEC2014	10:00	0		Uns Continuation
	Week 80	30DEC2014	10:00	0		Uns Continuation
	Week 84	29JAN2015	10:20	0		Uns Continuation
	Week 88	26FEB2015	10:50	0		Uns Continuation
	Week 92	26MAR2015	11:00	0		Uns Continuation
	Week 96	21APR2015	11:00	0		Uns Continuation
	Week 100	21MAY2015	11:00	0		Uns Continuation
205-0017/71/M/W2	Screening	02AUG2013	10:00	0		
	Unscheduled	08AUG2013	Unknown	0		Week 1
	Week 4	26AUG2013	10:00	0		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
205-0017/71/M/W2	Week 8	24SEP2013	09:00	2		
	Week 12	25OCT2013	12:30	3		
	Week 16	22NOV2013	09:30	4		
	Week 20	20DEC2013	09:15	4		
	Week 24	14JAN2014	08:45	4		
205-0020/82/M/W2	Screening	01OCT2013	09:30	1		
	Week 2	17OCT2013	12:30	0		
	Week 4	31OCT2013	11:30	0		
	Week 8	29NOV2013	09:30	3		
	Week 12	23DEC2013	09:00	4		
205-0022/67/M/W2	Screening	25OCT2013	10:00	0	0	
	Screening	25OCT2013	10:00	0		
	Week 2	12NOV2013	11:00	0		
205-0024/80/M/W2	Screening	19NOV2013	09:45	0		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
205-0024/80/M/W2	Week 2	13DEC2013	09:40	0		
	Week 4	23DEC2013	11:00	1		
	Week 8	23JAN2014	12:30	1		
	Week 12	25FEB2014	12:00	3		
205-0025/63/F/W2	Screening	21NOV2013	12:30	0		
	Week 2	03DEC2013	10:30	0		
	Week 4	19DEC2013	10:00	0		
	Week 8	14JAN2014	11:15	3		
	Week 12	14FEB2014	10:30	4		
207-0001/81/F/W2	Screening	08MAR2012	11:30	0		
207-0005/74/M/W2	Screening	21MAY2012	13:30	0	0.5	

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
	Screening	21MAY2012	13:30	1		Screening (collection date not found on visit report, date is between screening and week 1)
207-0006/73/M/W2	Screening	08JUN2012	11:30	2		
	Week 4	09JUL2012	09:30	1		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
207-0006/73/M/W2	Week 8	06AUG2012	09:40	1		
207-0008/66/M/W2	Screening	25JUN2012	12:00	0		
	Week 4	13AUG2012	09:25	1		
207-0011/78/M/W2	Screening	09JAN2013	12:45	1		
207-0015/77/M/W2	Screening	08AUG2013	11:20	0		
	Week 2	20AUG2013	09:00	0		
	Week 4	03SEP2013	11:45	0		
	Week 8	01OCT2013	09:50	1		
207-0020/77/M/W2	Screening	11JUN2014	10:20	0		
	Week 2	25JUN2014	09:45	0		
	Week 4	09JUL2014	09:50	1		
	Week 8	06AUG2014	09:45	3		
207-0021/74/M/W2	Screening	11JUN2014	11:15	0		
	Week 2	26JUN2014	10:35	0		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
207-0021/74/M/W2	Week 4	10JUL2014	11:30	0		
	Week 8	07AUG2014	11:15	0		
	Week 12	04SEP2014	11:00	2		
	Week 16	02OCT2014	11:30	3		
	Week 20	30OCT2014	09:40	3		
	Week 24	28NOV2014	13:00	3		
	Week 28	29DEC2014	10:30	4		
	Week 32	23JAN2015	09:30	4		
207-0022/74/M/W2	Screening	30JUN2014	10:45	1		
	Week 2	17JUL2014	11:05	0		
	Week 8	28AUG2014	10:30	4		
208-0001/59/M/W2	Screening	14SEP2012	09:15	0		
	Week 4	11OCT2012	08:30	1		
	Week 8	07NOV2012	08:30	3		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
208-0001/59/M/W2	Week 12	05DEC2012	08:50	3		
	Week 16	02JAN2013	08:20	3		
	Week 20	30JAN2013	08:40	4		
	Week 24	01MAR2013	09:00	5		
	Week 28	27MAR2013	08:45	5		
	Week 32	24APR2013	09:00	5		
	Week 36	22MAY2013	08:30	5		
	Week 40	19JUN2013	08:30	5		Uns Continuation
	Week 44	17JUL2013	08:30	5		Uns Continuation
	Week 48	19AUG2013	08:15	5		Uns Continuation
	Week 52	11SEP2013	08:30	5		Uns Continuation
	Week 56	09OCT2013	08:15	6		Uns Continuation
	Week 60	06NOV2013	08:30	5		Uns Continuation
	Week 64	04DEC2013	09:00	4		Uns Continuation

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
208-0001/59/M/W2	Week 68	02JAN2014	08:50	5		Uns Continuation
	Week 72	29JAN2014	08:30	5		Uns Continuation
	Week 76	26FEB2014	08:30	5		Uns Continuation
	Week 80	26MAR2014	08:40	5		Uns Continuation
	Week 84	23APR2014	09:00	5		Uns Continuation
	Week 86	07MAY2014	08:10	4		Uns Continuation
	Week 88	21MAY2014	08:30	4		Uns Continuation
	Unscheduled	18JUN2014	08:15	4		Week 92
	Unscheduled	16JUL2014	08:20	4		Week 96
	Week 100	13AUG2014	09:15	5		Uns Continuation
	Week 104	10SEP2014	09:00	5		Uns Continuation
	Week 108	08OCT2014	08:20	5		Uns Continuation

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
	Week 110	22OCT2014	08:15	4		Uns Continuation
	Week 112	05NOV2014	08:30	5		Retest in sample list from CLS

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
208-0001/59/M/W2	Week 116	03DEC2014	09:40	5		Uns Continuation
	Week 120	02JAN2015	08:30	5		Uns Continuation
	Week 124	28JAN2015	08:15	5		Uns Continuation
	Week 128	25FEB2015	08:30	5		Uns Continuation
	Week 132	25MAR2015	08:15	5		Uns Continuation
	Week 136	Unknown	Unknown	5		Uns Continuation
	Week 140	Unknown	Unknown	5		Uns Continuation
208-0002/82/F/W2	Screening	14SEP2012	10:00	0		
	Week 4	11OCT2012	09:00	3		
	Week 8	07NOV2012	08:45	3		
208-0006/69/F/W2	Screening	19AUG2013	09:45	3		
	Week 2	05SEP2013	09:00	4		
	Week 4	18SEP2013	09:00	0		
	Week 8	16OCT2013	09:15	0		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
208-0006/69/F/W2	Week 12	13NOV2013	08:45	3		
208-0007/53/M/W2	Screening	23JUN2014	10:00	0		
	Week 2	16JUL2014	08:30	0		
	Week 4	30JUL2014	08:30	1		
	Week 8	27AUG2014	08:20	3		
	Week 12	25SEP2014	08:30	4		
209-0001/66/M/W2	Screening	08NOV2012	10:30	2		
	Week 4	06DEC2012	10:10	2		
	Week 8	03JAN2013	09:50	2		
	Week 12	31JAN2013	10:15	4		
209-0004/74/M/W2	Screening	28MAR2013	10:15	0		
	Week 4	30APR2013	09:15	0		
	Week 8	30MAY2013	09:30	0		
	Week 12	25JUN2013	10:45	0		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
209-0008/66/M/W2	Screening	26JUN2013	07:45	1		
	Week 4	31JUL2013	09:30	0		
	Week 12	24SEP2013	09:00	4		
209-0012/63/M/W2	Screening	26NOV2013	10:10	0		
	Week 2	10DEC2013	10:20	0		
	Week 4	23DEC2013	09:00	1		
	Week 8	22JAN2014	09:30	3		
	Week 12	19FEB2014	09:00	4		
	Week 16	19MAR2014	10:00	5		
	Week 20	16APR2014	09:00	4		
	Week 24	15MAY2014	10:00	5		
209-0013/52/M/W2	Screening	10DEC2013	09:00	0		
	Week 4	14JAN2014	09:30	1		
	Week 8	12FEB2014	09:35	3		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
209-0013/52/M/W2	Week 12	11MAR2014	11:05	3		
	Week 16	08APR2014	10:40	4		
	Week 20	07MAY2014	09:30	5		
	Week 24	04JUN2014	10:15	4		
	Week 28	02JUL2014	09:15	4		
	Week 32	29JUL2014	10:15	4		
	Week 36	26AUG2014	09:40	5		
210-0001/67/M/W2	Screening	28AUG2013	09:30	0		
	Week 2	05SEP2013	11:00	1		
	Week 4	19SEP2013	09:30	0		
	Week 8	17OCT2013	10:00	2		
	Week 12	14NOV2013	10:15	4		
	Week 16	12DEC2013	09:45	0		Empty tube
	Week 20	09JAN2014	09:30	5		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
210-0001/67/M/W2	Week 24	06FEB2014	09:30	5		
210-0002/80/M/W2	Screening	02OCT2013	10:15	0		
	Week 2	16OCT2013	11:00	1		
	Week 4	31OCT2013	10:10	2		
	Week 8	29NOV2013	10:10	2		
	Week 12	23DEC2013	09:30	3		
	Week 16	22JAN2014	09:15	4		
	Week 20	19FEB2014	09:30	5		
	Week 24	19MAR2014	09:15	5		
	Week 32	14MAY2014	09:30	5		
	Week 36	12JUN2014	09:30	5		
	Week 40	09JUL2014	09:30	5		Uns Continuation
	Week 44	06AUG2014	09:20	5		Uns Continuation
210-0007/72/M/W2	Screening	03JUL2014	09:30	0		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
210-0007/72/M/W2	Week 2	16JUL2014	10:15	0		
	Week 4	31JUL2014	09:15	0		
	Week 8	28AUG2014	09:10	3		
	Week 12	24SEP2014	09:30	3		
	Week 20	27NOV2014	09:45	4		
	Week 24	22DEC2014	10:10	4		
	Week 28	22JAN2015	09:45	5		
	Week 32	19FEB2015	10:40	4		
	Week 36	19MAR2015	09:45	5		
210-0009/49/F/W2	Screening	05NOV2014	09:30	0		
	Week 2	19NOV2014	10:00	0		
	Week 4	03DEC2014	10:00	0		
	Week 8	29DEC2014	09:40	2		
	Week 12	28JAN2015	10:00	2		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
210-0011/73/M/W2	Screening	12NOV2014	09:30	0		
	Week 2	26NOV2014	10:05	0		
	Week 4	10DEC2014	10:00	0		
	Week 8	08JAN2015	10:15	0		
210-0012/47/F/W2	Screening	11DEC2014	09:30	1		
	Week 2	22DEC2014	10:00	0		
	Week 4	08JAN2015	09:35	0		
	Week 8	05FEB2015	09:55	2		
	Week 12	05MAR2015	09:40	3		
210-0014/71/F/W2	Screening	15JAN2015	10:15	0		
	Week 2	05FEB2015	10:00	1		
	Week 4	19FEB2015	10:35	0		
	Week 8	19MAR2015	09:40	2		
	Week 12	16APR2015	10:10	3		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
251-0001/55/F/W2	Screening	23JUL2012	14:50	0		
	Week 4	21AUG2012	12:00	0		Retest in sample list from CLS
	Week 8	18SEP2012	11:30	0		
	Week 12	16OCT2012	12:00	2		
252-0002/76/M/W2	Screening	21AUG2012	11:45	0	0	
	Unscheduled	21AUG2012	11:45	0		Screening
	Week 4	Unknown	Unknown	1		
252-0003/68/M/W2	Screening	11DEC2012	14:00	2		
	Week 4	22JAN2013	10:10	1		
	Week 8	19FEB2013	10:15	2		
	Week 12	19MAR2013	09:30	4		
252-0007/77/M/W2	Screening	11FEB2014	08:25	0		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
252-0011/81/M/BL	Screening	18NOV2014	11:20	0		
	Week 2	02DEC2014	08:45	0		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
252-0011/81/M/BL	Week 8	13JAN2015	08:15	0		
	Week 12	10FEB2015	08:25	0		
	Week 16	10MAR2015	12:00	1		
	Week 20	07APR2015	09:00	1		
	Week 24	05MAY2015	08:50	2		
253-0002/63/M/W2	Screening	02MAR2012	13:45	1		
	Week 4	30MAR2012	10:10	1		
	Week 8	27APR2012	11:15	4		
253-0010/76/M/W2	Screening	31MAY2013	10:30	2		
	Week 4	28JUN2013	11:00	3		
	Week 8	26JUL2013	11:30	3		
	Week 12	23AUG2013	11:00	3		
	Week 16	20SEP2013	10:40	4		
	Week 20	18OCT2013	10:30	5		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
253-0010/76/M/W2	Week 24	18NOV2013	10:30	4		
254-0001/69/M/W2	Screening	04MAY2012	12:15	0		
	Week 4	13JUN2012	12:30	0		
	Week 8	10JUL2012	13:05	3		
	Week 12	06AUG2012	13:00	3		
257-0001/47/M/A4	Screening	29MAR2012	12:45	0		
	Week 4	26APR2012	14:25	0		
	Week 8	24MAY2012	10:55	2		
257-0002/56/M/W2	Screening	12APR2012	10:35	0		
257-0007/80/M/W2	Screening	13FEB2013	09:13	0	0	

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
	Unscheduled	13FEB2013	09:13	0		Screening (collection date not found on visit report, date is between screening and week 1)
	Unscheduled	21FEB2013	Unknown	0		Week 1
	Week 2	28FEB2013	12:00	0		
	Week 4	14MAR2013	11:05	0		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
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[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
257-0007/80/M/W2	Week 8	11APR2013	10:50	1		
	Week 12	09MAY2013	11:20	1		
257-0008/80/F/W2	Screening	21MAR2013	13:15	1	2	
	Unscheduled	21MAR2013	13:15	3		Screening (collection date not found on visit report, date is between screening and week 1)
	Week 2	04APR2013	10:28	0		
	Week 4	18APR2013	10:05	0		
	Week 8	16MAY2013	12:05	0		
	Week 12	13JUN2013	12:50	0		
257-0010/42/M/BL	Screening	16MAY2013	14:35	1	1.5	

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[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
	Unscheduled	16MAY2013	14:35	2		Screening (collection date not found on visit report, date is between screening and week 1)
	Week 2	30MAY2013	10:19	1		
	Week 4	13JUN2013	12:40	2		
	Week 8	08JUN2013	14:13	0		
	Week 12	05AUG2013	14:12	1		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
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[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
257-0012/75/M/W2	Screening	09MAY2013	11:08	2		
	Week 2	23MAY2013	11:10	2		
	Week 4	07JUN2013	11:24	1		
257-0015/69/F/BL	Screening	31MAR2014	13:57	1		
257-0017/74/M/A8	Screening	28APR2014	14:20	1		
	Week 2	12MAY2014	14:10	0		
	Week 4	27MAY2014	15:30	0		
	Week 8	23JUN2014	15:05	0		
257-0018/53/M/A6	Screening	17APR2014	11:00	0		
	Week 2	02MAY2014	14:20	0		
	Week 4	19MAY2014	14:20	1		
257-0022/60/M/W2	Screening	26NOV2014	11:35	1		
	Week 2	08DEC2014	14:10	0		
	Week 4	22DEC2014	14:00	0		

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[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
257-0022/60/M/W2	Week 8	19JAN2015	15:20	0		
	Unscheduled	26JAN2015	Unknown	1		Week 9
257-0024/75/M/W2	Screening	15DEC2014	13:20	1		
	Week 2	29DEC2014	13:20	0		
	Week 4	12JAN2015	13:30	0		
	Week 8	09FEB2015	15:34	0		
257-0025/69/M/BL	Screening	15DEC2014	14:15	0		
	Week 2	29DEC2014	13:44	0		
	Week 4	12JAN2015	13:20	0		
	Week 8	09FEB2015	15:05	0		
	Unscheduled	16FEB2015	Unknown	0		Week 9
	Week 12	09MAR2015	14:00	0		
257-0026/65/M/W2	Screening	12JAN2015	15:10	0		
	Week 2	26JAN2015	13:45	0		

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[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
257-0026/65/M/W2	Week 4	09FEB2015	14:45	1		
	Week 8	09MAR2015	14:00	3		
	Week 12	Unknown	Unknown	4		
257-0027/52/M/A6	Screening	12JAN2015	15:45	0		
	Week 2	26JAN2015	16:10	0		
	Week 4	09FEB2015	15:00	0		
258-0005/64/M/OTH	Screening	31JUL2013	10:50	0		
	Week 2	21AUG2013	11:20	1		
	Week 4	04SEP2013	11:15	2		
	Week 8	02OCT2013	11:25	1		
258-0007/74/M/W2	Screening	02OCT2013	12:28	0		
	Week 2	18OCT2013	11:58	1		
	Week 4	01NOV2013	11:32	0		
258-0008/70/M/W2	Screening	06NOV2013	10:14	0		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
258-0009/64/M/W2	Screening	16MAY2014	12:09	0		
	Week 2	30MAY2014	10:05	1		
	Week 4	11JUN2014	10:05	1		
	Week 8	09JUL2014	10:38	2		
	Week 12	06AUG2014	10:40	2		
	Week 16	03SEP2014	10:45	3		
	Week 20	01OCT2014	10:25	4		
	Week 24	29OCT2014	11:43	4		
258-0010/53/M/W2	Screening	30MAY2014	11:12	0		
	Week 2	11JUN2014	11:20	1		
	Week 4	25JUN2014	10:10	2		
	Week 8	21JUL2014	10:20	3		
	Week 12	20AUG2014	09:12	4		
	Week 16	17SEP2014	10:20	5		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
258-0010/53/M/W2	Week 20	16OCT2014	09:30	5		
	Week 24	12NOV2014	10:05	5		
258-0012/66/F/W2	Screening	09JUL2014	10:30	1		
	Week 2	23JUL2014	12:20	1		
	Week 4	06AUG2014	12:15	2		
	Week 8	03SEP2014	12:05	2		
	Week 12	01OCT2014	11:20	4		
258-0015/65/M/W2	Screening	28NOV2014	09:33	0		
	Week 2	10DEC2014	09:43	0		
259-0001/68/F/W2	Screening	24MAY2013	09:15	0		
	Week 2	13JUN2013	13:20	0		
	Week 4	26JUN2013	14:00	2		
	Week 8	24JUL2013	13:20	4		
	Week 12	21AUG2013	13:50	4		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
259-0001/68/F/W2	Week 20	16OCT2013	13:20	5		
	Week 36	05FEB2014	10:15	5		
	Week 40	05MAR2014	13:00	5		Uns Continuation
	Week 48	30APR2014	10:45	5		Uns Continuation
	Week 52	28MAY2014	10:50	5		Uns Continuation
259-0002/54/F/W2	Screening	04SEP2013	12:45	0		
	Week 2	18SEP2013	11:15	0		
	Week 4	02OCT2013	11:56	1		
	Week 8	30OCT2013	12:05	2		
	Week 12	27NOV2013	11:30	2		
260-0003/81/M/A7	Screening	22OCT2014	14:00	0		
	Week 2	12NOV2014	11:40	0		
	Week 4	26NOV2014	10:50	0		
	Week 8	22DEC2014	11:30	1		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
260-0003/81/M/A7	Week 12	21JAN2015	11:30	3		
	Week 16	18FEB2015	11:00	4		
	Week 20	18MAR2015	11:00	4		
	Week 24	15APR2015	10:30	4		
	Week 28	13MAY2015	10:30	4		
301-0005/61/M/A2	Screening	17MAY2012	10:00	0		
	Week 4	14JUN2012	10:05	0		
	Week 8	12JUL2012	10:00	3		
	Week 12	09AUG2012	09:20	4		
301-0007/55/F/A2	Screening	26DEC2012	09:35	0		
	Week 4	25JAN2013	10:10	0		
	Week 8	22FEB2013	09:56	0		
301-0009/55/M/A2	Screening	08JAN2013	09:45	0		
	Week 4	31JAN2013	09:55	3		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
301-0009/55/M/A2	Week 8	01MAR2013	09:45	4		
	Week 12	28MAR2013	10:00	4		
302-0002/32/F/A2	Screening	03NOV2011	11:00	1		
	Week 4	29NOV2011	10:50	3		
302-0004/57/M/A2	Screening	04JAN2012	09:15	0		
	Week 4	01FEB2012	09:15	0		
	Week 8	28FEB2012	09:15	0		
302-0007/76/M/A2	Screening	08FEB2012	08:44	0		
	Week 4	06MAR2012	09:00	1		
	Week 8	03APR2012	09:10	0		
	Week 12	01MAY2012	08:35	3		
302-0008/37/M/A2	Screening	23FEB2012	09:12	0		
	Week 4	20MAR2012	09:30	0		
	Week 8	17APR2012	09:20	3		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
302-0010/45/M/A2	Screening	12APR2012	10:35	0		
	Week 4	08MAY2012	09:15	1		
	Week 8	05JUN2012	09:20	0		
	Week 12	03JUL2012	08:55	3		
302-0011/52/M/A2	Screening	17APR2012	11:02	0		
	Week 4	15MAY2012	09:25	0		
302-0015/60/M/A2	Screening	11APR2013	08:40	0		
	Week 2	23APR2013	08:50	0		
	Week 4	07MAY2013	08:55	0		
	Week 8	04JUN2013	09:10	4		
	Week 12	02JUL2013	08:40	3		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
302-0016/60/M/A2	Screening	11APR2013	09:05	0		Additional sample with visit screening-1 is listed in sample list
	Week 2	23APR2013	09:20	1		
	Week 4	07MAY2013	08:50	1		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
302-0016/60/M/A2	Week 8	04JUN2013	09:05	4		
	Week 12	02JUL2013	08:40	5		
302-0019/52/M/A2	Screening	09MAY2013	09:15	0		
	Week 2	21MAY2013	09:20	0		
	Week 4	04JUN2013	09:15	1		
	Week 8	02JUL2013	09:10	2		
	Week 12	30JUL2013	09:15	3		
302-0022/65/M/A2	Screening	04JUL2013	09:05	0		
	Week 2	16JUL2013	09:30	0		
	Week 4	30JUL2013	09:30	1		
	Week 8	27AUG2013	09:00	3		
302-0023/68/M/A2	Screening	15SEP2009	Unknown	0		
	Week 2	17SEP2013	08:20	0		
	Week 4	01OCT2013	09:13	0		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
302-0024/66/F/A2	Screening	04JAN2013	Unknown	0		
	Week 2	01OCT2013	09:08	0		
	Week 4	15OCT2013	08:28	0		
	Week 8	12NOV2013	08:20	4		
	Week 12	10DEC2013	08:10	4		
302-0025/40/M/A2	Screening	07SEP2011	Unknown	0		
	Week 2	29OCT2013	08:15	0		
302-0026/49/M/A2	Screening	05NOV2013	10:45	0		
	Week 2	19NOV2013	08:25	0		
	Week 4	03DEC2013	08:50	0		
	Week 8	31DEC2013	08:40	4		
	Week 12	28JAN2014	09:35	3		
	Week 16	25FEB2014	08:55	4		
	Week 20	25MAR2014	09:00	3		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
302-0026/49/M/A2	Week 24	22APR2014	09:00	4		
	Week 28	22MAY2014	09:10	4		
	Week 32	17JUN2014	09:30	4		
	Week 36	15JUL2014	08:40	4		
303-0001/50/M/A2	Screening	20JAN2012	09:20	0		
	Week 4	22FEB2012	13:25	2		
	Week 8	21MAR2012	14:30	3		
	Week 12	18APR2012	13:00	4		
303-0003/47/M/A2	Screening	14NOV2012	10:15	0		
	Week 4	19DEC2012	10:30	4		
	Week 8	16JAN2013	10:00	4		
	Week 12	15FEB2013	14:00	4		
303-0004/18/M/A2	Screening	26NOV2012	14:50	0		
	Week 4	02JAN2013	14:00	0		

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[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
303-0004/18/M/A2	Week 8	30JAN2013	13:30	2		
	Week 12	27FEB2013	13:50	3		
303-0006/64/M/A2	Screening	27MAR2013	15:10	0		
	Week 4	01MAY2013	13:30	2		
	Week 8	29MAY2013	13:25	4		
303-0007/50/M/A2	Screening	03JUL2013	Unknown	0		
	Week 2	31JUL2013	13:30	0		
	Week 4	14AUG2013	13:30	0		
	Week 8	11SEP2013	13:25	4		
304-0001/54/M/A2	Screening	30OCT2012	10:30	1		
	Week 4	27NOV2012	11:00	2		
304-0005/58/M/A2	Screening	30MAY2013	11:16	0		
	Week 2	13JUN2013	08:15	0		
	Week 4	26JUN2013	08:30	0		

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[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
305-0002/57/M/A2	Screening	13FEB2012	09:15	0		
305-0003/50/M/A2	Screening	26AUG2008	Unknown	0		
	Week 4	09MAR2012	09:00	3		
	Week 8	06APR2012	09:00	3		
	Week 12	04MAY2012	09:00	4		
	Week 16	01JUN2012	08:45	4		
	Week 20	29JUN2012	08:52	4		
	Week 24	27JUL2012	08:32	4		
305-0005/48/M/A2	Screening	15FEB2012	11:35	0		
	Week 4	15MAR2012	09:09	3		
305-0006/65/M/A2	Screening	07MAR2012	09:20	0		
	Week 4	28MAR2012	12:15	1		
	Week 8	25APR2012	12:30	5		
	Week 12	23MAY2012	12:09	5		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
305-0006/65/M/A2	Week 16	19JUN2012	12:25	5		
	Week 20	18JUL2012	12:40	5		
	Week 24	15AUG2012	12:40	5		
305-0009/45/F/A2	Screening	11APR2012	09:30	0		
	Week 4	01MAY2012	11:50	0		
	Week 8	30MAY2012	11:53	1		
	Week 12	27JUN2012	12:20	2		
	Week 16	25JUL2012	12:50	1		
	Week 20	22AUG2012	13:00	1		
	Week 24	19SEP2012	13:05	2		
305-0010/64/F/A2	Screening	16APR2012	11:20	0		
	Week 4	08MAY2012	12:40	0		
	Week 8	05JUN2012	13:35	2		
	Week 12	04JUL2012	13:00	3		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
305-0011/68/M/A2	Screening	20APR2012	12:00	0		
	Week 4	18MAY2012	08:20	0		
	Week 8	15JUN2012	07:50	3		
	Week 12	13JUL2012	07:20	4		
	Week 16	10AUG2012	07:50	4		
305-0012/62/F/A2	Screening	03MAY2012	15:10	0		
	Week 4	25MAY2012	08:20	0		
	Week 8	22JUN2012	08:20	1		
	Week 12	20JUL2012	09:02	4		
	Week 16	17AUG2012	07:42	5		
	Week 20	14SEP2012	08:11	4		
	Week 24	12OCT2012	07:56	3		
	Week 28	09NOV2012	07:55	3		
	Week 32	07DEC2012	07:40	3		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
305-0012/62/F/A2	Week 36	04JAN2013	07:55	3		
305-0014/61/F/A2	Screening	04JUL2012	08:00	0		
	Week 4	31JUL2012	11:30	0		
	Week 8	28AUG2012	12:22	0		
	Week 12	25SEP2012	12:09	0		
305-0019/35/M/A2	Screening	05SEP2012	10:33	0		
	Week 4	02OCT2012	11:55	0		
	Week 8	30OCT2012	12:33	2		
305-0023/54/M/A2	Screening	02JAN2013	09:45	0		
	Week 4	29JAN2013	12:10	1		
	Week 8	26FEB2013	12:09	3		
	Week 12	29MAR2013	07:40	4		
	Week 16	25APR2013	08:10	4		
305-0025/77/F/A2	Screening	15JAN2013	14:40	0		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
305-0025/77/F/A2	Week 4	15FEB2013	12:15	2		
	Week 8	12MAR2013	11:45	3		
	Week 12	09APR2013	10:50	4		
305-0026/45/M/A2	Screening	11MAR2002	Unknown	0		
	Week 4	19MAR2013	12:40	0		
	Week 8	16APR2013	13:00	0		
	Week 12	14MAY2013	13:05	2		
	Week 20	09JUL2013	13:05	4		
	Week 24	06AUG2013	13:00	4		
305-0028/73/F/A2	Screening	13MAR2013	14:00	0		
	Week 4	03APR2013	13:00	0		
	Week 8	30APR2013	13:22	2		
	Week 12	29MAY2013	12:50	4		
305-0030/61/M/A2	Screening	28MAR2013	10:00	0		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
305-0030/61/M/A2	Week 4	23APR2013	12:00	1		
305-0031/29/M/A2	Screening	26MAR2013	17:58	0		
	Week 4	26APR2013	09:33	0		
305-0034/53/M/A2	Screening	26JUN2013	15:15	4		
	Week 2	10JUL2013	13:05	2		
	Week 4	22JUL2013	11:20	2		
305-0036/38/M/A2	Screening	27AUG2013	15:03	0		
	Week 2	12SEP2013	08:01	0		
	Week 4	26SEP2013	08:30	1		
	Week 8	24OCT2013	08:15	3		
	Week 12	19NOV2013	09:32	3		
305-0037/50/M/A2	Screening	17OCT2013	15:07	0		
	Week 4	14NOV2013	09:00	1		
	Week 8	12DEC2013	09:07	3		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
305-0037/50/M/A2	Week 12	09JAN2014	09:20	4		
305-0039/35/M/A2	Screening	22NOV2013	15:25	0		
	Week 2	05DEC2013	10:46	0		
	Week 4	19DEC2013	10:50	0		
305-0040/61/M/A2	Screening	11NOV2013	08:57	0		
	Week 2	19NOV2013	12:50	0		
305-0043/70/M/A2	Screening	27JUN2014	09:00	0		
	Week 2	08JUL2014	12:40	0		
	Week 4	22JUL2014	13:00	0		
	Week 8	19AUG2014	13:00	0		
	Week 12	16SEP2014	10:51	2		
305-0044/67/M/A2	Screening	01JUL2014	16:30	1		
	Week 2	15JUL2014	12:30	0		
	Week 4	29JUL2014	12:35	0		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
305-0044/67/M/A2	Week 8	26AUG2014	12:50	0		
	Week 12	26SEP2014	13:00	1		
305-0045/65/M/A2	Screening	06OCT2014	08:06	0		
	Week 2	24OCT2014	08:00	0		
	Week 4	07NOV2014	07:43	1		
305-0047/58/M/A2	Screening	24DEC2014	09:30	0		
	Week 2	31DEC2014	14:00	0		
	Week 4	14JAN2015	12:55	0		
305-0048/55/M/A2	Screening	10FEB2015	15:20	1		
	Week 2	06MAR2015	09:30	0		
	Week 4	20MAR2015	12:50	0		
	Week 8	14APR2015	12:30	1		
	Week 12	12MAY2015	13:07	3		
306-0001/56/M/A2	Screening	13FEB2012	08:30	0		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
306-0001/56/M/A2	Week 4	09MAR2012	13:30	2		
	Week 8	06APR2012	13:30	3		
	Week 12	04MAY2012	09:00	4		
306-0002/73/M/A2	Screening	09FEB2012	09:30	0		
	Week 4	06MAR2012	09:30	0		
	Week 8	03APR2012	08:30	2		
	Week 12	30APR2012	15:00	4		
306-0005/69/F/A2	Screening	22FEB2012	10:30	0		
	Week 4	16MAR2012	09:00	1		
	Week 8	13APR2012	09:00	3		
306-0006/43/M/A2	Screening	13MAR2012	10:00	0	0	
	Screening	13MAR2012	10:00	0		
	Week 4	10APR2012	13:00	0		
306-0007/56/M/A2	Screening	01MAR2012	10:30	0		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
306-0007/56/M/A2	Week 4	26MAR2012	13:30	0		
306-0008/40/M/A2	Screening	07MAR2012	10:30	1		
	Week 4	02APR2012	09:00	0		
	Week 8	30APR2012	09:00	0		
306-0011/47/M/A2	Screening	13MAR2012	13:30	0		
	Week 4	05APR2012	10:00	1		
	Week 8	03MAY2012	10:00	3		
	Week 12	30MAY2012	10:00	4		
306-0012/61/M/A2	Screening	29MAR2012	10:06	0		
	Week 4	25APR2012	10:30	0		
	Week 8	21MAY2012	09:00	2		
	Week 12	19JUN2012	09:00	4		
	Week 16	17JUL2012	09:40	4		
	Week 20	13AUG2012	09:35	4		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
306-0012/61/M/A2	Week 24	11SEP2012	09:15	4		
306-0014/47/M/A2	Screening	13APR2012	11:00	0		
	Week 4	11MAY2012	08:30	2		
306-0017/49/M/A2	Screening	09JUL2012	09:00	0		
	Week 4	02AUG2012	09:00	1		
306-0019/78/M/A2	Screening	20AUG2012	09:10	0		
	Week 4	13SEP2012	10:00	3		
	Week 8	08OCT2012	08:20	3		
	Week 12	05NOV2012	08:20	4		
306-0020/63/M/A2	Screening	27SEP2012	08:20	0		
	Week 4	25OCT2012	09:00	0		
	Week 8	22NOV2012	09:00	2		
	Week 12	20DEC2012	09:30	3		
306-0023/68/M/A2	Screening	20NOV2012	09:00	0		

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[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
306-0023/68/M/A2	Week 4	18DEC2012	11:00	0		
306-0026/58/M/A2	Screening	24JAN2013	10:00	0		
	Week 4	25FEB2013	13:50	1		
	Week 8	28MAR2013	09:00	5		
	Week 12	25APR2013	08:30	4		
	Week 16	23MAY2013	09:00	5		
	Week 20	20JUN2013	09:30	5		
	Week 24	18JUL2013	09:00	5		
	Week 28	15AUG2013	09:00	5		
	Week 32	12SEP2013	09:00	5		
	Week 36	08OCT2013	08:30	5		
306-0027/67/M/A2	Screening	06FEB2013	13:00	1		
	Week 4	13MAR2013	10:00	0		
	Week 8	10APR2013	09:30	1		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
306-0027/67/M/A2	Week 12	08MAY2013	09:30	2		
	Week 16	05JUN2013	09:30	4		
	Week 20	03JUL2013	09:30	4		
	Week 24	31JUL2013	10:00	4		
	Week 28	28AUG2013	10:00	4		
	Week 32	25SEP2013	09:00	4		
	Week 36	23OCT2013	09:00	4		
	Week 40	20NOV2013	09:30	4		
	Week 44	18DEC2013	09:30	4		
	Week 48	15JAN2014	09:30	4		
	Week 52	12FEB2014	09:00	4		
	Week 56	12MAR2014	09:30	4		
	Week 60	09APR2014	09:30	4		
	Week 64	07MAY2014	09:40	4		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
306-0027/67/M/A2	Week 68	06JUN2014	09:40	5		
	Week 72	02JUL2014	09:30	4		
306-0030/63/M/A2	Screening	12APR2013	11:30	1		
	Week 4	14MAY2013	09:00	1		
306-0031/40/M/A2	Screening	07MAY2013	11:00	0		
	Week 4	05JUN2013	09:30	2		
	Week 8	03JUL2013	09:30	4		
306-0034/65/M/A2	Screening	20JUN2013	10:30	0		
	Week 2	08JUL2013	13:30	0		
	Week 4	25JUL2013	13:30	2		
306-0035/48/M/A2	Screening	27JUN2013	10:00	0		
	Week 2	15JUL2013	08:30	1		
	Week 4	29JUL2013	08:40	2		
	Week 8	26AUG2013	09:00	5		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
306-0036/73/M/A2	Screening	02JUL2013	10:00	0		
	Week 2	16JUL2013	10:00	0		
	Week 4	30JUL2013	08:40	2		
	Week 8	27AUG2013	08:30	5		
306-0038/66/M/A2	Screening	09AUG2013	13:30	3		
	Week 2	28AUG2013	09:00	1		
	Week 4	11SEP2013	08:30	0		
	Week 8	09OCT2013	08:30	4		
	Week 12	06NOV2013	08:30	4		
306-0039/62/M/A2	Screening	09AUG2013	13:30	0		
	Week 2	27AUG2013	09:00	0		
	Week 4	10SEP2013	09:00	0		
	Week 8	08OCT2013	08:30	0		
	Week 12	05NOV2013	08:30	1		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
306-0040/44/F/A2	Screening	17SEP2013	10:00	3		
	Week 2	01OCT2013	08:30	1		
	Week 4	15OCT2013	10:00	0		
	Week 8	12NOV2013	09:30	0		
	Week 12	12DEC2013	10:00	4		
	Week 16	07JAN2014	09:30	4		
	Week 20	07FEB2014	12:00	4		
	Week 24	04MAR2014	10:30	4		
306-0041/62/M/A2	Screening	18OCT2013	10:30	0		
	Week 2	08NOV2013	09:30	0		
	Week 4	22NOV2013	09:30	0		
	Week 8	20DEC2013	08:30	0		
	Week 12	17JAN2014	09:00	0		
	Week 16	11FEB2014	09:30	0		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
306-0043/56/M/A2	Screening	08MAY2014	10:30	0		
	Week 2	29MAY2014	09:30	2		
	Week 4	09JUN2014	09:20	2		
	Week 8	10JUL2014	09:00	4		
	Week 12	04AUG2014	09:00	5		
307-0002/61/M/A2	Screening	31OCT2011	10:30	1		
	Week 4	25NOV2011	11:05	2		
	Week 8	22DEC2011	10:25	4		
	Week 12	19JAN2012	13:26	5		
307-0003/68/M/A2	Screening	04NOV2011	08:00	0	0	Collected on 04Nov2011, screening in sample list
	Screening	08NOV2011	08:00	0		Collected on 08Nov2011

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
	Week 4	29NOV2011	09:10	0		
	Week 8	27DEC2011	10:45	0		
	Week 12	27JAN2012	08:45	3		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
307-0003/68/M/A2	Week 16	21FEB2012	08:46	4		
	Week 20	20MAR2012	08:14	5		
	Week 24	16APR2012	09:50	5		
	Week 28	15MAY2012	10:25	5		
	Week 32	14JUN2012	10:25	5		
	Week 36	10JUL2012	10:25	5		
307-0004/60/M/A2	Screening	08NOV2011	09:09	0		
	Week 4	29NOV2011	09:20	0		
	Week 8	27DEC2011	08:35	0		
307-0008/58/M/A2	Screening	13DEC2011	08:30	0		
	Week 4	10JAN2012	08:54	1		
	Week 8	07FEB2012	08:40	4		
	Week 12	08MAR2012	08:40	4		
307-0011/75/M/A2	Screening	31JAN2012	11:55	0	0	

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
307-0011/75/M/A2	Screening	31JAN2012	11:55	0		
	Week 4	29FEB2012	08:54	2		
307-0014/61/M/A2	Screening	14FEB2012	09:13	0		
	Week 4	08MAR2012	08:30	2		
	Week 8	05APR2012	13:30	3		
	Week 12	03MAY2012	13:40	4		
	Week 16	31MAY2012	13:23	4		
	Week 20	28JUN2012	13:28	5		
	Week 24	26JUL2012	09:09	5		
307-0018/70/M/A2	Screening	11JUN2012	09:40	1		
	Week 4	05JUL2012	14:00	1		
	Week 8	03AUG2012	10:30	5		
	Week 12	30AUG2012	09:45	3		
	Week 16	27SEP2012	08:52	4		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
307-0018/70/M/A2	Week 20	25OCT2012	08:50	4		
	Week 24	22NOV2012	09:20	4		
	Week 28	20DEC2012	09:07	4		
	Week 32	17JAN2013	08:42	4		
	Week 36	14FEB2013	09:18	5		
	Week 40	14MAR2013	18:34	5		
	Week 44	11APR2013	08:55	5		
	Week 48	09MAY2013	09:25	5		
307-0020/68/F/A2	Screening	14AUG2012	10:20	0		
	Week 4	04SEP2012	11:15	0		
	Week 8	02OCT2012	11:10	3		
	Week 12	30OCT2012	10:08	3		
307-0022/59/M/A2	Screening	21NOV2012	09:25	0		
	Week 4	17DEC2012	10:10	1		

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[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
307-0022/59/M/A2	Week 8	14JAN2013	08:31	3		
	Week 12	14FEB2013	09:53	4		
307-0025/68/M/A2	Screening	13DEC2012	10:00	0		
	Week 4	10JAN2013	09:55	0		
	Week 8	05FEB2013	12:00	3		
	Week 12	07MAR2013	09:40	4		
	Week 16	03APR2013	09:50	4		
	Week 20	02MAY2013	09:15	4		
	Week 24	30MAY2013	10:10	4		
307-0026/65/M/A2	Screening	25DEC2012	10:00	0		
	Week 4	15JAN2013	09:00	1		
	Week 8	14FEB2013	09:10	4		
	Week 12	12MAR2013	09:50	4		
	Week 16	09APR2013	08:20	5		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
307-0026/65/M/A2	Week 20	07MAY2013	08:32	5		
	Week 24	04JUN2013	11:05	5		
307-0030/53/M/A2	Screening	01MAR2013	09:35	0		
	Week 4	25MAR2013	09:36	0		
	Week 8	22APR2013	12:07	2		
307-0031/60/M/A2	Screening	12MAR2013	11:55	0		
	Week 4	03APR2013	09:15	0		
	Week 8	02MAY2013	09:25	2		
	Week 12	30MAY2013	10:26	3		
	Week 16	27JUN2013	09:15	4		
	Week 20	25JUL2013	10:30	5		
	Week 24	22AUG2013	10:25	5		
	Week 28	17SEP2013	11:57	4		
	Week 32	17OCT2013	09:18	5		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
307-0031/60/M/A2	Week 36	14NOV2013	09:40	4		
307-0032/74/F/A2	Screening	09APR2013	13:40	0		
	Week 2	18APR2013	13:30	0		
	Week 4	02MAY2013	13:20	0		
307-0037/61/M/A2	Screening	30SEP2013	09:53	0		
	Week 2	11OCT2013	08:54	0		
	Week 4	24OCT2013	13:13	0		
307-0039/51/M/A2	Screening	31OCT2013	11:14	0		
	Week 2	13NOV2013	09:25	0		
	Week 4	27NOV2013	09:15	0		
	Week 8	23DEC2013	09:05	2		
	Week 12	21JAN2014	10:13	4		
307-0040/65/M/A2	Screening	22MAY2014	09:35	0		
	Week 2	03JUN2014	13:45	0		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
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[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
307-0040/65/M/A2	Week 4	17JUN2014	13:40	1		
307-0043/54/M/A2	Screening	20JUN2014	11:10	0		
	Week 2	02JUL2014	08:55	0		
	Week 4	15JUL2014	08:59	0		
	Week 8	12AUG2014	09:04	3		
	Week 12	09SEP2014	09:30	3		
	Week 16	08OCT2014	09:04	5		
307-0044/53/M/A2	Screening	26SEP2013	Unknown	0		
	Week 2	04JUL2014	09:36	0		
307-0045/48/M/A2	Screening	06JAN2012	Unknown	0		
	Week 2	14JUL2014	10:22	0		
	Week 4	28JUL2014	11:15	0		
	Week 8	25AUG2014	09:55	1		
	Week 12	22SEP2014	10:43	3		

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[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
307-0046/46/M/A2	Screening	08JUL2014	13:12	0		
	Week 2	24JUL2014	10:40	0		
308-0003/54/M/A2	Screening	13NOV2010	Unknown	0		
	Week 4	19FEB2013	09:05	0		
	Week 8	19MAR2013	09:10	3		
	Week 12	16APR2013	09:30	4		
	Week 16	14MAY2013	09:25	4		
	Week 20	11JUN2013	09:30	4		
	Week 24	09JUL2013	09:05	4		
	Week 28	06AUG2013	09:00	6		
	Week 32	03SEP2013	09:00	4		
	Week 36	01OCT2013	12:20	4		
308-0005/68/F/A2	Screening	24APR2013	11:00	0		
	Week 4	21MAY2013	09:05	0		

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[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
308-0005/68/F/A2	Week 8	18JUN2013	08:55	1		
	Week 12	16JUL2013	09:00	3		
309-0001/46/M/A2	Screening	29MAY2012	13:00	0		
	Week 4	02JUL2012	16:00	2		
	Week 8	30JUL2012	15:35	3		
	Week 12	27AUG2012	16:10	4		
309-0002/56/M/A2	Screening	04JUN2012	10:35	0		
309-0003/52/F/A2	Screening	11JUN2012	10:50	0		
	Week 4	11JUL2012	10:30	0		
	Week 8	08AUG2012	10:10	3		
	Week 12	05SEP2012	10:30	4		
309-0004/55/M/A2	Screening	14JUN2012	11:50	0		
309-0008/38/M/A2	Screening	08FEB2013	11:50	2		
	Week 4	14MAR2013	09:45	2		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
309-0008/38/M/A2	Week 8	11APR2013	09:30	3		
	Week 12	09MAY2013	09:30	3		
309-0010/47/M/A2	Screening	07MAR2013	Unknown	0		
	Week 4	15APR2013	12:35	2		
	Week 8	13MAY2013	13:10	0		
	Week 12	10JUN2013	11:10	4		
	Week 16	08JUL2013	09:20	4		
	Week 20	05AUG2013	10:20	4		
	Week 24	02SEP2013	09:15	3		
	Week 28	30SEP2013	10:25	4		
	Week 32	28OCT2013	10:05	4		
	Week 36	25NOV2013	09:30	3		
	Week 40	23DEC2013	09:58	0		
	Week 44	20JAN2014	11:20	0		

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[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
309-0010/47/M/A2	Week 48	17FEB2014	09:40	4		
	Week 52	17MAR2014	09:45	4		
	Week 56	14APR2014	09:30	4		
	Week 60	12MAY2014	09:50	4		
	Week 64	09JUN2014	10:50	4		
	Week 68	07JUL2014	09:44	4		
	Week 72	04AUG2014	09:50	4		
	Week 76	01SEP2014	10:15	4		
	Week 80	29SEP2014	10:12	5		
	Week 84	27OCT2014	09:55	4		
309-0011/59/M/A2	Screening	28MAR2013	15:10	0		
	Week 2	15APR2013	14:30	1		
	Week 4	29APR2013	14:50	0		
	Week 8	27MAY2013	14:15	1		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
309-0011/59/M/A2	Week 12	24JUN2013	15:40	3		
309-0012/82/M/A2	Screening	13MAY2013	12:00	0		
	Week 2	30MAY2013	09:20	0		
	Week 4	13JUN2013	10:05	1		
	Week 8	11JUL2013	09:50	3		
	Week 12	08AUG2013	10:05	4		
309-0015/62/M/A2	Screening	18JUN2013	13:35	0		
	Week 2	01JUL2013	09:40	0		
	Week 4	15JUL2013	09:30	1		
	Week 8	12AUG2013	10:50	4		
	Week 12	09SEP2013	10:49	4		
309-0016/72/F/A2	Screening	26AUG2013	11:20	0		
	Week 2	12SEP2013	09:50	0		
	Week 4	26SEP2013	10:00	0		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
309-0016/72/F/A2	Week 8	24OCT2013	09:05	0		
	Week 12	21NOV2013	09:28	3		
309-0017/73/F/A2	Screening	20NOV2013	12:50	0		
	Week 2	09DEC2013	11:20	0		
	Week 4	23DEC2013	11:15	0		
	Week 8	20JAN2014	11:00	0		
	Week 12	17FEB2014	11:30	0		
309-0018/82/M/A2	Screening	03JUN2014	12:30	0		
	Week 2	23JUN2014	09:40	0		
	Week 4	07JUL2014	12:10	1		
	Week 8	04AUG2014	10:44	2		
	Week 12	01SEP2014	09:40	4		
309-0021/54/F/A2	Screening	04JUL2014	12:15	0		
	Week 2	24JUL2014	10:35	0		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
309-0021/54/F/A2	Week 4	07AUG2014	11:50	0		
	Week 8	04SEP2014	09:55	3		
309-0025/49/M/A2	Screening	12AUG2014	13:35	0		
	Week 2	01SEP2014	11:00	0		
309-0026/41/M/A2	Screening	09SEP2014	14:00	1		
	Week 2	29SEP2014	10:25	0		
	Week 4	13OCT2014	09:45	0		
	Week 8	10NOV2014	11:10	1		
	Week 12	08DEC2014	11:15	3		
	Week 16	05JAN2015	12:20	3		
309-0028/62/M/A2	Screening	22OCT2014	12:00	0		
	Week 2	10NOV2014	09:45	1		
	Week 4	24NOV2014	11:10	2		
	Week 8	22DEC2014	08:40	1		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
309-0028/62/M/A2	Week 12	19JAN2015	09:00	2		
	Week 16	16FEB2015	09:10	2		
	Week 20	16MAR2015	08:50	3		
	Week 24	13APR2015	09:32	3		
309-0030/33/M/A2	Screening	04DEC2014	13:30	1		
	Week 2	22DEC2014	10:45	1		
	Week 4	05JAN2015	11:25	2		
	Week 8	02FEB2015	10:10	4		
309-0031/34/M/A2	Screening	18DEC2014	13:25	0		
	Week 2	31DEC2014	10:55	0		
	Week 4	15JAN2015	10:50	0		
	Week 8	12FEB2015	10:40	0		
309-0032/63/M/A2	Screening	26DEC2014	12:20	1		
	Week 2	15JAN2015	12:00	0		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
309-0032/63/M/A2	Week 4	29JAN2015	10:20	0		
	Week 8	26FEB2015	09:55	3		
	Week 12	26MAR2015	09:40	4		
309-0033/78/F/A2	Screening	16JAN2015	12:30	0		
	Week 2	05FEB2015	10:55	0		
	Week 4	17FEB2015	13:10	0		
	Week 8	17MAR2015	16:10	1		
	Week 12	16APR2015	11:20	1		
	Week 16	14MAY2015	10:55	2		
310-0001/61/M/A2	Screening	12JUN2012	14:25	0		
	Week 4	10JUL2012	13:10	1		
	Week 8	07AUG2012	13:35	1		
310-0002/55/M/A2	Screening	28JUN2012	10:25	1		
	Week 4	31JUL2012	13:10	1		

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[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
310-0003/61/M/A2	Screening	23JAN2013	10:00	1		
	Week 4	27FEB2013	08:50	0		
	Week 8	27MAR2013	09:30	1		
	Week 12	24APR2013	09:15	2		
310-0008/49/M/A2	Screening	11JUN2013	09:30	0		
	Week 2	26JUN2013	09:00	0		
310-0012/73/M/A2	Screening	01NOV2013	08:40	0		
	Week 2	14NOV2013	09:00	0		
	Week 4	26NOV2013	14:29	0		
	Week 8	26DEC2013	09:08	0		
	Week 12	23JAN2014	09:05	2		
	Week 16	18FEB2014	13:30	2		
	Week 20	18MAR2014	13:30	3		
310-0013/54/M/A2	Screening	22AUG2014	07:59	0		

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[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
310-0013/54/M/A2	Week 2	10SEP2014	08:13	0		
	Week 4	24SEP2014	08:10	0		
	Week 8	22OCT2014	07:49	2		
311-0002/60/M/A2	Screening	08AUG2013	09:10	2		
	Week 2	21AUG2013	09:30	1		
	Week 4	04SEP2013	11:40	1		
	Week 8	02OCT2013	10:10	4		
311-0007/55/M/A2	Screening	11NOV2013	14:00	2		
	Week 2	25NOV2013	09:30	0		
	Week 4	09DEC2013	10:30	0		
	Week 8	08JAN2014	14:15	1		
311-0008/71/M/A2	Screening	14MAY2014	15:00	0		
	Week 2	28MAY2014	14:07	0		
	Week 4	11JUN2014	11:27	0		

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[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
311-0008/71/M/A2	Week 8	08JUL2014	08:45	3		
401-0003/36/M/A7	Screening	24JUN2013	10:20	0		
	Week 2	02JUL2013	13:07	0		
	Week 4	17JUL2013	09:46	1		
	Week 8	13AUG2013	10:21	2		
401-0005/58/M/A7	Screening	10OCT2013	08:14	0		
	Week 2	22OCT2013	09:04	0		
	Week 4	05NOV2013	08:05	0		
	Week 8	06DEC2013	12:24	2		
402-0003/75/M/A7	Screening	30APR2013	14:00	0		
	Week 2	07MAY2013	12:00	0		
	Week 4	21MAY2013	12:30	1		
	Week 8	19JUN2013	11:52	0		
	Week 12	16JUL2013	12:00	0		

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Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
402-0003/75/M/A7	Week 16	13AUG2013	15:00	0		
	Week 20	10SEP2013	12:00	0		
	Week 24	08OCT2013	12:30	0		
402-0006/71/M/A7	Screening	25APR2013	10:20	0		
	Week 2	09MAY2013	10:54	0		
	Week 4	28MAY2013	11:30	0		
	Week 8	25JUN2013	11:06	2		
	Week 12	22JUL2013	11:26	4		
402-0008/43/M/A7	Screening	08MAY2013	14:30	1		
	Week 2	28MAY2013	12:00	1		
402-0009/70/M/A7	Screening	09MAY2013	13:20	1		
	Week 2	23MAY2013	08:30	0		
	Week 4	07JUN2013	08:42	0		
	Week 8	04JUL2013	08:00	0		

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[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
402-0011/64/M/A7	Screening	14MAY2013	10:40	1		
	Week 2	31MAY2013	10:00	0		
	Week 4	13JUN2013	09:20	1		
	Week 8	Unknown	Unknown	2		
402-0017/50/M/A7	Screening	11JUN2013	11:20	0		
	Week 2	24JUN2013	12:00	0		
	Week 4	08JUL2013	12:30	0		
402-0018/48/M/A7	Screening	12JUN2013	11:20	0		
	Week 2	01JUL2013	14:00	0		
	Week 4	15JUL2013	12:00	0		
	Week 8	12AUG2013	12:00	3		
	Week 12	09SEP2013	12:30	3		
402-0019/54/M/A7	Screening	01JUL2013	14:00	2		
	Week 2	08JUL2013	12:00	0		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
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Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
402-0019/54/M/A7	Week 4	22JUL2013	12:00	1		
	Week 8	19AUG2013	14:00	3		
	Week 12	16SEP2013	13:00	3		
402-0021/64/M/A7	Screening	13AUG2013	13:30	2		
	Week 2	20AUG2013	12:00	1		
	Week 4	03SEP2013	12:30	2		
	Week 8	01OCT2013	12:30	2		
	Week 12	29OCT2013	11:50	4		
	Week 16	26NOV2013	12:20	4		
	Week 20	24DEC2013	11:50	4		
	Week 24	21JAN2014	11:50	4		
	Week 28	18FEB2014	12:00	4		
	Week 32	18MAR2014	11:49	5		
	Week 36	15APR2014	12:00	5		

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[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
402-0021/64/M/A7	Week 40	13MAY2014	11:30	5		
	Week 44	10JUN2014	12:00	5		
	Week 48	08JUL2014	12:30	5		
	Week 52	05AUG2014	11:30	5		
	Week 56	02SEP2014	11:30	5		
402-0024/57/M/A7	Screening	23AUG2013	10:10	2		
	Week 2	03SEP2013	12:00	0		
	Week 4	17SEP2013	12:30	0		
	Week 8	15OCT2013	11:40	1		
	Week 12	12NOV2013	11:50	4		
402-0025/58/M/A7	Screening	25SEP2013	13:30	0		
	Week 2	04OCT2013	09:40	0		
	Week 4	17OCT2013	09:00	0		
	Week 8	14NOV2013	09:10	3		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
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Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
402-0025/58/M/A7	Week 12	12DEC2013	09:38	3		
402-0027/52/M/A7	Screening	25SEP2013	15:10	0		
	Week 2	10OCT2013	08:40	0		
	Week 4	23OCT2013	12:30	3		
	Week 8	Unknown	Unknown	1		
402-0028/60/M/A7	Screening	26SEP2013	15:10	0		
	Week 2	10OCT2013	11:00	0		
	Week 4	22OCT2013	12:30	0		
	Week 8	26NOV2013	11:30	0		
402-0031/65/M/A7	Screening	05NOV2013	14:30	0		
	Week 2	21NOV2013	08:00	1		
	Week 4	06DEC2013	08:00	3		
	Week 8	02JAN2014	08:00	3		
	Week 12	29JAN2014	08:00	3		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
402-0033/63/F/A7	Screening	29NOV2013	16:00	0		
	Week 2	16DEC2013	12:00	1		
	Week 4	30DEC2013	12:10	0		
	Week 8	27JAN2014	13:00	3		
402-0035/44/M/A7	Screening	24DEC2013	12:00	1		
	Week 2	31DEC2013	12:00	1		
	Week 4	14JAN2014	12:00	0		
403-0001/55/M/A7	Screening	20MAY2013	15:41	0		
	Week 2	29MAY2013	08:45	0		
	Week 4	12JUN2013	08:38	0		
403-0002/52/M/A7	Screening	11JUN2013	15:23	1		
	Week 2	19JUN2013	09:03	2		
	Week 4	03JUL2013	09:30	5		
	Week 8	31JUL2013	08:14	6		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
403-0005/50/F/A7	Screening	15JUL2013	15:13	0		
	Week 2	22JUL2013	10:17	0		
403-0006/66/M/A7	Screening	25JUL2013	09:45	0		
	Week 2	07AUG2013	09:36	0		
	Week 4	22AUG2013	08:53	1		
	Week 8	16SEP2013	10:36	3		
	Week 12	17OCT2013	08:35	3		
403-0007/64/M/	Screening	16AUG2013	11:01	1		
	Week 2	27AUG2013	12:32	0		
	Week 4	11SEP2013	13:56	0		
	Week 8	08OCT2013	11:10	1		
	Week 12	07NOV2013	11:58	2		
404-0001/71/M/A7	Screening	08JUL2013	08:30	0		
	Week 2	29JUL2013	09:30	0		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
404-0001/71/M/A7	Week 4	12AUG2013	09:30	0		
404-0002/56/F/A7	Screening	22AUG2013	14:30	0		
	Week 2	29AUG2013	13:40	0		
	Week 4	12SEP2013	09:20	0		
405-0002/46/M/A7	Screening	10APR2013	17:30	2		
	Week 2	24APR2013	14:30	1		
405-0004/38/M/A7	Screening	19APR2013	11:03	3		
	Week 2	29APR2013	10:07	1		
	Week 4	15MAY2013	12:23	1		
	Week 8	10JUN2013	09:00	1		
	Week 12	10JUL2013	Unknown	2		
405-0006/62/M/A7	Screening	23APR2013	10:30	1		
	Week 2	08MAY2013	Unknown	1		
	Week 4	22MAY2013	10:30	1		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
405-0007/53/M/A7	Screening	23APR2013	16:35	1		
	Week 2	14MAY2013	09:40	1		
	Week 4	28MAY2013	10:40	3		
	Week 8	25JUN2013	10:25	4		
	Week 12	23JUL2013	11:25	4		
	Week 16	20AUG2013	11:05	4		
	Week 20	Unknown	Unknown	4		
405-0009/50/M/A7	Screening	07MAY2013	11:30	0		
	Week 2	21MAY2013	10:06	0		
	Week 4	05JUN2013	12:45	0		
	Week 8	03JUL2013	13:10	3		
405-0010/39/M/A7	Screening	23MAY2013	13:10	1		
	Week 2	31MAY2013	10:35	1		
	Week 4	11JUN2013	10:10	0		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
405-0010/39/M/A7	Week 8	08JUL2013	10:10	0		
	Week 12	06AUG2013	10:17	2		
405-0011/63/M/A7	Screening	08MAY2013	19:12	0		
	Week 2	20MAY2013	09:40	0		
	Week 4	03JUN2013	10:00	1		
	Week 8	01JUL2013	09:32	2		
	Week 12	29JUL2013	08:52	3		
	Week 16	26AUG2013	08:55	4		
	Week 20	23SEP2013	08:45	4		
	Week 24	21OCT2013	08:45	4		
405-0013/45/M/A7	Screening	13MAY2013	12:05	0		
	Week 2	20MAY2013	09:53	0		
	Week 4	10JUN2013	09:50	1		
	Week 8	08JUL2013	09:15	3		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
405-0013/45/M/A7	Week 12	05AUG2013	09:07	3		
	Week 16	02SEP2013	10:00	1		
405-0014/35/M/A7	Screening	23MAY2013	16:50	2		
	Week 2	05JUN2013	12:40	0		
	Week 4	19JUN2013	13:00	2		
405-0016/41/M/A7	Screening	27MAY2013	09:30	1		
	Week 2	03JUN2013	09:20	1		
	Week 4	17JUN2013	09:15	1		
405-0018/70/F/A7	Screening	07JUN2013	15:30	1		
	Week 2	21JUN2013	09:40	1		
405-0020/69/M/A7	Screening	19JUN2013	15:00	0		
	Week 2	26JUN2013	10:40	0		
	Week 4	10JUL2013	11:05	0		
	Week 8	07AUG2013	10:40	0		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
405-0020/69/M/A7	Week 12	04SEP2013	09:25	1		
	Week 16	30SEP2013	09:45	1		
	Week 20	30OCT2013	10:50	1		
	Week 24	27NOV2013	11:20	0		
	Week 28	23DEC2013	09:15	0		
	Week 32	22JAN2014	10:25	0		
	Week 36	19FEB2014	09:55	0		
	Week 40	19MAR2014	11:00	0		
	Week 44	14APR2014	10:30	0		
	Week 48	14MAY2014	09:55	0		
405-0021/47/M/A7	Screening	17JUN2013	13:20	2		
	Week 2	26JUN2013	12:25	2		
	Week 4	10JUL2013	11:50	5		
	Week 8	07AUG2013	11:40	1		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
405-0021/47/M/A7	Week 12	04SEP2013	11:40	3		
	Week 16	02OCT2013	11:55	2		
	Week 20	30OCT2013	11:05	3		
	Week 24	27NOV2013	12:00	3		
	Week 28	23DEC2013	09:07	3		
	Week 32	22JAN2014	10:25	3		
	Week 36	17FEB2014	09:40	3		
	Week 40	17MAR2014	09:25	3		
	Week 44	18APR2014	10:30	3		
	Week 48	14MAY2014	11:50	3		
	Week 52	09JUN2014	09:35	3		
	Week 56	14JUL2014	09:00	3		
405-0022/65/M/A7	Screening	04JUL2013	12:30	1	2.5	
	Screening	04JUL2013	12:30	4		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
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[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
405-0022/65/M/A7	Week 2	10JUL2013	11:10	4		
	Week 4	22JUL2013	10:48	1		
	Week 8	21AUG2013	10:53	2		
	Week 12	16SEP2013	10:00	4		
	Week 16	14OCT2013	10:00	4		
	Week 20	13NOV2013	10:20	4		
	Week 24	11DEC2013	10:55	4		
405-0023/46/M/A7	Screening	17JUN2013	08:35	0		
	Week 2	24JUN2013	09:35	0		
	Week 4	08JUL2013	09:40	0		
	Week 8	05AUG2013	09:25	4		
	Week 12	02SEP2013	09:53	4		
405-0025/47/M/A7	Screening	24JUN2013	10:30	0		
	Week 2	03JUL2013	13:30	0		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
405-0025/47/M/A7	Week 4	17JUL2013	11:45	2		
405-0028/67/M/A7	Screening	17JUL2013	11:07	2		
	Week 2	29JUL2013	08:56	2		
	Week 4	14AUG2013	10:50	1		
	Week 8	11SEP2013	10:49	2		
	Week 12	07OCT2013	08:50	1		
405-0030/35/M/A7	Screening	17JUL2013	16:38	0		
	Week 2	05AUG2013	08:45	0		
	Week 4	19AUG2013	08:45	0		
	Week 8	16SEP2013	09:15	1		
405-0032/69/M/A7	Screening	19JUL2013	14:25	0		
	Week 2	29JUL2013	08:50	0		
	Week 4	12AUG2013	08:35	0		
	Week 8	09SEP2013	10:30	0		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
405-0032/69/M/A7	Week 12	08OCT2013	08:43	3		
	Week 16	04NOV2013	08:40	3		
	Week 20	02DEC2013	08:40	4		
	Week 24	30DEC2013	08:40	4		
	Week 28	27JAN2014	08:32	4		
	Week 32	24FEB2014	08:35	5		
	Week 36	24MAR2014	08:30	4		
	Week 40	21APR2014	08:50	4		
	Week 44	19MAY2014	08:40	4		
	Week 48	16JUN2014	08:40	4		
	Week 52	14JUL2014	08:45	4		
	Week 56	12AUG2014	08:40	4		
	Week 60	05SEP2014	08:50	4		
405-0033/43/M/A7	Screening	29JUL2013	11:20	5		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
405-0033/43/M/A7	Week 2	14AUG2013	11:25	0		
	Week 4	28AUG2013	11:40	0		
	Week 8	25SEP2013	12:00	1		
	Week 12	23OCT2013	11:45	2		
405-0034/61/M/A7	Screening	29JUL2013	09:58	2		
	Week 2	14AUG2013	09:42	0		
	Week 4	28AUG2013	10:00	3		
	Week 8	25SEP2013	09:55	3		
	Week 12	23OCT2013	10:00	3		
405-0035/66/M/A7	Screening	04MAY2010	Unknown	1		
	Week 2	26AUG2013	08:50	0		
	Week 4	11SEP2013	11:40	1		
	Week 8	11OCT2013	09:03	1		
405-0039/73/M/A7	Screening	13AUG2012	Unknown	0		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
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[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
405-0039/73/M/A7	Week 2	23SEP2013	08:35	1		
	Week 4	07OCT2013	08:43	0		
	Week 8	04NOV2013	08:38	3		
	Week 12	29NOV2013	08:30	3		
405-0040/65/M/A7	Screening	09SEP2013	12:12	0		
	Week 2	30SEP2013	09:40	0		
	Week 4	14OCT2013	09:55	1		
	Week 8	11NOV2013	09:05	3		
	Week 12	09DEC2013	08:40	4		
405-0042/53/M/A7	Screening	24SEP2013	Unknown	0		
	Week 2	14OCT2013	09:45	0		
	Week 4	30OCT2013	10:55	2		
	Week 8	27NOV2013	11:10	3		
405-0043/49/M/A7	Screening	16SEP2013	11:53	2		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
405-0043/49/M/A7	Week 2	02OCT2013	14:40	0		
	Week 4	17OCT2013	12:15	1		
	Week 8	14NOV2013	12:05	2		
405-0044/56/M/A7	Screening	25SEP2013	13:35	0		
	Week 2	02OCT2013	12:48	0		
	Week 4	18OCT2013	11:40	0		
	Week 8	13NOV2013	11:40	3		
501-0001/59/M/A1	Screening	13NOV2013	07:20	0		
	Week 2	20NOV2013	06:30	0		
	Week 4	04DEC2013	07:00	0		
	Week 8	02JAN2014	06:00	1		
501-0002/36/F/A1	Screening	29NOV2013	07:00	0		
	Week 2	09DEC2013	08:50	0		
	Week 4	23DEC2013	08:30	0		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
501-0002/36/F/A1	Week 8	20JAN2014	08:30	2		
	Week 12	18FEB2014	07:00	4		
501-0005/80/M/A1	Screening	17JAN2014	07:00	0		
	Week 2	29JAN2014	08:00	0		
	Week 4	13FEB2014	09:10	0		
	Week 8	14MAR2014	08:20	0		
	Week 12	11APR2014	08:30	0		
	Week 16	10MAY2014	09:50	0		
	Week 20	06JUN2014	07:58	0		
	Week 24	03JUL2014	08:30	0		
	Week 28	01AUG2014	08:15	0		
	Week 32	29AUG2014	07:10	0		
	Week 36	30SEP2014	08:30	0		
	Week 40	23OCT2014	08:30	0		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
501-0005/80/M/A1	Week 44	20NOV2014	08:38	0		
	Week 48	18DEC2014	08:45	0		
	Week 52	15JAN2015	08:37	0		
	Week 56	10FEB2015	08:46	0		
	Week 60	12MAR2015	08:45	0		
	Week 64	10APR2015	08:20	1		
	Week 68	07MAY2015	10:55	1		
	Week 72	04JUN2015	07:45	1		
501-0006/60/M/A1	Screening	12FEB2014	09:00	0		
	Week 2	20FEB2014	08:30	1		
	Week 4	06MAR2014	08:30	2		
	Week 8	03APR2014	07:30	2		
	Week 12	28APR2014	08:00	3		
501-0007/43/M/A1	Screening	03MAR2014	11:30	0		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
501-0007/43/M/A1	Week 2	10MAR2014	09:55	0		
	Week 4	24MAR2014	10:15	0		
	Week 8	21APR2014	07:20	0		
	Week 12	19MAY2014	09:50	0		
501-0008/76/F/A1	Screening	15APR2014	07:45	0		
	Week 2	23APR2014	08:30	0		
	Week 4	09MAY2014	09:15	0		
	Week 8	04JUN2014	07:30	0		
	Week 12	01JUL2014	09:05	0		
501-0009/62/M/A1	Screening	17JUL2014	06:00	0		
	Week 2	25JUL2014	08:00	0		
	Week 4	08AUG2014	08:00	0		
	Week 8	04JUN2014	07:30	0		
	Week 12	30SEP2014	06:00	0		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
501-0010/65/M/A1	Screening	04SEP2014	07:40	0		
	Week 2	16SEP2014	07:00	0		
	Week 4	28SEP2014	07:30	0		
	Week 8	29OCT2014	09:15	0		
	Week 12	27NOV2014	08:00	2		
502-0002/65/M/A1	Screening	09JAN2014	07:40	0		
503-0001/32/M/A1	Screening	09DEC2013	15:30	0		
	Week 2	16DEC2013	09:23	0		
	Week 4	31DEC2013	12:10	0		
503-0004/49/M/A1	Screening	11MAR2014	10:30	1		
	Week 2	18MAR2014	09:30	0		
503-0006/54/M/A1	Screening	06AUG2014	11:20	0		
	Week 2	13AUG2014	08:46	0		
	Week 4	27AUG2014	08:30	0		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
503-0006/54/M/A1	Week 8	25SEP2014	08:40	0		
	Week 12	22OCT2014	08:54	0		
	Week 16	19NOV2014	Unknown	4		
	Week 20	17DEC2014	Unknown	5		
	Week 24	15JAN2015	15:20	5		
	Week 28	09FEB2015	Unknown	5		
503-0007/57/M/A1	Screening	28OCT2014	16:00	0		
	Week 2	04NOV2014	09:55	0		
	Week 4	18NOV2014	Unknown	0		
	Week 8	16DEC2014	09:36	0		
	Week 12	13JAN2015	09:30	0		
503-0008/50/M/A1	Screening	30OCT2014	16:50	0		
	Week 2	05NOV2014	09:25	0		
	Week 4	19NOV2014	09:45	0		

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[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
503-0009/57/M/A1	Screening	19NOV2014	15:42	0		
	Week 2	26NOV2014	15:21	0		
504-0001/47/M/A1	Screening	17FEB2014	10:36	0		
	Week 2	25FEB2014	10:15	0		
	Week 4	11MAR2014	10:40	0		
	Week 8	08APR2014	09:35	3		
	Week 12	06MAY2014	09:25	3		
	Week 16	03JUN2014	09:15	4		
504-0007/32/M/A1	Screening	11OCT2014	14:26	0		
	Week 2	17OCT2014	08:50	0		
505-0001/70/M/A1	Screening	13AUG2014	08:00	0		
	Week 2	02SEP2014	07:50	0		
	Week 4	16SEP2014	08:15	0		
506-0002/54/M/A1	Screening	12MAY2014	06:30	0		

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[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
506-0002/54/M/A1	Week 2	19MAY2014	08:30	0		
	Week 4	04JUN2014	08:45	0		
	Week 8	02JUL2014	08:55	3		
	Week 12	30JUL2014	08:40	3		
	Week 16	27AUG2014	08:40	4		
	Week 20	24SEP2014	08:55	4		
	Week 24	22OCT2014	08:45	4		
	Week 28	19NOV2014	08:25	4		
	Week 32	17DEC2014	08:50	4		
	Week 36	14JAN2015	09:10	5		
	Week 40	11FEB2015	08:40	5		
	Week 44	11MAR2015	08:20	5		
	Week 48	08APR2015	09:00	5		
506-0003/66/M/A1	Screening	10SEP2014	08:30	0		

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[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
506-0003/66/M/A1	Week 2	17SEP2014	09:20	0		
	Week 4	30SEP2014	09:20	0		
506-0004/49/M/A1	Screening	27OCT2014	08:10	0		
	Week 2	05NOV2014	08:50	0		
	Week 4	19NOV2014	08:35	0		
	Week 8	17DEC2014	08:55	3		
508-0001/36/M/A1	Screening	31DEC2013	09:00	0		Week 2 in sample list
	Week 2	15JAN2014	09:50	0		Screening in sample list
	Week 4	27JAN2014	09:40	0		
508-0003/49/F/A1	Screening	13MAR2014	09:50	1		
	Week 2	25MAR2014	09:50	0		
	Week 4	08APR2014	11:08	3		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
509-0001/45/M/A1	Screening	28APR2014	11:00	0		
	Week 2	07MAY2014	10:20	0		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
509-0001/45/M/A1	Week 4	21MAY2014	10:05	1		
	Week 8	17JUN2014	10:10	3		
	Week 12	15JUL2014	10:45	4		
509-0002/51/M/A1	Screening	22MAY2014	10:10	0		
	Week 2	04JUN2014	10:20	0		
510-0002/50/M/A1	Screening	22MAY2014	09:10	0		
	Week 2	28MAY2014	08:30	0		
	Week 4	11JUN2014	08:30	1		
	Week 8	09JUL2014	08:20	3		
510-0004/72/M/A1	Screening	30JUL2014	08:30	0		
	Week 2	06AUG2014	08:30	0		
	Week 4	20AUG2014	07:30	0		
	Week 8	17SEP2014	14:10	1		
	Week 12	15OCT2014	07:30	3		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
511-0001/35/M/A1	Screening	18JAN2014	08:00	0		
	Week 2	28JAN2014	07:35	0		
	Week 4	11FEB2014	08:15	0		
511-0002/49/M/A1	Screening	07MAR2014	06:30	0		
	Week 2	18MAR2014	08:10	0		
	Week 4	01APR2014	09:20	0		
	Week 8	29APR2014	09:00	0		
	Week 12	27MAY2014	09:00	0		
	Week 16	24JUN2014	08:55	0		
	Week 20	22JUL2014	08:49	0		
	Week 24	19AUG2014	08:20	0		
512-0001/59/M/A1	Screening	25FEB2014	10:21	0		
	Week 2	11MAR2014	09:15	0		
	Week 4	25MAR2014	08:45	0		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
512-0001/59/M/A1	Week 8	22APR2014	08:32	0		
	Week 12	20MAY2014	09:18	0		
	Week 16	18JUN2014	09:26	0		
513-0001/28/M/A1	Screening	10APR2014	08:02	1		
	Week 2	18APR2014	09:14	1		
	Week 4	04MAY2014	09:44	1		
513-0004/46/M/A1	Screening	18JUN2014	10:18	0		
	Week 2	25JUN2014	09:02	0		
	Week 4	08JUL2014	08:58	1		
513-0005/61/M/A1	Screening	30OCT2014	11:11	0		
	Week 2	06NOV2014	09:26	0		
	Week 4	20NOV2014	09:10	2		
	Week 8	18DEC2014	09:25	4		
	Week 12	14JAN2015	09:40	4		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
515-0001/64/M/A1	Screening	14FEB2014	09:30	1		
	Week 2	26FEB2014	15:15	0		
	Week 4	12MAR2014	15:10	0		
	Week 8	09APR2014	15:10	1		
	Week 12	07MAY2014	15:10	3		
515-0003/69/M/A1	Screening	13MAY2014	10:20	0		
	Week 2	20MAY2014	09:36	0		
	Week 4	05JUN2014	10:00	0		
	Week 9	11JUL2014	Unknown	0		
	Week 12	29JUL2014	09:30	2		
515-0004/52/M/A1	Screening	27MAY2014	14:20	0		
	Week 2	05JUN2014	09:15	0		
	Week 4	16JUN2014	09:30	0		
	Week 8	14JUL2014	09:50	1		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
515-0004/52/M/A1	Week 12	11AUG2014	10:00	3		
	Week 16	09SEP2014	10:00	3		
515-0006/47/M/A1	Screening	05AUG2014	09:00	0		
	Week 2	11AUG2014	09:00	0		
	Week 4	26AUG2014	09:03	0		
	Week 8	22SEP2014	09:40	0		
	Week 12	20OCT2014	10:10	2		
515-0007/39/M/A1	Screening	17SEP2014	09:30	1		
	Week 2	22SEP2014	09:48	0		
	Week 4	08OCT2014	10:10	1		
515-0008/60/M/A1	Screening	27NOV2014	08:53	0		
	Week 2	03DEC2014	09:40	0		
	Week 4	17DEC2014	10:30	0		
	Week 8	14JAN2015	09:40	1		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
515-0008/60/M/A1	Week 12	09FEB2015	09:05	1		
516-0001/45/M/A1	Screening	07AUG2014	09:20	0		
	Week 2	15AUG2014	09:10	0		
	Week 4	29AUG2014	08:48	0		
	Week 8	26SEP2014	08:40	0		
	Week 12	24OCT2014	08:10	1		
	Week 16	21NOV2014	09:15	0		
	Week 20	19DEC2014	08:50	0		
	Week 24	16JAN2015	09:00	0		
517-0001/42/M/A1	Screening	18DEC2013	09:41	0		
	Week 2	30DEC2013	08:45	0		
	Week 4	13JAN2014	09:05	0		
517-0002/43/M/A1	Screening	24MAR2014	08:55	0		
	Week 2	02APR2014	09:12	0		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
517-0002/43/M/A1	Week 4	15APR2014	09:25	0		
	Week 8	13MAY2014	08:43	2		
	Week 12	10JUN2014	09:10	2		
	Week 16	08JUL2014	09:00	3		
	Week 20	05AUG2014	09:00	2		
	Week 24	02SEP2014	08:54	3		
517-0005/46/M/	Screening	22MAY2014	11:33	0		
517-0006/67/F/A1	Screening	12AUG2014	08:40	0		
	Week 2	27AUG2014	09:15	0		
	Week 4	10SEP2014	09:08	0		
	Week 8	08OCT2014	09:15	2		
	Week 12	05NOV2014	09:30	3		
	Week 16	03DEC2014	09:15	3		
	Week 20	30DEC2014	09:17	4		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
517-0006/67/F/A1	Week 24	28JAN2015	09:30	4		
	Week 28	25FEB2015	09:35	4		
	Week 32	25MAR2015	09:05	4		
	Week 36	22APR2015	09:10	4		
517-0007/66/M/A1	Screening	12AUG2014	09:20	0		
	Week 2	27AUG2014	08:55	0		
	Week 4	12SEP2014	09:10	0		
517-0008/59/M/A1	Screening	15AUG2014	08:40	0		
	Week 2	29AUG2014	11:30	0		
	Week 4	12SEP2014	09:20	0		
517-0009/23/M/A1	Screening	11SEP2014	10:05	0		
	Week 2	24SEP2014	09:31	0		
	Week 4	08OCT2014	10:15	0		
	Week 8	05NOV2014	09:35	2		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
517-0009/23/M/A1	Week 12	03DEC2014	11:10	3		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
101-0002/70/M/OTH	Screening	08JUN2011	Unknown	1		
	Week 4	19AUG2011	13:43	1		
	Week 8	20SEP2011	08:08	0		
	Week 12	18OCT2011	07:47	0		
101-0004/78/F/A2	Screening	02AUG2011	08:40	1		
	Week 4	26AUG2011	10:55	1		
	Week 8	23SEP2011	11:52	2		
	Week 12	21OCT2011	12:51	2		
	Week 16	18NOV2011	14:51	2		
	Week 20	15DEC2011	16:05	2		
	Week 28	10FEB2012	11:45	2		
	Week 32	09MAR2012	10:23	2		
	Week 36	10APR2012	15:25	2		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
101-0004/78/F/A2	Week 40	11MAY2012	11:52	2		Uns Continuation
	Week 44	08JUN2012	12:31	1		Uns Continuation
	Week 48	06JUL2012	11:14	1		Uns Continuation
	Week 52	03AUG2012	11:01	1		Uns Continuation
	Week 56	31AUG2012	09:55	1		
	Week 60	28SEP2012	14:30	1		Uns Continuation
101-0010/43/M/BL	Screening	13SEP2011	07:43	0		
101-0014/61/M/W2	Screening	03MAY2012	Unknown	0		
	Week 4	27JAN2012	10:07	1		
	Week 8	24FEB2012	11:16	0		
	Week 12	23MAR2012	07:52	0		
101-0015/65/M/A4	Screening	06JAN2012	16:14	0		
	Week 4	31JAN2012	13:01	0		
	Week 8	28FEB2012	14:56	1		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
101-0015/65/M/A4	Week 12	27MAR2012	15:20	1		
101-0017/60/M/W2	Screening	06APR2011	Unknown	0		
	Week 4	13MAR2012	10:09	2		
	Week 8	10APR2012	12:29	2		
	Week 12	08MAY2012	12:50	1		
101-0020/86/M/W2	Screening	13MAR2012	Unknown	1	0.5	Collected on 13Mar2012
	Screening	13MAR2012	Unknown	0		Collected on 13Mar2012
	Week 4	03APR2012	08:15	1		
	Week 8	01MAY2012	07:47	1		
	Week 12	05JUN2012	08:58	1		
	Week 16	03JUL2012	07:15	1		
	Week 20	31JUL2012	07:27	1		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
	Week 24	28AUG2012	07:35	1		
101-0027/72/M/W2	Screening	22MAY2012	11:02	0		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
101-0027/72/M/W2	Week 4	15JUN2012	09:08	0		
101-0031/69/F/W2	Screening	06DEC2010	Unknown	0		
	Week 4	07AUG2012	10:23	1		
	Week 8	04SEP2012	12:51	0		
	Week 12	Unknown	Unknown	1		
101-0034/44/M/OTH	Screening	22NOV2013	Unknown	0		
	Week 4	02OCT2012	17:34	0		
101-0035/37/M/A6	Screening	26OCT2012	Unknown	0		
101-0043/69/M/W1	Screening	22OCT2013	15:53	0		
	Week 2	29OCT2013	11:18	0		
	Week 4	19NOV2013	08:54	0		
	Week 8	10DEC2013	08:56	0		
	Week 12	14JAN2014	08:01	0		
101-0051/70/F/W2	Screening	23JAN2014	Unknown	0		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
101-0051/70/F/W2	Week 2	03FEB2014	13:45	0		
	Week 4	17FEB2014	13:31	0		
102-0006/66/M/BL	Screening	05DEC2013	09:45	0		
	Week 2	17DEC2013	10:06	0		
	Week 4	02JAN2014	09:53	0		
	Week 8	29JAN2014	09:22	0		
	Week 12	26FEB2014	09:25	0		
102-0007/61/M/W2	Screening	23DEC2013	09:25	2		
	Week 2	09JAN2014	11:45	1		
	Week 4	23JAN2014	10:24	0		
	Unscheduled	27FEB2014	Unknown	1		Week 9
	Week 12	20MAR2014	10:12	0		
103-0002/74/M/W2	Screening	29OCT2009	Unknown	0		
	Week 4	02JAN2013	10:48	2		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
103-0002/74/M/W2	Week 8	30JAN2013	10:00	2		
	Week 12	27FEB2013	10:15	1		
	Week 16	27MAR2013	10:00	0		
	Week 20	24APR2013	10:00	0		
103-0006/57/M/W2	Screening	06NOV2014	10:30	0		
	Week 2	25NOV2014	10:30	0		
	Week 4	11DEC2014	08:30	0		
	Week 8	06JAN2015	09:25	0		
104-0002/80/M/W2	Screening	30APR2012	09:10	0	0	
	Unscheduled	30APR2012	09:10	0		Screening (collection date not found on visit report, date is between screening and week 1)

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
	Week 4	29MAY2012	10:25	0		
	Week 8	25JUN2012	09:05	0		
	Week 12	23JUL2012	08:55	0		
	Week 16	20AUG2012	08:55	0		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
104-0002/80/M/W2	Week 20	17SEP2012	09:55	0		
	Week 24	15OCT2012	11:02	0		
	Week 28	12NOV2012	09:50	0		
	Week 32	10DEC2012	10:10	0		
	Week 36	07JAN2013	09:33	0		
104-0007/89/M/A1	Screening	30JUN2015	Unknown	0		
	Week 2	12AUG2013	09:52	0		
	Week 4	26AUG2013	08:42	0		
	Week 8	23SEP2013	09:50	0		
	Week 12	21OCT2013	09:40	0		
	Week 16	18NOV2013	09:00	0		
	Week 20	16DEC2013	09:45	0		
	Week 22	02JAN2014	09:05	0		
	Week 24	13JAN2014	09:05	0		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
104-0007/89/M/A1	Week 28	10FEB2014	09:35	0		
	Week 32	10MAR2014	09:05	0		
	Week 34	27MAR2014	09:21	0		
	Week 36	09APR2014	09:25	0		
	Week 40	05MAY2014	09:24	0		Uns Continuation
	Week 42	19MAY2014	09:33	0		Uns Continuation
	Week 44	02JUN2014	09:30	0		Uns Continuation
	Week 48	02JUL2014	09:50	0		Uns Continuation
	Week 50	14JUL2014	09:39	0		Uns Continuation
	Week 52	28JUL2014	09:44	1		Uns Continuation
	Week 54	13AUG2014	10:00	1		Uns Continuation
	Week 56	25AUG2014	09:35	1		Uns Continuation
	Week 58	08SEP2014	09:30	1		Uns Continuation
	Week 60	22SEP2014	09:15	1		Uns Continuation

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
104-0007/89/M/A1	Week 62	08OCT2014	09:54	2		Uns Continuation
	Week 64	20OCT2014	10:05	2		Uns Continuation
	Week 66	03NOV2014	09:35	2		Uns Continuation
	Week 68	17NOV2014	09:40	2		Uns Continuation
	Week 70	01DEC2014	09:20	2		Uns Continuation
	Week 72	15DEC2014	09:49	2		Uns Continuation
	Week 74	29DEC2014	09:33	2	2	Uns Continuation
	Week 74	29DEC2014	09:33	2		Uns Continuation
	Week 76	12JAN2015	10:43	1		Uns Continuation
	Week 78	26JAN2015	09:48	2		Uns Continuation
	Week 80	09FEB2015	09:54	2		Uns Continuation
	Week 82	26FEB2015	08:43	2		Uns Continuation
	Week 86	25MAR2015	10:18	2		Uns Continuation
	Week 88	06APR2015	09:52	2		Uns Continuation

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
104-0007/89/M/A1	Week 90	20APR2015	09:45	2		Uns Continuation
	Week 92	04MAY2015	09:40	2		Uns Continuation
	Week 94	20MAY2015	09:23	2		Uns Continuation
105-0003/57/M/W2	Screening	31OCT2013	Unknown	1		
	Week 2	12NOV2013	10:45	1		
	Week 4	26NOV2013	11:05	1		
	Week 8	27DEC2013	11:35	1		
	Week 12	24JAN2014	10:15	1		
	Week 16	21FEB2014	10:30	0		
	Week 20	18MAR2014	10:20	0		
	Week 24	15APR2014	10:20	0		
	Week 28	16MAY2014	11:34	0		
	Week 32	12JUN2014	10:40	0		
	Week 36	08JUL2014	12:00	0		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
105-0003/57/M/W2	Week 40	08AUG2014	11:00	0		Uns Continuation
	Week 44	05SEP2014	09:50	0		Uns Continuation
	Week 48	30SEP2014	13:10	0		Uns Continuation
105-0006/60/F/BL	Screening	17DEC2014	Unknown	0		
	Week 2	06JAN2015	10:15	0		
	Week 4	20JAN2015	10:45	0		
	Week 8	19FEB2015	11:35	1		
	Week 12	17MAR2015	08:30	1		
	Week 16	15APR2015	10:30	0		
108-0003/85/M/W2	Screening	14NOV2012	15:00	0		
	Week 4	10DEC2012	09:35	0		
109-0002/63/M/W2	Screening	20MAR2013	13:10	0		
	Week 2	29MAR2013	12:52	1		
	Week 4	12APR2013	08:30	0		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
109-0002/63/M/W2	Week 8	10MAY2013	09:00	1		
	Week 12	07JUN2013	09:10	1		
	Week 16	05JUN2013	10:28	1		
	Week 20	02AUG2013	08:40	1		
	Week 24	30AUG2013	08:35	1		
109-0005/64/F/W2	Screening	24JUL2013	12:25	0		
	Week 2	07AUG2013	15:00	0		
	Week 4	21AUG2013	13:15	0		
109-0012/21/F/W2	Screening	07MAY2012	Unknown	1		
	Week 2	01OCT2014	13:54	1		
	Week 4	14OCT2014	11:45	0		
	Week 8	11NOV2014	12:25	0		
109-0014/50/F/W2	Screening	12JAN2015	16:00	0		
	Week 2	04FEB2015	14:24	0		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
109-0014/50/F/W2	Week 4	18FEB2015	15:25	0		
111-0003/37/M/A1	Screening	02JAN2013	10:40	0		
	Week 4	31JAN2013	13:20	0		
	Week 8	28FEB2013	10:35	0		
112-0010/56/F/W2	Screening	27NOV2013	11:15	0	0	
	Screening	27NOV2013	11:15	0		
	Week 2	13DEC2013	07:45	0		
	Week 4	27DEC2013	07:28	0		
	Week 8	24JAN2014	10:55	0		
	Week 12	21FEB2014	11:10	0		
113-0007/74/M/W2	Screening	17DEC2013	Unknown	0		
	Week 2	05FEB2014	09:20	1		
	Week 4	20FEB2014	09:20	1		
	Week 8	19MAR2014	08:58	0		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
113-0007/74/M/W2	Week 12	18APR2014	08:30	1		
	Week 16	16MAY2014	08:17	0		
	Week 20	10JUN2014	12:35	0		
113-0015/58/F/BL	Screening	20NOV2014	14:54	1		
	Week 2	05DEC2014	08:20	1		
114-0001/25/F/OTH	Screening	24JUL2012	15:20	0		
	Week 4	21AUG2012	11:50	1		
114-0004/54/F/A1	Screening	30JAN2013	11:35	0		
	Week 4	27FEB2013	11:10	1		
	Week 8	27MAR2013	09:35	0		
115-0005/60/M/W2	Screening	08MAR2013	11:31	1		
115-0006/62/M/W2	Screening	04APR2013	13:02	1		
	Week 2	18APR2013	14:10	1		
	Week 4	02MAY2013	10:25	2		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
115-0006/62/M/W2	Week 8	30MAY2013	13:10	1		
	Week 12	27JUN2013	07:38	1		
115-0007/57/M/W2	Screening	10APR2013	13:20	2		
	Week 2	25APR2013	09:45	2		
	Week 4	09MAY2013	08:20	2		
115-0010/54/M/A4	Screening	27MAR2014	Unknown	1		
	Week 2	21APR2014	10:50	0		
	Week 4	05MAY2014	08:47	0		
	Week 8	02JUN2014	10:38	0		
121-0003/65/M/BL	Screening	03JUN2013	Unknown	0		
	Week 2	09JUL2014	07:00	0		
	Week 4	23JUL2014	08:00	0		
	Week 8	20AUG2014	08:35	0		
201-0002/76/M/W2	Screening	11APR2008	Unknown	0		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
201-0002/76/M/W2	Week 4	05APR2012	08:00	2		
	Week 12	31MAY2012	08:00	0		
	Week 16	28JUN2012	08:30	0		
	Week 20	26JUL2012	08:30	1		
	Week 24	23AUG2012	08:15	2		
	Week 28	20SEP2012	08:30	1		
	Week 32	18OCT2012	08:30	1		
	Week 36	15NOV2012	08:00	1		
	Week 40	12DEC2012	08:00	0		Uns Continuation
	Week 44	10JAN2013	08:00	0		Uns Continuation
	Week 48	07FEB2013	08:00	0		Uns Continuation
201-0006/71/M/W2	Screening	05JUL2012	08:10	0		
	Week 4	02AUG2012	08:30	0		
	Week 8	30AUG2012	08:30	0		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
201-0006/71/M/W2	Week 12	27SEP2012	08:30	0		
	Week 16	25OCT2012	08:30	0		
	Week 20	22NOV2012	08:05	1		
	Week 24	18DEC2012	08:10	0		
201-0007/71/M/W2	Screening	16JUL2012	08:00	1		
	Week 8	12SEP2012	08:30	1		
	Week 12	11OCT2012	08:00	1		
	Week 16	08NOV2012	08:00	1		
	Week 20	06DEC2012	07:50	1		
	Week 24	03JAN2013	08:00	0		
	Week 32	28FEB2013	08:00	2		
	Week 36	28MAR2013	07:50	2		
201-0009/64/M/W2	Screening	13JUN2013	08:30	0		
	Week 2	27JUN2013	08:20	0		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
201-0009/64/M/W2	Week 4	11JUL2013	08:30	0		
	Week 8	08AUG2013	07:50	0		
	Week 12	05SEP2013	09:05	1		
	Week 16	03OCT2013	08:00	0		
	Week 20	31OCT2013	08:10	0		
	Week 24	28NOV2013	07:45	0		
	Week 36	20FEB2014	08:30	0		
	Week 38	06MAR2014	08:30	0		Uns Continuation
	Week 40	20MAR2014	08:15	0		Uns Continuation
	Week 42	03APR2014	08:15	0		Uns Continuation
	Week 44	17APR2014	08:40	0		Uns Continuation
	Week 46	30APR2014	08:15	0		Uns Continuation
	Week 48	15MAY2014	08:00	0		Uns Continuation
	Week 50	29MAY2014	08:10	0		Uns Continuation

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
201-0009/64/M/W2	Week 52	12JUN2014	08:15	0		Uns Continuation
	Week 54	26JUN2014	08:00	0		Uns Continuation
	Week 56	11JUL2014	08:00	0		Uns Continuation
	Week 58	24JUL2014	08:00	0		Uns Continuation
	Week 60	07AUG2014	08:00	0		Uns Continuation
	Week 64	04SEP2014	08:00	1		Uns Continuation
	Week 68	01OCT2014	08:00	0		Uns Continuation
	Week 72	30OCT2014	08:00	0		Uns Continuation
	Week 76	27NOV2014	08:00	0		Uns Continuation
	Week 84	21JAN2015	08:30	0		Uns Continuation
	Week 88	19FEB2015	08:10	0		Uns Continuation
	Week 92	19MAR2015	07:50	0		Uns Continuation
	Week 96	16APR2015	07:50	0		Uns Continuation
	Week 100	14MAY2015	07:50	0		Uns Continuation

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
201-0010/81/F/W2	Screening	20JUN2013	08:00	0		
	Week 2	04JUL2013	08:00	0		
	Week 4	17JUL2013	08:40	0		
	Week 12	12SEP2013	07:50	2		
201-0014/73/M/W2	Screening	11JUL2013	08:50	2		
	Week 2	24JUL2013	08:25	1		
	Week 4	08AUG2013	08:25	2		
	Week 8	05SEP2013	08:50	2		
	Week 12	03OCT2013	08:15	0		
201-0015/49/M/W2	Screening	01AUG2013	09:05	0		
	Week 4	29AUG2013	09:05	3		
	Week 8	26SEP2013	08:35	2		
	Week 12	24OCT2013	08:00	1		
	Week 16	21NOV2013	08:15	0		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
201-0015/49/M/W2	Week 20	19DEC2013	08:20	0		
	Week 24	16JAN2014	08:30	0		
	Week 28	13FEB2014	08:30	0		
	Week 32	13MAR2014	08:00	0		
201-0022/80/F/W2	Screening	09MAY2014	09:30	0		
	Week 2	21MAY2014	08:00	0		
	Week 4	05JUN2014	08:00	0		
	Week 8	03JUL2014	08:30	0		
	Week 12	31JUL2014	08:20	0		
	Week 16	28AUG2014	08:30	0		
	Week 20	25SEP2014	08:00	0		
	Week 24	23OCT2014	08:00	0		
203-0004/81/M/W2	Screening	22MAR2012	08:00	1		
	Week 4	19APR2012	08:00	1		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
203-0004/81/M/W2	Week 8	22MAY2012	08:00	1		
	Week 12	28JUN2012	08:00	1		
	Week 16	26JUL2012	08:00	0		
	Week 24	20SEP2012	08:30	0		
	Week 28	18OCT2012	08:00	1		
	Week 32	15NOV2012	08:00	0		
	Week 36	13DEC2012	08:00	1		
203-0006/76/M/W2	Screening	30MAR2012	08:00	0		
	Week 4	04MAY2012	08:00	0		
	Week 8	30MAY2012	08:30	0		
203-0007/59/M/W2	Screening	28MAY2012	08:30	0		
	Week 4	06JUL2012	08:00	0		
	Week 8	01AUG2012	08:00	0		
203-0009/73/M/W2	Screening	30AUG2012	08:00	1		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
203-0009/73/M/W2	Week 4	08OCT2012	08:00	1		
	Week 8	15NOV2012	08:00	1		
	Week 12	20DEC2012	08:00	1		
	Week 16	25JAN2013	08:00	1		
	Week 20	27FEB2013	08:00	0		
	Week 24	04APR2013	08:00	0		
	Week 28	13MAY2013	08:00	0		
	Week 32	27JUN2013	08:00	0		
	Week 36	01AUG2013	08:00	0		
	Week 38	22AUG2013	08:00	0		Uns Continuation
	Week 40	12SEP2013	08:00	0		Uns Continuation
	Week 42	27SEP2013	09:00	0		Uns Continuation
	Week 44	14OCT2013	08:00	0		Uns Continuation
	Week 46	31OCT2013	09:00	0		Uns Continuation

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
203-0010/74/M/W2	Screening	17SEP2012	08:00	0		
	Week 4	18OCT2012	08:00	0		
	Week 8	15NOV2012	08:00	0		
	Week 12	13DEC2012	08:00	0		
	Week 16	17JAN2013	08:00	0		
	Week 20	15FEB2013	08:00	0		
	Week 24	21MAR2013	08:00	0		
	Week 28	17APR2013	08:00	0		
	Week 32	17MAY2013	08:00	0		
	Week 36	20JUN2013	08:00	0		
	Week 40	25JUL2013	08:00	0		Uns Continuation
	Week 46	12SEP2013	08:00	0		Uns Continuation
	Week 48	26SEP2013	09:00	0	0	Uns Continuation
	Week 48	26SEP2013	09:00	0		Uns Continuation

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
203-0010/74/M/W2	Week 50	17OCT2013	09:00	0	0	Uns Continuation
	Week 50	17OCT2013	09:00	0		Uns Continuation
	Week 52	30OCT2013	09:00	0	0	Uns Continuation
	Week 52	30OCT2013	09:00	0		Uns Continuation
	Week 54	15NOV2013	08:00	0		Uns Continuation
	Week 56	02DEC2013	09:00	0		Uns Continuation
	Week 58	20DEC2013	08:00	0		Uns Continuation
	Week 60	09JAN2014	08:00	0		Uns Continuation
	Week 62	24JAN2014	09:00	0		Uns Continuation
	Week 64	10FEB2014	09:00	0		Uns Continuation
	Week 66	24FEB2014	08:00	0		Uns Continuation
	Week 70	28MAR2014	09:00	0		Uns Continuation
	Week 72	17APR2014	08:30	0		Uns Continuation
	Week 74	02MAY2014	09:00	0		Uns Continuation

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
203-0010/74/M/W2	Week 76	19MAY2014	08:00	0		Uns Continuation
	Week 78	05JUN2014	09:00	0		Uns Continuation
	Week 80	19JUN2014	09:00	0		Uns Continuation
	Week 82	04JUL2014	08:30	0		Uns Continuation
	Week 84	17JUL2014	09:00	0		Uns Continuation
	Week 86	31JUL2014	09:00	0		Uns Continuation
	Week 90	04SEP2014	09:00	0		Uns Continuation
	Week 92	22SEP2014	09:00	0		Uns Continuation
	Week 96	24OCT2014	09:00	0		Uns Continuation
203-0014/73/M/W2	Screening	10JAN2014	08:00	0		
	Week 2	30JAN2014	08:00	0		
	Week 4	13FEB2014	09:00	0		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
	End of Treatment	06MAR2014	09:00	0		Week 8 (7 days after week 7 visit)
203-0016/57/M/W2	Screening	28JAN2014	09:00	0		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
203-0016/57/M/W2	Week 2	11FEB2014	09:00	0		
	Week 4	27FEB2014	09:00	0		
	Week 8	31MAR2014	08:30	0		
	Week 12	02MAY2014	09:00	0		
	Week 16	03JUN2014	09:00	0		
	Week 20	03JUL2014	09:00	0		
	Week 24	31JUL2014	09:00	0		
203-0019/68/M/W2	Unscheduled	Unknown	Unknown	0		Week 1
	Screening	12MAY2014	09:00	0		
	Week 2	30MAY2014	09:00	0		
	Week 4	13JUN2014	09:00	0		
204-0003/64/M/W2	Screening	27JUN2013	13:50	0		
	Week 4	22JUL2013	09:30	1		
	Week 8	26AUG2013	09:55	0		

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[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
204-0003/64/M/W2	Week 12	26SEP2013	08:20	0		
204-0004/76/F/W2	Screening	04SEP2013	10:20	0		
	Week 2	24SEP2013	09:15	2		
	Week 4	11OCT2013	09:58	1		
	Week 8	14NOV2013	08:30	0		
	Week 12	12DEC2013	09:25	0		
205-0002/71/M/W2	Screening	14FEB2012	09:00	1		Retest in sample list from CLS
	Week 4	16MAR2012	09:00	0		
	Unscheduled	30MAR2012	09:00	0		Week 6
	Week 8	13APR2012	09:00	0		
	Week 12	08MAY2012	09:00	0		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
205-0003/79/M/W2	Unscheduled	Unknown	Unknown	0		Week 1 (collection date not found on visit report, date is between week 1 and week2)
	Screening	16MAR2012	09:00	0		
	Week 4	17APR2012	09:00	0		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
205-0003/79/M/W2	Week 8	15MAY2012	09:00	0		
	Week 12	12JUN2012	09:00	0		
	Week 16	10JUL2012	09:00	0		
	Week 20	14AUG2012	09:00	0		
	Week 24	11SEP2012	09:00	0		
	Week 28	09OCT2012	09:00	0		Back up sample, no primary sample was received
	Week 32	06NOV2012	09:00	0		
	Week 36	04DEC2012	09:00	0		
205-0005/71/M/W2	Screening	12MAR2012	09:00	1		
	Week 4	12APR2012	09:00	1		
	Week 8	10MAY2012	09:00	1		
	Week 12	05JUN2012	09:00	2		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
205-0014/70/M/W2	Screening	07JUN2013	07:30	0		
	Week 2	28JUN2013	09:30	1		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
205-0014/70/M/W2	Week 4	26JUL2013	10:30	1		
	Week 5	02AUG2013	10:30	1		
205-0023/72/M/W2	Screening	29OCT2013	13:30	0	0	
	Screening	29OCT2013	13:30	0		
	Week 2	15NOV2013	09:15	0		
	Week 4	29NOV2013	08:30	0		
	Week 8	23DEC2013	09:30	0		
	Week 12	21JAN2014	08:45	0		
205-0026/61/F/W2	Screening	02MAR2012	Unknown	0	0.5	
	Screening	02MAR2012	Unknown	1		Screening (collection date not found on visit report, date is between screening and week 1)

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
	Week 2	17FEB2015	10:00	0		
	Week 4	03MAR2015	10:30	0		
	Week 8	31MAR2015	10:00	0		
	Week 12	28APR2015	11:00	0		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
205-0028/73/F/W2	Screening	19JAN2015	12:00	0		
	Week 2	03FEB2015	10:30	1		
207-0002/71/M/W2	Screening	08MAR2012	12:30	0		
	Week 4	12APR2012	09:40	0		
	Week 8	10MAY2012	09:40	0		
	Week 12	07JUN2012	09:30	0		
207-0007/71/M/W2	Screening	18JUN2012	10:30	0		
	Week 4	23JUL2012	10:00	1		
	Week 8	20AUG2012	10:55	0		
207-0012/66/M/W2	Screening	12MAR2013	08:30	0		
	Week 4	11APR2013	09:50	0		
	Week 8	09MAY2013	08:30	0		
	Week 12	06JUN2013	08:45	0		
	Week 16	04JUL2013	08:45	0		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
207-0012/66/M/W2	Week 20	01AUG2013	09:15	0		
	Week 24	30AUG2013	08:30	0		
	Week 28	04OCT2013	08:50	0		
	Week 32	31OCT2013	08:50	0		
	Week 36	29NOV2013	09:30	0		
	Week 42	10JAN2014	11:30	1		Uns Continuation
	Week 44	24JAN2014	09:45	0		Uns Continuation
	Week 46	06FEB2014	10:30	0		Uns Continuation
207-0016/82/F/W2	Screening	30SEP2013	10:00	0		
	Week 4	31OCT2013	10:40	0		
	Week 8	28NOV2013	09:40	0		
	Week 12	27DEC2013	09:30	0		
207-0017/81/F/W2	Screening	22NOV2013	10:00	1		
	Week 2	05DEC2013	10:45	0		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
207-0017/81/F/W2	Week 4	19DEC2013	10:00	1		
	Week 8	17JAN2014	10:50	0		
	Week 12	13FEB2014	12:30	0		
207-0019/55/M/W2	Screening	27MAY2014	13:15	0		
	Week 2	10JUN2014	10:20	1		
209-0006/68/M/W2	Screening	18APR2013	09:45	0		
	Week 2	07MAY2013	09:30	0		
	Week 4	21MAY2013	09:30	0		
	Week 8	18JUN2013	10:45	0		
	Week 12	24JUL2013	08:00	0		
	Week 16	20AUG2013	10:00	0		
	Week 20	20SEP2013	09:30	1		
	Week 24	15OCT2013	10:30	1		
	Week 28	14NOV2013	11:00	2		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
209-0006/68/M/W2	Week 32	10DEC2013	09:30	2		
	Week 36	07JAN2014	09:15	2		
209-0011/69/M/W2	Screening	21NOV2013	10:50	0		
	Week 2	10DEC2013	11:30	0		
	Week 4	23DEC2013	09:00	1		
	Week 8	22JAN2014	09:50	0		
	Week 12	19FEB2014	09:30	0		
209-0014/79/M/W2	Screening	04MAR2014	10:05	1		
	Week 2	26MAR2014	10:15	1		
	Week 4	08APR2014	11:00	1		
	Week 8	07MAY2014	10:20	0		
	Week 12	04JUN2014	10:30	0		
	Week 16	02JUL2014	09:00	0		
	Week 20	29JUL2014	10:00	0		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
209-0014/79/M/W2	Week 24	26AUG2014	10:10	0		
	End of Treatment	23SEP2014	09:00	0		Week 28 (4 weeks after week 24 visit)
210-0003/74/M/W2	Screening	30OCT2013	10:00	1	0.5	
	Screening	30OCT2013	10:00	0		
	Week 2	14NOV2013	10:30	1		
	Week 4	28NOV2013	11:15	1		
210-0004/71/M/W2	Screening	02JAN2014	09:45	1		
	Week 2	15JAN2014	09:40	1		
	Week 4	29JAN2014	09:30	1		
	Week 8	26FEB2014	09:35	1		
	Week 12	26MAR2014	10:00	2		
210-0005/53/M/W2	Screening	13FEB2014	09:20	0		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
	Week 2	27FEB2014	09:30	1		
	Week 4	13MAR2014	11:30	1		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
210-0005/53/M/W2	Week 8	10APR2014	09:15	1		
	Week 12	07MAY2014	09:10	1		
210-0006/45/M/W2	Screening	18JUN2014	10:45	1		
	Week 2	02JUL2014	09:20	1		
	Week 4	16JUL2014	10:15	1		
	Week 8	14AUG2014	09:30	1		
	Week 12	10SEP2014	10:20	1		
251-0002/69/M/W2	Screening	06AUG2013	11:00	0		
	Week 2	20AUG2013	11:30	0		
	Week 4	03SEP2013	11:45	0		
	Week 8	01OCT2013	11:30	2		
251-0003/68/M/W2	Screening	29OCT2013	09:36	0	0	
	Screening	29OCT2013	09:36	0		
	Week 2	12NOV2013	09:00	0		

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[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
251-0003/68/M/W2	Week 4	26NOV2013	09:15	0		
	Week 12	21JAN2014	10:00	0		
	Week 16	18FEB2014	10:00	0		
	Week 20	18MAR2014	10:30	0		
	Week 24	15APR2014	11:00	0		
252-0001/65/M/A3	Screening	30MAY2008	Unknown	0		
	Week 4	29MAY2012	11:25	0		
	Week 8	26JUN2012	11:35	0		
252-0004/50/M/A1	Screening	21MAY2013	11:20	2		
	Week 2	04JUN2013	11:00	0		
	Week 4	18JUN2013	11:30	2		
	Unscheduled	16JUL2013	10:35	0		Week 8
252-0006/64/M/W2	Screening	25JUL2013	Unknown	1		
	Week 2	08OCT2013	08:25	2		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
252-0006/64/M/W2	Week 4	22OCT2013	08:30	2		
	Week 8	19NOV2013	08:30	1		
	Week 12	17DEC2013	08:30	1		
	Week 16	14JAN2014	08:20	0		
	Week 20	11FEB2014	08:00	0		
	Week 24	11MAR2014	08:00	0		
252-0008/76/M/W2	Screening	20MAY2014	11:30	0		
	Week 2	03JUN2014	11:05	0		
	Week 4	17JUN2014	11:25	0		
	Week 8	15JUL2014	11:15	0		
	Week 12	12AUG2014	12:40	0		
252-0010/56/F/W2	Screening	28OCT2014	10:40	0		
	Week 2	11NOV2014	11:10	2		
	Week 4	25NOV2014	10:10	1		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
252-0010/56/F/W2	Week 8	23DEC2014	10:03	1		
	Week 12	20JAN2015	10:45	1		
253-0003/75/M/W2	Screening	25MAY2012	11:30	0		
	Week 4	06JUL2012	11:44	0		
	Week 8	03AUG2012	11:35	0		
	Week 12	31AUG2012	11:20	0		
	Week 16	28SEP2012	11:20	0		
	Week 20	26OCT2012	11:30	1		
	Week 24	23NOV2012	11:30	0		
	Week 28	21DEC2012	11:30	0		
	Week 32	18JAN2013	12:00	0		
	Week 36	15FEB2013	11:20	0		
253-0004/79/M/W2	Screening	04SEP2012	14:30	0		
	Week 4	28SEP2012	10:20	1		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
253-0004/79/M/W2	Week 8	26OCT2012	10:30	0		
	Week 12	23NOV2012	10:00	0		
253-0005/74/F/W2	Screening	03MAR2011	Unknown	1		
253-0006/63/M/A3	Screening	16NOV2012	Unknown	0		
	Week 4	18JAN2013	12:00	0		
	Week 8	15FEB2013	11:45	0		
	Week 12	15MAR2013	11:30	0		
	Week 16	12APR2013	11:05	0		
	Week 20	10MAY2013	10:00	0		
253-0011/67/M/W2	Screening	25SEP2014	10:00	1		
	Week 2	13OCT2014	10:10	1		
	Week 4	27OCT2014	10:30	1		
	Week 8	24NOV2014	10:20	1		
	Week 12	22DEC2014	10:00	1		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
253-0011/67/M/W2	Week 16	19JAN2015	11:00	1		
	Week 20	16FEB2015	09:50	1		
	Week 24	16MAR2015	10:50	1		
	Week 28	13APR2015	09:40	1		
	Week 32	11MAY2015	09:58	1		
253-0012/67/M/W2	Screening	24NOV2014	12:10	0		
	Week 2	15DEC2014	09:40	0		
	Week 4	29DEC2014	09:30	0		
257-0005/66/M/W2	Screening	11DEC2012	09:50	1	0.5	
	Unscheduled	11DEC2012	09:50	0		Screening (collection date not found on visit report, date is between screening and week 1)

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
	Week 4	24JAN2013	11:56	1		
	Unscheduled	28FEB2013	Unknown	2		Week 9
	Week 12	21MAR2013	10:35	1		
257-0013/63/M/W2	Screening	23MAY2013	12:10	0		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
257-0013/63/M/W2	Week 2	07JUN2013	11:53	1		
	Week 4	20JUN2013	11:45	1		
257-0020/72/M/A1	Screening	21OCT2014	14:10	0		
	Week 2	03NOV2014	15:30	1		
	Week 4	17NOV2014	13:43	1		
258-0002/69/F/W2	Screening	08APR2013	10:00	2	1	
	Unscheduled	08APR2013	10:00	0		Screening (collection date not found on visit report, date is between screening and week 1)
	Week 2	17APR2013	11:50	3		
	Week 4	01MAY2013	11:00	3		
	Week 8	29MAY2013	11:08	3		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
	Week 12	26JUN2013	11:30	2		
	Week 16	24JUL2013	09:45	2		
	Week 20	21AUG2013	10:26	0		
	Week 24	18SEP2013	10:34	0		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
258-0002/69/F/W2	Week 28	16OCT2013	10:46	0		
	Week 36	11DEC2013	12:13	0		
258-0003/67/F/W2	Screening	09MAY2013	11:30	1		
	Week 4	05JUN2013	11:25	1		
	Week 8	03JUL2013	11:05	0		
	Week 12	31JUL2013	11:24	1		
	Week 16	30AUG2013	10:07	1		
	Week 24	23OCT2013	10:25	1		
258-0004/65/M/W2	Screening	13MAY2013	11:20	1		
	Week 2	29MAY2013	Unknown	2		
258-0006/69/M/W2	Screening	02OCT2013	10:50	0		
	Week 2	25OCT2013	10:41	1		
	Week 4	08NOV2013	10:45	0		
258-0013/59/M/W2	Screening	05NOV2014	10:05	0		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
258-0013/59/M/W2	Week 2	19NOV2014	10:21	1		
	Week 4	03DEC2014	10:40	1		
	Week 8	29DEC2014	11:25	1		
	Week 12	28JAN2015	12:00	0		
259-0003/73/M/W2	Unscheduled	09JUN2014	13:50	0		Screening
	Week 2	18JUN2014	11:55	0		
	Week 4	02JUL2014	11:15	0		
	Week 8	30JUL2014	12:05	0		
	Week 12	27AUG2014	11:40	0		
	Week 16	24SEP2014	11:55	0		
	Week 20	22OCT2014	11:10	0		
	Week 24	19NOV2014	11:00	0		
	Week 28	17DEC2014	11:30	0		
	Week 32	14JAN2015	11:10	0		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
259-0003/73/M/W2	Week 40	11MAR2015	11:14	0		Uns Continuation
	Week 44	08APR2015	11:40	0		Uns Continuation
	Week 48	06MAY2015	10:50	0		Uns Continuation
259-0004/52/M/W2	Screening	16JUL2014	10:45	0		
	Unscheduled	23JUL2014	Unknown	0		Week 1 (2 days after week 1 visit)
	Week 2	30JUL2014	12:40	1		
	Week 4	13AUG2014	11:25	0		
260-0002/66/M/W2	Screening	18SEP2013	15:15	2		
	Week 2	09OCT2013	14:15	1		
	Week 4	23OCT2013	14:15	1		
301-0001/47/F/A2	Screening	27OCT2011	10:05	0		
	Week 4	22NOV2011	09:25	1		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
	Week 8	20DEC2011	09:25	1		
	Week 12	17JAN2012	11:50	0		

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[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
301-0003/61/F/A2	Screening	23FEB2012	11:40	0		
	Week 4	22MAR2012	10:40	0		
	Week 8	19APR2012	11:10	0		
	Week 12	17MAY2012	11:10	0		
301-0008/53/M/A2	Screening	26DEC2012	09:50	0		
	Week 4	25JAN2013	09:50	0		
	Week 8	22FEB2013	09:50	0		
	Week 12	22MAR2013	10:35	0		
302-0006/49/M/A2	Screening	04JAN2012	09:30	0		
	Week 4	31JAN2012	09:45	0		
	Week 8	28FEB2012	09:40	1		
302-0009/73/M/A2	Screening	11APR2012	09:02	2		
	Week 4	08MAY2012	09:03	0		
	Week 8	05JUN2012	09:12	0		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
302-0012/62/M/A2	Screening	18APR2012	08:30	0		
	Week 4	15MAY2012	08:15	1		
	Week 8	12JUN2012	10:22	1		
	Week 12	10JUL2012	08:23	1		
302-0013/62/M/A2	Screening	21MAR2013	09:55	0		
	Week 2	02APR2013	08:35	0		
	Week 4	16APR2013	08:05	0		
	Week 8	14MAY2013	08:10	1		
302-0020/52/M/A2	Screening	16MAY2013	09:00	0		
	Week 2	28MAY2013	09:25	2		
	Week 4	11JUN2013	09:00	2		
302-0021/75/F/A2	Screening	06JUN2013	10:25	0		
	Week 2	18JUN2013	09:50	1		
	Week 4	02JUL2013	09:30	4		

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[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
302-0021/75/F/A2	Week 8	30JUL2013	09:45	5		
	Week 12	27AUG2013	09:10	3		
	Week 16	24SEP2013	09:45	2		
	Week 20	22OCT2013	10:15	2		
	Week 24	19NOV2013	09:20	2		
304-0003/56/F/A2	Screening	11MAR2013	11:50	0		
	Week 4	03APR2013	10:00	0		
	Week 8	02MAY2013	10:00	0		
	Week 12	30MAY2013	09:02	0		
304-0004/69/M/A2	Screening	30MAY2013	13:00	0		
	Week 2	11JUN2013	11:40	0		
	Week 4	25JUN2013	08:02	0		
304-0007/72/M/A2	Screening	07NOV2013	11:20	0		
	Week 2	20NOV2013	09:30	0		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
304-0007/72/M/A2	Week 4	04DEC2013	10:00	0		
	Week 8	02JAN2014	10:00	0		
	Week 12	28JAN2014	09:48	1		
305-0004/79/M/A2	Screening	14FEB2012	16:50	1		
	Week 4	15MAR2012	08:07	2		
	Week 8	12APR2012	09:00	2		
	Week 12	10MAY2012	08:16	1		
305-0007/67/M/A2	Screening	10SEP2009	Unknown	1		
	Week 4	30MAR2012	08:00	2		
	Week 8	27APR2012	08:00	1		
	Week 12	25MAY2012	07:40	1		
	Week 16	22JUN2012	07:32	1		
	Week 20	20JUL2012	07:55	0		
	Week 24	17AUG2012	07:38	1		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
305-0015/84/M/A2	Screening	04JUL2012	11:50	0		
	Week 4	26JUL2012	07:13	0		
	Week 8	21AUG2012	12:47	0		
	Week 12	20SEP2012	08:14	0		
305-0016/78/M/A2	Screening	04JUL2012	16:10	0		
	Week 4	01AUG2012	12:40	2		
	Week 8	28AUG2012	09:05	3		
	Week 12	25SEP2012	12:40	2		
305-0021/83/F/A2	Screening	16NOV2012	16:34	1		
	Week 4	11DEC2012	12:58	1		
	Week 8	08JAN2013	12:10	1		
	Week 12	05FEB2013	13:00	1		
305-0024/68/M/A2	Screening	14JAN2013	10:30	0		
	Week 4	08FEB2013	08:00	0		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
305-0024/68/M/A2	Week 8	05MAR2013	13:15	0		
	Week 12	03APR2013	13:10	0		
305-0033/37/F/A2	Screening	25JUN2013	15:20	0		
	Week 2	09JUL2013	15:05	0		
	Week 4	23JUL2013	15:00	0		
	Week 8	20AUG2013	15:25	0		
	Week 12	17SEP2013	16:00	0		
305-0035/60/M/A2	Screening	27AUG2013	15:30	0		
	Week 2	04SEP2013	12:55	1		
	Week 4	18SEP2013	11:40	0		
	Week 8	16OCT2013	12:00	0		
	Week 12	13NOV2013	12:25	0		
	Week 16	11DEC2013	12:50	0		
	Week 20	08JAN2014	12:53	0		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
305-0035/60/M/A2	Week 24	05FEB2014	12:20	0		
305-0046/60/M/A2	Screening	03NOV2014	12:20	0		
	Week 2	14NOV2014	13:00	0		
	Week 4	28NOV2014	13:21	0		
	Week 8	26DEC2014	13:15	0		
	Week 12	23JAN2015	12:50	0		
	Week 16	17FEB2015	13:05	0		
	Week 20	20MAR2015	12:40	0		
	Week 24	14APR2015	12:50	0		
306-0004/46/M/A2	Screening	09FEB2012	Unknown	1		
	Week 4	13MAR2012	09:00	2		
306-0010/69/M/A2	Screening	18APR2006	Unknown	0		
	Week 4	11APR2012	11:00	0		
	Week 8	09MAY2012	10:30	0		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
306-0010/69/M/A2	Week 12	06JUN2012	10:00	0		
306-0013/42/M/A2	Screening	09APR2012	09:30	1		
	Week 4	07MAY2012	10:00	1		
	Week 8	04JUN2012	09:00	1		
306-0015/73/M/A2	Screening	15MAY2012	10:30	0		
	Week 4	07JUN2012	09:00	1		
306-0016/58/M/A2	Screening	21JUN2012	09:00	0		
	Week 4	16JUL2012	09:20	0		
	Week 8	13AUG2012	09:05	0		
	Week 12	11SEP2012	08:20	0		
306-0022/56/M/A2	Screening	22MAR2012	Unknown	0		
	Week 4	04DEC2012	09:00	1		
	Week 8	02JAN2013	08:50	1		
	Week 12	29JAN2013	08:50	1		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
306-0022/56/M/A2	Week 16	26FEB2013	08:20	1		
	Week 20	26MAR2013	08:30	2		
	Week 24	23APR2013	08:20	1		
306-0028/53/M/A2	Screening	18MAR2013	13:30	0		
	Week 4	18APR2013	09:00	2		
	Week 8	16MAY2013	09:30	2		
	Week 12	13JUN2013	09:30	2		
306-0045/60/F/A1	Screening	11JUN2014	12:30	0		
	Week 2	25JUN2014	13:00	0		
	Week 4	08JUL2014	13:00	0		
	Week 8	05AUG2014	13:00	0		
	Week 12	02SEP2014	13:00	0		
307-0006/72/M/A2	Screening	25NOV2011	09:09	0		
307-0009/53/M/A2	Screening	28DEC2011	09:45	0		

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[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
307-0009/53/M/A2	Week 4	27JAN2012	09:15	0		
307-0012/42/M/A2	Screening	31JAN2012	09:00	1		
307-0015/75/M/A2	Screening	18APR2012	08:43	0		
	Week 4	16MAY2012	08:45	0		
	Week 8	13JUN2012	09:25	0		
	Week 12	11JUL2012	10:50	0		
	Week 16	08AUG2012	09:57	0		
	Week 20	05SEP2012	09:30	0		
	Week 24	04OCT2012	10:50	0		
307-0021/68/M/A2	Screening	14AUG2012	09:30	0		
	Week 4	13SEP2012	08:57	0		
	Week 8	09OCT2012	08:35	0		
	Week 12	08NOV2012	09:18	0		
	Week 16	06DEC2012	09:20	0		

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[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
307-0028/69/F/A2	Screening	09JAN2013	09:49	0		
	Week 4	04FEB2013	09:35	0		
	Week 8	04MAR2013	09:34	0		
	Week 12	01APR2013	09:32	0		
307-0034/48/M/A2	Screening	08AUG2013	11:48	1		
	Week 2	20AUG2013	10:25	1		
	Week 4	03SEP2013	10:24	1		
	Week 8	01OCT2013	09:10	1		
	Week 12	29OCT2013	09:35	0		
307-0036/76/M/A2	Screening	27SEP2013	08:06	0		
	Week 2	08OCT2013	10:50	0		
	Week 4	24OCT2013	08:33	1		
	Week 8	21NOV2013	09:20	1		
	Week 12	18DEC2013	09:09	1		

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[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
307-0042/55/M/A2	Screening	10JUN2014	10:35	0		
	Week 2	26JUN2014	10:55	1		
	Week 4	10JUL2014	09:22	0		
	Week 8	07AUG2014	09:40	0		
	Week 12	04SEP2014	10:50	0		
	Week 16	02OCT2014	09:37	0		
	Week 20	30OCT2014	09:28	0		
	Week 24	27NOV2014	10:37	0		
308-0002/36/F/A2	Screening	27DEC2012	09:15	0		
	Week 4	22JAN2013	11:30	0		
	Week 8	19FEB2013	12:30	0		
	Week 12	19MAR2013	12:30	0		
308-0004/52/M/A2	Screening	31JAN2013	11:10	0		
	Week 4	26FEB2013	12:30	1		

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[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
308-0004/52/M/A2	Week 8	26MAR2013	12:30	0		
	Week 12	23APR2013	12:10	1		
308-0006/64/M/A2	Screening	12OCT2007	Unknown	0		
	Week 2	21MAY2013	09:20	1		
	Week 4	04JUN2013	13:20	1		
	Week 8	02JUL2013	13:05	0		
308-0008/47/M/A2	Screening	11JUL2013	14:10	0		
	Week 2	30JUL2013	12:40	0		
	Week 4	13AUG2013	09:15	0		
	Week 8	10SEP2013	09:10	0		
	Week 12	08OCT2013	09:00	0		
308-0009/61/M/A2	Screening	11JUL2013	13:40	1		
	Week 2	25JUL2013	14:30	1		
	Week 4	08AUG2013	11:10	3		

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[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
308-0009/61/M/A2	Week 8	05SEP2013	13:30	0		
309-0006/56/M/A2	Screening	19NOV2012	12:15	0		
	Week 4	17DEC2012	10:45	0		
	Week 8	14JAN2013	11:20	0		
	Week 12	08FEB2013	10:00	0		
	Week 16	11MAR2013	09:40	0		
	Week 20	08APR2013	10:50	0		
	Week 24	06MAY2013	09:20	0		
	Week 28	03JUN2013	10:20	0		
	Week 32	01JUL2013	09:10	0		
	Week 36	29JUL2013	09:50	0		
309-0007/58/M/A2	Screening	19MAY2011	Unknown	0		
	Week 4	07JAN2013	11:30	1		
	Week 8	04FEB2013	09:40	1		

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[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
309-0007/58/M/A2	Week 12	04MAR2013	09:20	1		
309-0013/45/M/A2	Screening	11DEC2012	Unknown	0		
	Week 2	27JUN2013	10:10	0		
	Week 4	11JUL2013	09:35	1		
	Week 8	08AUG2013	09:30	1		
	Week 12	05SEP2013	09:15	3		
309-0014/39/M/A2	Screening	14JUN2013	12:30	1		
	Week 2	27JUN2013	09:50	1		
	Week 4	11JUL2013	09:51	1		
	Week 8	08AUG2013	09:35	0		
	Week 12	05SEP2013	10:05	0		
309-0019/68/M/A2	Screening	17JUN2014	12:30	0		
	Week 2	01JUL2014	11:00	1		
	Week 4	15JUL2014	10:50	1		

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Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
309-0019/68/M/A2	Week 8	12AUG2014	13:10	0		
	Week 12	09SEP2014	11:20	1		
	Week 16	07OCT2014	11:15	0		
	Week 20	04NOV2014	11:20	0		
	Week 24	01DEC2014	11:20	0		
	Week 28	29DEC2014	10:40	0		
	Week 32	28JAN2015	09:10	0		
	Week 36	24FEB2015	11:00	0		
	Week 40	24MAR2015	11:25	0		
	Week 44	22APR2015	09:30	0		
	Week 48	19MAY2015	11:20	0		
309-0027/49/M/A2	Screening	22OCT2014	12:20	0		
	Week 2	10NOV2014	10:45	1		
	Week 4	24NOV2014	10:55	0		

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Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
309-0027/49/M/A2	Week 8	22DEC2014	10:16	0		
	Week 12	19JAN2015	10:14	0		
309-0029/50/M/A2	Screening	18NOV2014	13:00	0		
	Week 2	08DEC2014	10:30	1		
	Week 4	22DEC2014	10:25	1		
	Week 8	19JAN2015	09:35	0		
310-0004/50/F/A2	Screening	25JAN2013	09:40	0		
	Week 4	27FEB2013	09:00	0		
	Week 8	27MAR2013	08:50	0		
	Week 12	24APR2013	11:10	0		
310-0005/58/M/A2	Screening	13MAR2013	14:00	0		
	Week 2	03APR2013	10:45	0		
	Week 4	17APR2013	11:00	0		
	Week 8	15MAY2013	09:40	0		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
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[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
310-0005/58/M/A2	Week 12	10JUN2013	09:30	0		
310-0006/50/F/A2	Screening	24APR2013	08:50	0		
	Week 2	08MAY2013	08:40	0		
	Week 4	22MAY2013	09:20	0		
	Week 8	19JUN2013	08:30	0		
	Week 12	17JUL2013	11:25	0		
	Week 16	14AUG2013	09:00	0		
	Week 20	11SEP2013	10:00	0		
	Week 24	09OCT2013	09:50	0		
	Week 28	06NOV2013	10:50	0		
	Week 32	02DEC2013	11:00	0		
310-0007/74/M/A2	Screening	03JUN2013	14:30	1		
	Week 2	20JUN2013	10:30	0		
	Week 4	04JUL2013	11:00	0		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
310-0007/74/M/A2	Week 8	01AUG2013	10:45	0		
	Week 12	30AUG2013	11:00	0		
	Week 16	26SEP2013	10:45	0		
	Week 20	24OCT2013	11:00	0		
	Week 24	21NOV2013	10:50	0		
	Week 28	19DEC2013	10:55	0		
	Week 32	16JAN2014	09:40	0		
	Week 36	13FEB2014	11:00	0		
	Week 40	11MAR2014	11:00	0		
	Week 44	08APR2014	11:10	0		
310-0009/46/M/A2	Screening	31JUL2013	09:30	0		
	Week 2	14AUG2013	10:45	0		
	Week 4	28AUG2013	10:45	0		
	Week 8	25SEP2013	10:30	0		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
310-0010/34/F/A2	Screening	15AUG2013	14:20	0		
	Week 2	02SEP2013	10:00	0		
	Week 4	16SEP2013	08:20	1		
310-0011/52/M/A2	Screening	17OCT2013	12:40	0		
	Week 2	31OCT2013	12:20	1		
	Week 4	14NOV2013	12:15	0		
	Week 8	09DEC2013	08:40	0		
310-0014/64/M/A2	Screening	17SEP2014	08:37	0		
	Week 2	01OCT2014	08:03	0		
	Week 4	15OCT2014	07:05	0		
	Week 8	10NOV2014	07:01	0		
311-0003/44/M/A2	Screening	18SEP2013	10:10	1		
	Week 2	02OCT2013	14:20	2		
	Week 4	16OCT2013	09:00	4		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
311-0003/44/M/A2	Week 8	13NOV2013	10:10	4		
	Week 12	10DEC2013	08:00	1		
311-0004/68/M/A2	Screening	26SEP2013	09:00	0		
	Week 2	07OCT2013	08:55	0		
311-0005/58/M/A2	Screening	07OCT2013	14:00	0		
	Week 2	28OCT2013	14:00	0		
	Week 4	11NOV2013	14:00	0		
	Week 8	09DEC2013	13:30	0		
311-0006/73/F/A2	Screening	04NOV2013	15:00	0		
	Week 2	12NOV2013	10:00	0		
	Week 4	26NOV2013	09:45	0		
	Week 8	24DEC2013	08:30	0		
311-0009/51/F/A2	Screening	01JUL2014	16:10	0		
	Week 2	22JUL2014	09:25	0		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
311-0009/51/F/A2	Week 4	05AUG2014	14:40	0		
	Week 8	02SEP2014	12:00	0		
	Week 12	30SEP2014	09:47	0		
311-0010/47/M/A2	Screening	26AUG2014	08:55	0		
	Week 2	09SEP2014	14:00	1		
	Week 4	23SEP2014	14:30	0		
	Week 8	21OCT2014	13:25	0		
	Week 12	18NOV2014	09:45	0		
	Week 16	17DEC2014	11:00	0		
	Week 20	14JAN2015	10:50	0		
	Week 24	12FEB2015	13:10	0		
	Week 28	11MAR2015	13:32	0		
	Week 32	09APR2015	13:30	0		
	Week 36	07MAY2015	13:20	0		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
311-0011/46/M/A2	Screening	28OCT2014	09:20	0		
	Week 2	05NOV2014	14:30	0		
	Week 4	19NOV2014	09:15	0		
	Week 8	17DEC2014	12:10	0		
311-0012/55/M/A2	Screening	20JAN2015	09:56	0		
	Week 2	05FEB2015	13:46	0		
	Week 4	17FEB2015	14:49	0		
	Week 8	19MAR2015	13:57	0		
	Week 12	16APR2015	11:27	0		
	Week 16	14MAY2015	14:00	0		
401-0001/70/M/A7	Screening	03JUN2013	09:30	0		
	Week 2	Unknown	Unknown	0		
401-0002/55/M/A7	Screening	12JUN2013	11:30	0		
	Week 2	27JUN2013	10:15	0		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
402-0001/35/M/A7	Screening	15APR2013	14:30	1		
	Week 2	29APR2013	13:00	1		
	Week 4	13MAY2013	12:40	1		
	Week 8	10JUN2013	12:00	1		
402-0002/58/M/A7	Screening	23APR2013	15:00	2		
	Week 2	30APR2013	14:12	1		
	Week 4	14MAY2013	13:00	1		
	Week 8	11JUN2013	12:30	1		
	Week 12	09JUL2013	12:00	1		
402-0005/70/M/A7	Screening	09MAY2013	09:30	0		
	Week 2	16MAY2013	09:40	1		
	Week 4	28MAY2013	09:30	1		
	Week 8	27JUN2013	09:10	1		
	Week 12	23JUL2013	08:20	1		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
402-0010/50/M/A7	Screening	10MAY2013	11:30	1		
	Week 2	27MAY2013	13:20	1		
	Week 4	10JUN2013	12:00	1		
	Week 8	Unknown	Unknown	1		
402-0022/60/F/A7	Screening	09AUG2013	09:30	1		
	Week 2	30AUG2013	09:00	2		
	Week 4	12SEP2013	08:10	2		
	Week 8	10OCT2013	09:10	2		
	Week 12	11NOV2013	08:11	2		
402-0023/57/M/A7	Screening	22AUG2013	14:20	0		
	Week 2	10SEP2013	12:10	3		
	Week 4	24SEP2013	12:30	3		
	Week 8	22OCT2013	12:20	1		
	Week 12	19NOV2013	12:00	1		

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[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
402-0029/49/M/A7	Screening	06NOV2013	14:40	1		
	Week 2	18NOV2013	12:30	1		
	Week 4	02DEC2013	11:40	1		
	Week 8	30DEC2013	12:00	1		
402-0032/49/F/A7	Screening	28NOV2013	14:10	0		
	Week 2	12DEC2013	10:00	0		
	Week 4	26DEC2013	09:50	0		
	Week 8	23JAN2014	10:00	0		
	Week 12	20FEB2014	10:00	0		
402-0034/43/F/A7	Screening	11DEC2013	11:20	1		
	Week 2	26DEC2013	10:00	1		
	Week 4	09JAN2014	10:00	1		
	Week 8	07FEB2014	10:30	0		
	Week 12	06MAR2014	10:00	0		

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[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
402-0034/43/F/A7	Week 16	03APR2014	10:00	1		
	Week 20	02MAY2014	10:00	1		
	Week 24	29MAY2014	10:00	1		
403-0004/37/M/A7	Screening	03JUL2013	08:34	0		
	Week 2	17JUL2013	10:11	1		
	Week 4	31JUL2013	09:08	1		
	Week 8	28AUG2013	12:28	1		
	Week 12	25SEP2013	09:32	0		
404-0003/53/M/A7	Screening	02SEP2013	08:30	0		
	Week 2	17SEP2013	07:30	1		
404-0004/61/F/A7	Screening	08OCT2013	11:00	0		
	Week 2	21OCT2013	12:05	0		
	Week 4	04NOV2013	12:00	0		
	Week 8	02DEC2013	11:45	0		

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[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
405-0001/55/M/A7	Screening	22APR2013	08:55	1		
	Week 2	29APR2013	08:45	1		
	Week 4	15MAY2013	13:20	1		
	Week 8	10JUN2013	08:35	1		
	Week 12	10JUL2013	10:10	1		
405-0005/35/M/A6	Screening	19APR2013	13:40	1		
	Week 2	29APR2013	09:00	1		
	Week 4	15MAY2013	11:05	0		
	Week 8	10JUN2013	09:00	1		
	Week 12	10JUL2013	09:05	2		
	Week 16	07AUG2013	09:25	2		
	Week 20	04SEP2013	09:20	1		
	Week 24	02OCT2013	09:05	0		
	Week 28	30OCT2013	09:10	0		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
405-0005/35/M/A6	Week 32	27NOV2013	09:20	0	0	
	Week 32	27NOV2013	09:20	0		
405-0012/72/M/A7	Screening	09MAY2013	15:51	1		
	Week 2	22MAY2013	11:35	1		
	Week 4	05JUN2013	10:25	2		
	Week 8	01JUL2013	09:00	1		
	Week 12	29JUL2013	08:40	1		
	Week 16	26AUG2013	09:00	1		
	Week 20	23SEP2013	08:50	3		
	Week 24	21OCT2013	09:00	1		
405-0019/61/M/A7	Screening	17JUN2013	10:50	0		
	Week 2	01JUL2013	10:10	1		
	Week 4	15JUL2013	09:15	4		
405-0024/69/M/A7	Screening	19JUN2013	17:25	0		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
405-0024/69/M/A7	Week 2	10JUL2013	10:20	2		
405-0026/67/M/A7	Screening	27JUN2013	15:20	1		
	Week 2	17JUL2013	11:40	1		
	Week 4	31JUL2013	12:35	1		
	Week 8	28AUG2013	11:27	0		
	Week 12	25SEP2013	11:47	0		
405-0036/70/M/A7	Screening	17APR2012	Unknown	0		
	Week 2	28AUG2013	08:50	0		
	Week 4	13SEP2013	09:20	0		
	Week 8	14OCT2013	08:45	0		
	Week 12	11NOV2013	08:45	0		
405-0041/57/M/A7	Screening	11SEP2013	14:40	0		
	Week 2	16SEP2013	09:45	0		
	Week 4	02OCT2013	10:30	0		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
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[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
405-0041/57/M/A7	Week 8	28OCT2013	08:35	0		
	Week 12	25NOV2013	08:40	0		
	Week 16	23DEC2013	08:30	0		
	Week 20	22JAN2014	12:10	0		
	Week 24	17FEB2014	08:35	0		
	Week 28	12MAR2014	13:58	0		
	Week 32	11APR2014	10:30	0		
	Week 36	09MAY2014	10:35	0		
501-0003/22/M/A1	Screening	10DEC2013	09:00	0		
	Week 2	17DEC2013	10:00	0		
	Week 4	31DEC2013	09:00	0		
	Week 8	28JAN2014	08:17	0		
	Week 12	25FEB2014	08:20	0		
501-0004/26/M/A1	Screening	17DEC2013	06:00	0		

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[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
501-0004/26/M/A1	Week 2	25DEC2013	08:30	0		
	Week 4	09JAN2014	08:00	0		
	Week 8	07FEB2014	08:35	0		
	Week 12	05MAR2014	08:00	0		
501-0011/61/M/A1	Screening	25SEP2014	10:10	0		
	Week 2	29SEP2014	08:00	0		
	Week 4	23OCT2014	10:40	0		
	Week 8	12NOV2014	08:30	0		
	Week 12	10DEC2014	08:30	0		
502-0001/70/M/A1	Screening	23DEC2013	08:30	0		
	Week 2	20DEC2013	08:20	0		
	Week 4	03JAN2014	08:20	0		
502-0003/48/M/A1	Screening	13JAN2014	08:00	0		
	Week 2	22JAN2014	09:20	0		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
502-0003/48/M/A1	Week 4	07FEB2014	08:30	0		
	Week 8	07MAR2014	09:30	0		
	Week 12	04APR2014	08:40	0		
503-0002/71/F/A1	Screening	20FEB2014	09:00	0		
	Week 2	27FEB2014	09:00	0		
	Week 4	13MAR2014	10:00	0		
	Week 8	10APR2014	09:30	0		
	Week 12	08MAY2014	08:50	0		
	Week 16	03JUN2014	08:35	0		
	Week 20	01JUL2014	08:40	0		
	Week 24	29JUL2014	08:35	0		
	Week 28	26AUG2014	09:01	0		
	Week 32	23SEP2014	08:15	0		
	Week 36	21OCT2014	09:00	1		

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[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
503-0003/47/F/A1	Screening	07MAR2014	18:15	0		
	Week 2	13MAR2014	10:00	0		
	Week 4	27MAR2014	12:00	0		
503-0005/72/M/A1	Screening	25MAR2014	09:50	0		
	Week 2	01APR2014	09:00	0		
	Week 4	15APR2014	09:00	0		
	Week 8	13MAY2014	08:30	0		
	Week 12	10JUN2014	08:30	0		
	Week 16	08JUL2014	09:25	0		
	Week 20	05AUG2014	09:10	1		
	Week 24	02SEP2014	08:15	3		
	Week 28	29SEP2014	08:30	4		
	Week 32	28OCT2014	08:35	0		
	Week 36	25NOV2014	Unknown	0		

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[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
503-0005/72/M/A1	Week 40	23DEC2014	09:30	2		
	Week 44	21JAN2015	09:15	3		
	Week 48	15FEB2015	Unknown	3		
504-0003/53/M/A1	Screening	13MAR2014	15:15	1		
	Week 2	20MAR2014	10:40	1		
	Week 4	03APR2014	08:30	1		
504-0005/41/F/A1	Screening	02SEP2014	14:15	0		
	Week 2	10SEP2014	09:40	0		
	Week 4	24SEP2014	09:35	0		
504-0006/51/M/A1	Screening	04SEP2014	15:30	0		
506-0001/43/M/A1	Screening	15APR2014	06:30	0		
	Week 2	22APR2014	10:30	0		
	Week 4	06MAY2014	09:10	0		
506-0005/24/M/A1	Screening	21DEC2014	09:45	0		

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[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
506-0005/24/M/A1	Week 2	31DEC2014	09:15	0		
507-0001/51/M/A1	Screening	23JUL2014	16:30	1		
	Week 2	31JUL2014	09:30	1		
	Week 4	14AUG2014	09:20	1		
	Week 8	11SEP2014	09:10	1		
	Week 12	09OCT2014	09:40	1		
507-0002/44/M/A1	Screening	29JUL2014	10:55	0		
	Week 2	05AUG2014	10:00	0		
	Week 4	20AUG2014	08:45	0		
	Week 8	16SEP2014	08:09	0		
508-0002/64/M/A1	Screening	13FEB2014	08:28	0		
	Week 2	27FEB2014	09:25	0		
	Week 4	10MAR2014	10:43	0		
	Week 8	11APR2014	10:35	0		

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[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
508-0004/58/M/A1	Screening	25AUG2014	10:05	0		
	Week 2	03SEP2014	10:08	1		
509-0003/39/M/A1	Screening	23JUL2014	15:30	0		
	Week 2	31JUL2014	09:35	0		
	Week 4	14AUG2014	10:30	0		
	Week 8	11SEP2014	10:56	0		
	Week 12	09OCT2014	10:45	0		
510-0001/67/M/A1	Screening	25FEB2014	08:30	0		
	Week 2	05MAR2014	08:20	0		
	Week 4	19MAR2014	08:30	0		
	Week 8	16APR2014	08:00	0		
	Week 12	14MAY2014	07:55	0		
	Week 16	11JUN2014	08:20	0		
	Week 20	09JUL2014	08:30	0		

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[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
510-0001/67/M/A1	Week 24	06AUG2014	08:30	0		
	Week 28	04SEP2014	08:50	0		
	Week 32	30SEP2014	07:30	0		
	Week 36	29OCT2014	07:30	0		
	Week 40	26NOV2014	07:30	0		
510-0003/43/M/A1	Screening	04JUN2014	08:30	0		
	Week 2	11JUN2014	08:10	0		
	Week 4	25JUN2014	08:30	1		
	Week 8	30JUL2014	09:30	0		
513-0003/46/M/A1	Screening	25APR2014	10:14	0		
	Week 2	07MAY2014	08:38	0		
515-0005/45/M/A1	Screening	23JUN2014	10:00	1		
	Week 2	30JUN2014	09:30	0		
	Week 4	14JUL2014	09:55	0		

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[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.8
Immunogenicity Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	Anti-ADI-PEG 20 Antibody Level (-)	Average Antibody Level[3] (-)	Comment
515-0005/45/M/A1	Week 8	11AUG2014	09:20	0		
517-0003/45/M/A1	Screening	12MAY2014	09:30	0		
	Week 2	20MAY2014	09:05	0		
	Week 4	04JUN2014	09:30	0		
	Week 8	02JUL2014	09:01	0		
	Week 12	30JUL2014	10:04	0		
517-0010/67/M/A1	Screening	04NOV2014	09:04	0		
	Week 2	19NOV2014	09:10	0		
	Week 4	03DEC2014	09:10	0		
	Week 8	30DEC2014	08:54	0		
	Week 12	28JAN2015	09:26	0		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple antibody measurements at one visit.

Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
101-0001/59/M/A2	Screening	20JAN2009	Unknown	129		33.8		
	Week 4	16AUG2011	14:39	<0.750		521		
	Week 8	16SEP2011	10:34	<0.750		694		
	Week 12	14OCT2011	12:44	<0.750		316		
	Week 16	11NOV2011	15:22	72.9		73.9		
	Week 24	06JAN2012	15:39	67.5		54.5		
101-0005/77/M/W2	Screening	02AUG2011	09:45	68.7		26.8		
	Week 4	30AUG2011	12:40	<0.750		499		
	Week 8	27SEP2011	12:23	<0.750		426		
	Week 12	25OCT2011	14:11	<0.750		361		
101-0006/62/M/W2	Screening	05AUG2011	08:25	95.1		42.1		
	Week 4	02SEP2011	07:48	1.65		426		
	Week 8	30SEP2011	Unknown	3.43		350		
101-0007/77/M/A1	Screening	10DEC2009	Unknown	69.7		23.3		

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[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
101-0007/77/M/A1	Week 4	13SEP2011	10:31	<0.750		741		
	Week 8	11OCT2011	11:14	<0.750		812		
	Week 12	08NOV2011	15:26	<0.750		735		
101-0008/83/M/BL	Screening	22FEB2008	Unknown	67.4		28.0		
	Week 4	20SEP2011	08:38	<0.750		485		
	Week 8	18OCT2011	15:22	<0.750		108		
	Week 12	15NOV2011	14:51	37.8		33.3		
101-0009/82/M/A1	Week 4	25OCT2011	15:53	2.61		773		
	Week 8	15NOV2011	17:53	2.34		231		
	Week 12	20DEC2011	14:42	57.8		44.7		
101-0011/75/F/W2	Screening	27JUN2011	Unknown	50.2		46.4		
101-0012/68/M/W2	Screening	01SEP2010	Unknown	54.5		30.8		
	Week 4	20DEC2011	11:16	1.01		197		
	Week 8	17JAN2012	09:34	48.4		36.6		

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[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
101-0013/66/F/A5	Screening	29NOV2011	10:38	58.1	73.6	33.8	33.4	Collected on 29Nov2011
	Screening	02JAN2012	10:38	89.1		33.0		Collected on 02Jan2012
	Week 4	31JAN2012	09:57	1.92		443		
	Week 8	28FEB2012	11:09	71.9		60.8		
	Week 12	27MAR2012	10:18	94.3		39.0		
	Week 16	24APR2012	14:55	103		38.3		
	Week 20	Unknown	Unknown	88.3		34.8		
101-0016/61/M/A4	Screening	05JUN2007	Unknown	45.0		27.0		
	Week 4	07FEB2012	10:23	0.803		609		
	Week 8	06MAR2012	15:24	<0.750		518		
	Week 12	06APR2012	15:45	<0.750		428		
	Week 16	04MAY2012	07:37	0.856		376		

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[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
	Week 20	29MAY2012	12:57	<0.750		359		
	Week 24	26JUN2012	09:43	0.769		361		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
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[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
101-0016/61/M/A4	Week 28	24JUL2012	12:01	<0.750		135		
	Week 32	21AUG2012	07:54	1.16		122		
	Week 36	18SEP2012	11:45	2.36		124		
	Week 40	19OCT2012	09:35	20.6		69.0		Uns Continuation
	Week 44	16NOV2012	12:59	30.0		70.7		Uns Continuation
	Week 48	11DEC2012	13:01	3.62		106		Uns Continuation
	Week 52	08JAN2013	13:09	6.46		133		Uns Continuation
	Week 56	08FEB2013	07:49	54.9		25.1		Uns Continuation
	Week 60	08MAR2013	12:37	10.6		102		Uns Continuation

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
101-0018/51/M/A1	Screening	21FEB2012	16:28	32.7		22.9		Back up sample, no primary sample was received
101-0019/68/M/W2	Screening	28FEB2012	09:11	89.3		59.7		Week 4 in sample list from CLS
	Week 8	17APR2012	11:39	<0.750		128		
	Week 12	15MAY2012	15:26	55.9		35.2		
101-0021/74/M/W2	Screening	20MAR2012	11:57	102		57.9		

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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
101-0021/74/M/W2	Week 4	10APR2012	14:24	<0.750		501		
	Week 8	08MAY2012	10:43	66.0		69.5		
	Week 12	05JUN2012	08:58	47.1		23.7		
101-0022/55/M/BL	Screening	26NOV2008	Unknown	64.4		23.0		
	Week 4	10APR2012	18:21	0.793		139		
101-0023/70/M/W2	Screening	30MAR2012	16:40	62.5		17.1		
	Week 4	20APR2012	07:52	<0.750		401		
	Week 8	18MAY2012	08:20	0.785		470		
	Week 12	15JUN2012	08:13	1.34		286		
	Week 12	15JUN2012	08:13	1.66		298		
101-0024/35/F/A4	Screening	19MAR2012	Unknown	97.2		37.4		
	Week 4	22MAY2012	11:59	<0.750		752		
	Week 8	19JUN2012	15:19	<0.750		169		
	Week 12	17JUL2012	14:58	140		64.4		

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[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
101-0025/57/F/W2	Screening	01MAR2012	Unknown	64.6		30.8		
	Week 4	11MAY2012	08:36	<0.750		275		
	Week 8	08JUN2012	12:48	51.7		22.3		
101-0026/82/M/W2	Screening	17NOV2003	Unknown	48.5		17.7		
	Week 4	05JUN2012	15:39	<0.750		401		
	Week 8	05JUL2012	11:09	<0.750		457		
	Week 12	03AUG2012	14:54	<0.750		642		
	Week 16	31AUG2012	14:19	<0.750		163		
	Week 20	28SEP2012	15:54	<0.750		79.2		
	Week 24	23OCT2012	11:22	64.9		39.5		
	Week 28	23NOV2012	13:02	93.7		40.7		
	Week 32	18DEC2012	09:39	32.0		43.9		
	Week 36	Unknown	Unknown	58.4		43.8		
101-0028/60/M/W2	Screening	14DEC2011	Unknown	73.7		39.8		

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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
101-0028/60/M/W2	Week 4	03JUL2012	07:58	<0.750		913		
	Week 8	31JUL2012	07:37	1.31		160		
	Week 12	28AUG2012	07:41	66.1		47.8		
101-0029/70/M/A1	Screening	15JUN2012	10:31	76.7		30.5		
	Week 4	10JUL2012	10:23	0.819		773		
	Week 8	07AUG2012	10:35	65.6		62.0		
	Week 12	Unknown	Unknown	120		121		
101-0030/51/M/W2	Screening	04APR2011	Unknown	60.7		23.2		
	Week 4	24JUL2012	08:03	1.11		409		
	Week 8	21AUG2012	07:38	2.28		183		
101-0032/84/M/W2	Screening	04DEC2006	Unknown	32.0		138		
	Week 4	21AUG2012	11:52	0.899		160		
	Week 8	21SEP2012	09:30	79.4		45.1		
101-0033/66/F/W2	Screening	03AUG2012	11:57	57.1		38.1		

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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
101-0033/66/F/W2	Week 4	24AUG2012	10:20	1.77		712		
	Week 8	21SEP2012	10:22	0.804		148		
	Week 12	16OCT2012	11:29	5.15		128		
	Week 16	16NOV2012	10:55	44.6		39.4		
	Week 20	14DEC2012	07:04	81.9		46.9		
	Week 24	11JAN2013	Unknown	46.7		35.5		
101-0036/67/M/A4	Screening	23OCT2012	15:02	19.3		25.3		
	Week 4	27NOV2012	14:30	<0.750		339		
101-0037/57/M/A1	Screening	11JUN2008	Unknown	80.1		31.3		
	Week 4	28DEC2012	09:26	<0.750		537		
101-0038/56/M/W2	Screening	27JUN2012	Unknown	104		52.1		
	Week 2	12FEB2013	14:28	<0.750		441		
	Week 4	01MAR2013	11:10	1.34		676		
101-0039/77/F/W2	Screening	05APR2013	12:07	28.8		52.9		

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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
101-0039/77/F/W2	Week 2	12APR2013	08:57	<0.750		207		
	Week 4	26APR2013	08:38	80.6		46.6		
	Week 8	24MAY2013	11:21	39.6		62.6		
	Week 12	21JUN2013	08:44	75.9		60.1		
	Week 16	16JUL2013	08:41	77.8		53.4		
	Week 20	13AUG2013	10:51	80.5		61.0		
	Week 24	10SEP2013	07:36	29.0		51.3		
	Week 28	08OCT2013	07:15	53.4		51.1		
	Week 32	04NOV2013	07:43	58.0		51.2		
	Week 36	02DEC2013	07:33	77.0		60.1		
101-0040/60/M/W2	Screening	18OCT2013	Unknown	58.5		35.6		
	Week 2	08JUL2013	08:04	<0.750		475		
	Week 4	22JUL2013	08:40	<0.750		443		
101-0041/54/M/W2	Screening	21DEC2012	Unknown	60.3		45.4		

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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
101-0041/54/M/W2	Week 2	06AUG2013	12:33	0.782		253		
101-0042/64/M/W2	Screening	22MAY2012	Unknown	107		45.9		
	Week 2	13AUG2013	09:42	<0.750		471		
	Week 4	27AUG2013	16:02	<0.750		944		
	Week 8	23SEP2013	14:50	2.10		267		
101-0044/78/M/W2	Screening	18OCT2013	07:26	78.7		47.3		
	Week 4	08NOV2013	07:16	<0.750		794		
	Week 8	06DEC2013	07:30	<0.750		310		
	Week 12	03JAN2014	08:58	85.0		67.4		
101-0045/74/F/W2	Screening	22OCT2013	08:26	73.0		36.2		
	Week 2	12NOV2013	07:21	<0.750		287		
	Week 4	26NOV2013	07:40	111		69.9		
	Week 8	23DEC2013	07:51	51.8		48.0		
	Week 12	21JAN2014	10:49	67.7		25.5		

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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
101-0046/70/M/OTH	Screening	17DEC2012	Unknown	41.9		27.0		
	Week 2	29OCT2013	10:39	2.12		164		
	Week 4	12NOV2013	08:03	<0.750		204		
	Week 8	10DEC2013	07:30	0.804		165		
	Week 12	07JAN2014	07:28	<0.750		146		
101-0047/52/M/W2	Screening	10JAN2012	Unknown	51.2		38.9		
	Week 2	28OCT2013	10:50	<0.750		275		
	Week 4	11NOV2013	08:29	<0.750		388		
	Week 8	09DEC2013	07:43	<0.750		320		
101-0048/66/F/W2	Screening	22OCT2013	09:35	69.5		56.9		
	Week 2	29OCT2013	09:30	3.05		573		
	Week 4	19NOV2013	09:19	<0.750		440		

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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
	Week 8	10DEC2013	10:05	1.10		102		
	Week 12	06JAN2014	10:15	76.1		41.5		

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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
101-0049/71/M/A8	Screening	28OCT2013	11:03	115		48.9		
	Week 2	04NOV2013	10:02	0.957		426		
	Week 4	18NOV2013	10:01	<0.750		432		
	Week 8	16DEC2013	12:06	26.4		31.5		
	Week 12	13JAN2014	08:36	108		44.6		
101-0050/59/M/W2	Screening	29OCT2013	17:51	91.0		29.7		
	Week 2	04NOV2013	12:37	0.861		293		
	Week 4	18NOV2013	08:46	<0.750		447		
102-0001/53/M/BL	Screening	19APR2012	09:09	84.0		21.1		
	Week 4	15MAY2012	08:45	111		26.1		
	Week 8	12JUN2012	08:57	89.6		25.4		
102-0003/63/M/BL	Screening	29AUG2012	09:28	65.4		37.5		
	Week 4	02OCT2012	08:18	<0.750		221		
	Week 8	31OCT2012	07:22	62.8		33.1		

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[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
102-0003/63/M/BL	Week 12	28NOV2012	08:36	66.5		30.4		
102-0008/64/M/BL	Screening	02JAN2013	13:23	60.7	57.7	33.3	32.05	
	Screening	02JAN2013	13:23	54.7		30.8		
	Week 2	15JAN2014	09:20	<0.750		411		
	Week 4	28JAN2014	08:16	1.08		593		
102-0009/58/M/W2	Screening	23OCT2014	09:35	88.9		23.7		
	Week 2	05NOV2014	10:25	<0.750		281		
	Week 4	19NOV2014	11:25	96.8		31.4		
103-0001/56/M/W2	Screening	07MAY2012	11:15	58.7		35.5		
	Week 4	01JUN2012	10:10	<0.750		364		
	Week 8	29JUN2012	10:30	<0.750		125		
103-0003/66/M/W2	Screening	04FEB2013	12:30	118		28.3		
	Week 4	06MAR2013	11:00	<0.750		657		
	Week 8	03APR2013	11:45	<0.750		265		

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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
103-0003/66/M/W2	Week 12	01MAY2013	14:45	117		54.8		
	Week 16	29MAY2013	14:45	163		48.8		
	Week 20	24JUN2013	10:40	85.4		32.3		
103-0004/40/F/A1	Screening	19NOV2012	Unknown	107		28.5		
	Week 2	28APR2014	10:00	<0.750		408		
	Week 4	13MAY2014	13:00	<0.750		491		
	End of Treatment	09JUN2014	10:00	<0.750		192		Week 8
104-0003/56/F/W2	Screening	11JUL2012	09:55	116		42.2		
	Week 4	08AUG2012	09:50	84.4		37.3		
	Week 8	Unknown	Unknown	79.5		21.3		
104-0004/74/M/W2	Screening	15JUN2012	Unknown	87.6		32.4		
	Week 4	13NOV2012	10:35	1.63		334		

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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
104-0008/55/M/PI	Screening	29AUG2013	13:32	93.3		31.2		
	Week 2	13SEP2013	12:55	<0.750		286		

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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
104-0008/55/M/PI	Week 4	26SEP2013	07:41	0.828		487		
	Week 8	24OCT2013	07:52	1.08		190		
	Week 12	21NOV2013	08:00	16.5		133		
104-0010/71/F/A8	Screening	02JAN2014	10:20	97.8		54.6		
	Week 2	15JAN2014	09:20	<0.750		433		
	Week 4	29JAN2014	10:15	<0.750		847		
	Week 8	26FEB2014	10:21	22.0		122		
	Week 12	27MAR2014	09:20	84.2		61.3		
	Week 16	23APR2014	09:25	84.9		30.8		
	Week 20	21MAY2014	09:24	75.6		37.2		
	Week 24	18JUN2014	09:00	105		40.4		Back up sample
	Week 28	16JUL2014	09:05	103		44.3		

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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
	Week 32	13AUG2014	09:06	74.9		44.3		
	Week 36	10SEP2014	08:56	83.4		45.8		Uns Continuation

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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
104-0012/78/F/A2	Screening	23SEP2014	11:15	101		44.3		
	Week 2	07OCT2014	11:14	2.20		304		
	Week 4	22OCT2014	11:04	2.27		134		
	Week 8	18NOV2014	11:00	116		37.5		
106-0001/42/F/W2	Screening	20FEB2012	Unknown	88.1	84.7	30.5	31.3	Collected on 20Feb2012
	Screening	20FEB2012	Unknown	81.3		32.1		Collected on 20Feb2012
	Week 4	26MAR2012	09:30	<0.750		379		
	Week 8	23APR2012	10:20	57.1		37.9		
	Week 12	21MAY2012	10:35	80.3		36.3		
	Week 16	18JUN2012	11:40	62.6		21.3		
107-0002/71/M/W2	Screening	21JUL2010	Unknown	69.0		45.5		
	Week 4	21SEP2012	13:10	<0.750		265		

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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
	Week 8	15OCT2012	12:15	0.796		255		
	Week 12	12NOV2012	10:00	1.54		279		

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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
107-0003/73/M/BL	Screening	18FEB2013	12:05	57.8		13.5		
	Week 4	18MAR2013	09:49	1.57		277		
	Week 8	16APR2013	13:45	97.3		60.5		
107-0004/63/M/W2	Screening	26FEB2013	13:16	87.6		44.0		
	Week 2	12MAR2013	10:14	0.825		183		
	Week 4	26MAR2013	10:20	<0.750		180		
	Week 8	23APR2013	07:45	<0.750		154		
	Week 12	21MAY2013	10:30	<0.750		155		
107-0006/60/M/W2	Screening	06MAY2013	09:15	58.8		44.6		
	Week 2	20MAY2013	09:26	<0.750		361		
	Week 4	04JUN2013	13:05	<0.750		482		
	Week 8	01JUL2013	10:00	<0.750		442		
	Week 12	29JUL2013	09:00	1.06		176		
108-0001/60/F/W2	Screening	07MAR2012	15:00	142		36.4		

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Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
108-0001/60/F/W2	Week 4	11APR2012	10:45	<0.750		477		
108-0002/78/M/BL	Screening	25MAY2012	09:55	129		41.7		
	Week 4	21JUN2012	10:00	<0.750		610		
108-0004/61/M/W2	Screening	04APR2013	10:31	51.0		32.2		
	Week 3	02MAY2013	09:07	<0.750		255		
	Week 4	09MAY2013	07:35	<0.750		435		
108-0005/68/M/W2	Screening	26APR2013	08:40	87.5		15.6		
	Week 2	15MAY2013	14:40	0.927		360		
	Week 4	29MAY2013	13:30	<0.750		398		
	Week 8	26JUN2013	09:30	0.809		342		
	Week 12	24JUL2013	09:20	1.37		249		
108-0008/77/M/W2	Screening	01OCT2014	08:05	104		43.9		
	Week 2	16OCT2014	09:10	<0.750		359		
	Week 4	30OCT2014	09:20	<0.750		398		

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Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
108-0008/77/M/W2	Week 8	26NOV2014	12:06	44.4		73.3		
	Week 12	23DEC2014	08:54	102		35.7		
	Week 16	22JAN2015	09:15	81.7		23.0		
	Week 20	19FEB2015	08:15	85.6		32.0		
	End of Treatment	16APR2015	Unknown	58.7		26.7		Week 24 in sample list from CLS
109-0003/68/M/W2	Screening	30APR2013	11:33	83.9		35.9		
	Week 2	13MAY2013	13:38	<0.750		257		
	Week 4	28MAY2013	16:00	0.855		372		
109-0004/57/M/W2	Screening	13FEB2012	Unknown	86.9		61.0		
	Week 2	26JUL2013	09:20	1.16		398		
	Week 4	12AUG2013	13:45	0.992		323		
	Week 8	11SEP2013	13:55	1.35		438		

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Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
	Week 12	09OCT2013	09:10	1.75		231		
109-0006/62/M/PI	Screening	14AUG2013	12:25	90.0		27.9		

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Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
109-0006/62/M/PI	Week 2	30AUG2013	11:40	1.23		326		
	Week 4	12SEP2013	11:40	1.76		463		
	Week 8	09OCT2013	13:15	62.3		27.8		
	Week 12	06NOV2013	11:45	89.4		27.2		
109-0007/55/M/W2	Screening	02DEC2013	15:40	72.2		27.7		
	Unscheduled	10DEC2013	Unknown	76.5		23.7		Week 1 (backup sample)
	Unscheduled	10DEC2013	Unknown	76.0		23.0		Week 1
	Week 2	18DEC2013	11:20	1.51		155		
	Week 4	03JAN2014	12:40	1.81		161		
	Week 8	30JAN2014	13:20	69.8		40.0		
	Week 12	26FEB2014	12:40	78.2		29.2		
	Week 16	25MAR2014	13:52	91.2		37.8		

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[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
	Week 20	23APR2014	11:25	73.6		39.6		
109-0008/70/F/W2	Screening	21MAY2014	11:35	126		55.7		

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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
109-0008/70/F/W2	Week 2	12JUN2014	13:30	<0.750		243		
	Week 4	25JUN2014	12:20	96.4		58.1		
	Week 8	23JUL2014	12:40	138		60.4		
	Week 12	20AUG2014	13:10	150		53.4		
	Week 16	17SEP2014	12:45	99.7		51.3		
	Week 20	14OCT2014	08:39	108		42.9		
	Week 24	13NOV2014	09:20	124		47.7		
109-0009/57/M/W2	Screening	25JUN2014	11:45	81.2		41.9		
	Week 2	15JUL2014	14:55	<0.750		198		
	Week 4	30JUL2014	12:15	108		44.5		
	Week 8	26AUG2014	11:19	64.5		23.4		
	Week 12	23SEP2014	13:30	71.0		34.5		
109-0010/65/M/W2	Screening	25JUN2014	14:45	69.4		52.4		
	Week 2	16JUL2014	15:19	<0.750		318		

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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
109-0010/65/M/W2	Week 4	30JUL2014	14:10	<0.750		440		
	Week 8	27AUG2014	12:25	64.1		89.5		
	Week 12	24SEP2014	11:30	89.5		58.0		
109-0011/64/M/A4	Screening	23JAN2013	Unknown	181		59.1		
	Week 2	01OCT2014	15:25	<0.750		468		
	Week 4	15OCT2014	15:05	<0.750		944		
	Week 8	11NOV2014	15:20	71.5		89.9		
	Week 12	10DEC2014	14:50	133		80.8		
109-0013/64/F/W2	Screening	30OCT2014	14:30	75.6		31.4		
	Week 2	11NOV2014	12:31	<0.750		296		
	Week 4	Unknown	Unknown	<0.750		360		
	Week 8	22DEC2014	14:55	<0.750		659		
	Week 12	20JAN2015	11:45	<0.750		362		
	Unscheduled	24FEB2015	Unknown	<0.750		156		Week 17

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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
109-0013/64/F/W2	Week 24	13APR2015	12:30	42.8		41.4		
110-0003/63/M/OTH	Screening	25JUN2012	16:00	62.5		34.9		
	Week 4	30JUL2012	12:15	<0.750		768		
	Week 8	27AUG2012	11:30	<0.750		551		
	Week 12	25SEP2012	12:30	<0.750		157		
	Week 16	22OCT2012	11:55	82.1		40.8		
	Week 20	19NOV2012	11:35	67.3		28.6		
110-0004/53/M/A4	Screening	11OCT2012	13:05	154		55.2		
	Week 8	13DEC2012	11:15	<0.750		260		
110-0005/77/M/W2	Screening	22SEP2010	Unknown	46.7		30.7		
	Week 4	02APR2013	14:30	1.07		545		
	Week 8	30APR2013	13:58	0.851		332		

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Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
	Week 12	28MAY2013	12:30	0.948		177		
110-0007/62/M/A4	Screening	03MAY2013	11:58	94.3		47.2		

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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
110-0007/62/M/A4	Week 4	07JUN2013	13:05	120		64.8		
	Week 12	02AUG2013	12:00	121		41.0		
	Week 16	30AUG2013	11:15	78.5		50.6		
	Week 24	25OCT2013	12:05	104		44.3		
	Week 28	22NOV2013	11:35	81.6		37.9		
110-0008/63/F/BL	Screening	26JUN2013	12:18	52.7		18.3		
	Week 4	29JUL2013	12:05	41.6		37.4		
110-0011/77/M/A1	Screening	26JUL2013	Unknown	69.8		45.8		
	Week 2	29JAN2015	11:33	1.51		450		
	Week 4	12FEB2015	11:55	0.798		528		
	Week 8	12MAR2015	11:31	39.3		55.3		
	Week 12	10APR2015	15:35	89.6		77.3		
111-0001/37/M/A4	Screening	02JUL2012	11:05	130		54.6		
	Week 4	02AUG2012	13:00	<0.750		933		

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Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
111-0004/64/M/W2	Screening	10MAY2013	11:25	74.4		24.0		
	Week 2	30MAY2013	09:54	<0.750		251		
	Week 4	13JUN2013	09:52	<0.750		382		
	Week 8	11JUL2013	09:25	<0.750		323		
111-0006/59/M/W2	Screening	03OCT2013	08:25	65.5		40.0		
	Week 2	17OCT2013	08:28	<0.750		345		
	Week 4	30OCT2013	07:15	<0.750		269		
	Week 8	27NOV2013	08:24	51.5		30.7		
	Week 8	27NOV2013	08:24	59.0		33.1		
	Week 12	02JAN2014	09:15	70.0		38.6		
	Week 16	29JAN2014	11:20	58.7		40.0		
	Week 20	26FEB2014	10:40	98.1		56.6		
	Week 24	26MAR2014	07:25	73.2		45.5		
	Week 28	23APR2014	07:55	73.3		31.4		

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Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
111-0007/55/M/W2	Screening	23JAN2014	15:46	57.7		32.9		
	Week 2	13FEB2014	15:10	<0.750		223		
	Week 4	27FEB2014	11:12	<0.750		455		
	Week 8	27MAR2014	11:35	<0.750		463		
	Week 12	25APR2014	07:50	<0.750		161		
112-0006/58/M/W2	Screening	15MAR2013	10:23	39.3		24.4		
	Week 2	01APR2013	07:09	1.11		236		
	Week 4	15APR2013	11:53	63.0		36.5		
	Week 8	13MAY2013	12:09	40.5		26.5		
112-0009/50/M/A8	Screening	05JUN2013	Unknown	60.1		36.3		
	Week 2	26JUN2013	07:12	<0.750		284		
	Week 8	07AUG2013	09:27	0.788		282		
	Week 12	04SEP2013	07:53	87.5		68.9		
112-0011/56/M/A4	Screening	03JAN2014	10:10	50.8		24.1		

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Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
112-0011/56/M/A4	Week 2	17JAN2014	11:38	0.821		237		
	Week 4	31JAN2014	08:44	0.852		271		
	Week 8	28FEB2014	09:02	26.5		19.5		
112-0012/71/M/W2	Screening	16MAY2014	08:05	36.8		48.0		
	Week 2	30MAY2014	08:00	1.04		290		
	Week 4	13JUN2014	07:42	1.09		97.1		
	Week 8	11JUL2014	08:00	16.1		64.7		
	Week 12	08AUG2014	07:24	28.5		47.7		
112-0013/28/F/W2	Screening	16MAY2014	11:25	63.3		24.1		
	Week 2	30MAY2014	09:00	<0.750		379		
	Week 4	13JUN2014	08:00	0.920		337		
	Week 8	11JUL2014	08:21	1.63		166		
112-0014/79/M/A8	Screening	30MAY2014	13:10	76.8		33.7		
	Week 2	13JUN2014	13:20	<0.750		310		

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Pharmacodynamic Analysis Results
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Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
112-0014/79/M/A8	Week 4	27JUN2014	11:38	<0.750		387		
	Week 8	25JUL2014	09:20	<0.750		320		
	Week 12	22AUG2014	07:56	0.935		262		
112-0015/66/M/A8	Screening	17OCT2014	09:31	49.6		20.6		
	Week 2	31OCT2014	08:20	<0.750		376		
	Week 4	14NOV2014	08:41	<0.750		310		
	Week 8	12DEC2014	10:20	14.2		15.8		
113-0001/60/M/W2	Screening	09AUG2012	15:45	83.2		72.6		
	Week 4	17SEP2012	14:10	<0.750		797		
	Week 8	15OCT2012	12:30	87.9		69.5		
	Week 12	15NOV2012	14:35	83.0		39.8		
	Week 16	10DEC2012	11:49	95.1		69.9		
	Week 20	07JAN2013	13:10	94.9		67.2		
	Week 24	06FEB2013	13:00	117		69.8		

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Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
113-0002/64/F/W2	Screening	08OCT2012	15:27	60.5	79.75	49.1	59.65	
	Unscheduled	08OCT2012	15:27	99.0		70.2		Screening (collection date not found on visit report, date is between screening and week 1)
	Week 4	05NOV2012	11:00	<0.750		438		
	Week 8	26NOV2012	11:45	<0.750		378		
	Week 20	20FEB2013	09:05	<0.750		309		
	Week 24	25MAR2013	09:50	<0.750		401		
	Week 28	22APR2013	08:45	<0.750		413		
	Week 32	20MAY2013	08:04	<0.750		474		
113-0005/58/M/W2	Screening	08JAN2014	09:50	82.1		32.6		

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(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
	Week 2	30JAN2014	09:13	1.18		396		
	Week 4	13FEB2014	09:27	<0.750		181		
	Week 8	12MAR2014	14:26	90.4		26.0		
113-0008/78/M/A8	Screening	07FEB2014	13:25	84.3		29.4		
113-0010/59/M/W2	Screening	30APR2014	14:17	75.7		23.9		

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[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE – ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE – WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
113-0010/59/M/W2	Week 2	07MAY2014	08:59	0.972		236		
	Week 4	23MAY2014	08:40	<0.750		219		
113-0013/56/M/W2	Screening	03MAR2011	Unknown	81.3		38.6		
	Week 2	14NOV2014	08:08	<0.750		334		
	Week 4	24NOV2014	08:24	<0.750		722		
	Week 8	22DEC2014	08:35	<0.750		625		
113-0016/72/M/A8	Screening	22JAN2015	14:27	125		42.2		
	Week 2	10FEB2015	14:25	<0.750		455		
	Week 4	25FEB2015	13:34	1.65		768		
	Week 8	23MAR2015	08:37	1.12		797		
114-0003/59/M/W2	Screening	19NOV2012	11:15	48.1		24.5		
	Week 4	19DEC2012	11:40	<0.750		404		
	Week 8	16JAN2013	11:45	<0.750		328		
	Week 12	13FEB2013	11:34	<0.750		204		

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[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
114-0003/59/M/W2	Week 16	13MAR2013	11:32	56.3		40.7		
	Week 20	10APR2013	12:12	71.2		54.1		
114-0005/73/M/W2	Screening	11SEP2012	Unknown	48.0		11.3		
	Week 2	18DEC2013	08:37	0.796		166		
	Week 4	31DEC2013	08:39	<0.750		245		
	Week 8	29JAN2014	08:08	<0.750		171		
114-0007/60/F/W2	Screening	14NOV2014	11:46	122		38.0		
	Week 2	26NOV2014	11:17	1.87		511		
	Week 4	09DEC2014	11:49	21.5		852		
	Week 8	06JAN2014	10:11	4.69		229		
	Week 12	04FEB2015	10:20	14.0		135		
	Week 20	31MAR2015	10:27	49.1		45.8		
	Week 24	28APR2015	10:29	59.4		31.8		
	Week 28	26MAY2015	10:41	76.3		42.8		

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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
115-0001/59/F/A4	Screening	15JUN2011	Unknown	103		28.9		
	Week 4	18DEC2012	09:30	0.827		130		
	Week 8	15JAN2013	08:45	67.6		25.3		
	Week 12	14FEB2013	07:25	82.5		25.6		
115-0002/45/F/W2	Screening	26NOV2012	12:44	94.8		45.6		
	Week 4	18DEC2012	13:26	3.44		100		
115-0003/63/M/W2	Screening	17DEC2008	Unknown	57.9		39.5		
	Week 4	07FEB2013	08:12	<0.750		473		
	Week 8	07MAR2013	08:14	<0.750		392		
	Week 12	04APR2013	07:16	<0.750		599		
	Week 16	02MAY2013	07:50	<0.750		558		
	Week 20	30MAY2013	07:25	<0.750		429		
115-0008/51/M/A8	Screening	13JUN2013	13:50	73.2		47.5		
	Week 2	25JUN2013	09:54	<0.750		410		

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[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
115-0009/85/M/W2	Screening	03DEC2013	15:25	52.2		42.0		
	Week 2	19DEC2013	13:54	1.07		184		
	Week 4	02JAN2014	08:25	3.55		222		
	Week 8	28JAN2014	09:55	<0.750		212		
	Week 16	27MAR2014	09:17	63.7		43.0		
	Week 20	22APR2014	13:07	60.9		52.8		
	Week 24	21MAY2014	08:54	58.4		39.7		
115-0011/56/M/W2	Screening	30MAY2014	07:08	111		58.0		
	Week 2	13JUN2014	08:00	<0.750		261		
	Week 4	26JUN2014	08:45	79.9		43.0		
	Week 12	22AUG2014	07:34	94.5		30.2		
115-0014/72/M/W2	Week 2	18FEB2015	11:40	1.03		223		
	Week 4	03MAR2015	08:45	0.812		364		
	Week 8	01APR2015	12:30	61.3		65.7		

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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
116-0002/67/F/W2	Screening	11MAR2013	16:44	67.9		28.2		
	Week 2	25MAR2013	16:02	<0.750		146		
	Week 4	08APR2013	14:02	65.1		76.1		
	Week 8	06MAY2013	13:54	39.3		36.4		
	Week 12	03JUN2013	14:00	49.7		21.7		
	Week 16	01JUL2013	13:35	70.1		22.9		
	Week 20	29JUL2013	13:52	40.7		23.7		
	Week 24	26AUG2013	14:09	52.2		31.2		
	Week 28	23SEP2013	13:52	33.2		24.9		
	Week 32	21OCT2013	13:41	32.0		32.4		
	Week 36	18NOV2013	14:00	23.2		26.6		
116-0003/66/M/BL	Screening	18MAR2013	16:20	46.6		17.3		
	Week 2	04APR2013	09:12	<0.750		142		
	Week 4	18APR2013	10:34	49.9		25.2		

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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
117-0001/69/M/W2	Screening	19MAR2013	13:35	95.5		31.2		
	Week 2	09APR2013	13:00	<0.750		256		
	Week 4	23APR2013	13:45	<0.750		471		
	Week 8	21MAY2013	13:00	<0.750		704		
118-0001/67/F/A8	Screening	06AUG2013	13:20	44.2	60.875	33.9	35.375	
	Unscheduled	06AUG2013	13:20	69.8		38.0		Screening
	Unscheduled	06AUG2013	13:20	73.7		42.1		Screening
	Unscheduled	06AUG2013	13:20	55.8		27.5		Screening
	Week 2	20AUG2013	14:15	<0.750		628		
	Week 4	03SEP2013	13:00	<0.750		1120		
	Week 8	03OCT2013	13:15	91.0		57.2		
	Week 12	29OCT2013	09:35	87.1		46.0		
119-0001/80/M/A8	Screening	07JAN2014	15:58	68.6		24.2		
	Week 2	28JAN2014	13:32	1.22		351		

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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
121-0001/62/M/W2	Screening	12MAR2012	Unknown	89.3		32.2		
	Week 2	25FEB2014	07:50	<0.750		288		
	Week 4	11MAR2014	09:00	<0.750		372		
	Week 8	08APR2014	09:40	<0.750		193		
	Week 12	06MAY2014	09:05	15.9		116		
121-0004/64/F/W2	Screening	18DEC2014	14:33	71.3		26.5		
	Unscheduled	05JAN2015	Unknown	38.0		33.9		Week 1 (3 days after week 1 visit)
201-0001/68/F/W2	Screening	20JAN2012	08:00	100		41.9		
	Week 4	16FEB2012	08:00	<0.750		470		
	Week 8	15MAR2012	09:20	<0.750		718		
	Week 12	11APR2012	08:10	<0.750		639		
201-0005/73/M/W2	Screening	05JUL2012	08:00	136		60.3		

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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
	Week 4	09AUG2012	07:50	<0.750		894		
	Week 8	06SEP2012	08:00	<0.750		394		

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Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
201-0005/73/M/W2	Week 12	04OCT2012	08:00	1.37		128		
201-0008/79/M/W2	Screening	10MAY2013	08:30	87.8		39.9		
	Week 2	23MAY2013	08:00	<0.750		397		
	Week 4	06JUN2013	08:00	<0.750		343		
	Week 8	04JUL2013	08:15	<0.750		516		
201-0011/73/M/W2	Screening	16MAR2011	Unknown	67.0		44.0		
	Week 2	11JUL2013	08:15	<0.750		293		
	Week 4	24JUL2013	08:40	<0.750		417		
	Week 8	22AUG2013	08:10	<0.750		263		
	Week 12	18SEP2013	07:50	<0.750		575		
201-0012/79/M/W2	Screening	11JUL2013	08:40	71.4	76.35	46.4	49.75	

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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
	Unscheduled	11JUL2013	08:40	81.3		53.1		Screening (collection date not found on visit report, date is between screening and week 1)
	Week 2	01AUG2013	08:25	<0.750		304		
	Week 8	12SEP2013	08:05	0.926		492		

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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
201-0012/79/M/W2	Week 12	10OCT2013	08:00	<0.750		444		
	Week 16	07NOV2013	08:40	0.989		467		
	Week 20	06DEC2013	07:50	<0.750		359		
	Week 24	03JAN2014	07:50	0.766		439		
	Week 28	30JAN2014	08:30	0.791		500		
	Week 32	27FEB2014	08:20	<0.750		554		
	Week 36	27MAR2014	08:30	<0.750		318		
	Week 38	09APR2014	08:10	0.993		420		Uns Continuation
	Week 40	24APR2014	08:00	0.863		397		Uns Continuation
	Week 42	08MAY2014	08:00	<0.750		290		Uns Continuation
	Week 44	21MAY2014	08:25	<0.750		397		Uns Continuation

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[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
	Week 46	05JUN2014	08:20	<0.750		357		Uns Continuation
	Week 48	19JUN2014	08:15	<0.750		405		Uns Continuation
	Week 50	03JUL2014	08:00	2.22		356		Uns Continuation

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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
201-0012/79/M/W2	Week 52	16JUL2014	08:00	2.39		438		Uns Continuation
	Week 54	31JUL2014	08:00	<0.750		285		Uns Continuation
	Week 58	28AUG2014	08:10	1.82		338		Uns Continuation
	Week 60	11SEP2014	08:30	1.35		368		Uns Continuation
201-0013/67/F/W2	Screening	11JUL2013	09:05	105	106	62.0	61.9	
	Unscheduled	11JUL2013	09:05	107		61.8		Screening (collection date not found on visit report, date is between screening and week 1)
	Week 2	01AUG2013	08:40	0.916		505		

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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
	Week 8	12SEP2013	08:20	<0.750		473		
	Week 12	10OCT2013	08:30	<0.750		417		
	Week 12	10OCT2013	08:30	<0.750		358		
201-0016/72/M/W2	Screening	31OCT2013	08:30	85.5	78	43.7	41.25	
	Unscheduled	31OCT2013	08:30	70.5		38.8		Screening (collection date not found on visit report, date is between screening and week 1)
	Week 2	21NOV2013	08:30	<0.750		471		
	Week 4	06DEC2013	08:20	<0.750		419		

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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
201-0016/72/M/W2	Week 8	03JAN2014	08:10	0.867		229		
	Week 12	30JAN2014	08:10	<0.750		541		
	Week 16	27FEB2014	08:00	<0.750		377		
	Week 20	27MAR2014	08:15	<0.750		580		
201-0017/82/M/W2	Screening	18NOV2013	08:00	100		55.1		
	Week 2	06DEC2013	08:40	<0.750		492		
201-0018/78/F/W2	Screening	28NOV2013	08:20	70.7		21.2		
	Week 2	12DEC2013	08:25	0.870		163		
201-0019/68/M/W2	Screening	12DEC2013	09:00	114		55.9		
	Week 2	27DEC2013	08:25	1.03		557		
	Week 4	09JAN2014	08:15	0.967		789		
	Week 8	06FEB2014	08:20	70.4		116		
	Week 12	06MAR2014	08:10	101		29.0		
201-0020/67/M/W2	Screening	17JAN2014	09:30	101		41.9		

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Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
201-0020/67/M/W2	Week 2	30JAN2014	09:00	1.21		341		
201-0021/54/M/W2	Screening	04FEB2014	08:00	119		64.4		
	Week 2	20FEB2014	08:00	<0.750		445		
	Week 4	06MAR2014	07:50	<0.750		663		
	Week 8	03APR2014	08:00	<0.750		391		
	Week 12	30APR2014	08:00	11.7		109		
201-0024/74/M/W2	Screening	16JAN2015	09:30	62.8		35.6		
	Week 2	05FEB2015	08:00	1.14		260		
	Week 4	19FEB2015	07:50	60.2		36.7		
201-0025/75/M/W2	Screening	21JAN2015	08:00	97.6		69.1		
	Week 2	05FEB2015	07:45	<0.750		416		
203-0001/61/F/W2	Screening	29FEB2012	08:00	70.1		23.8		
	Week 4	29MAR2012	08:00	64.9		24.3		
203-0002/72/M/W2	Screening	02MAR2012	08:00	52.6		43.7		

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Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
203-0002/72/M/W2	Week 4	27MAR2012	08:00	<0.750		340		
203-0005/53/M/W2	Screening	29MAR2012	08:00	74.9		26.9		
	Week 4	27APR2012	08:00	<0.750		112		
	Week 8	31MAY2012	09:00	83.7		30.0		
203-0013/68/M/W2	Screening	23DEC2013	09:00	71.6		34.2		
	Week 2	08JAN2014	08:00	<0.750		267		
	Week 4	22JAN2014	08:00	<0.750		345		
	End of Treatment	31JAN2014	09:00	<0.750		281		Week 6 (9 days after week 4 visit)
203-0015/85/M/W2	Screening	17JAN2014	09:00	44.8		34.8		
	Week 2	07FEB2014	08:00	<0.750		344		
	Week 4	24FEB2014	09:00	64.2		29.5		
	Week 8	28MAR2014	09:00	45.5		32.3		

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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
203-0017/58/M/W2	Screening	18FEB2014	09:00	94.3		34.1		
	Week 2	12MAR2014	09:00	<0.750		236		

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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
203-0018/58/F/W2	Screening	26MAR2014	08:00	54.0		47.1		
	Week 2	14APR2014	09:00	<0.750		418		
	Week 8	04JUN2014	09:00	69.8		44.7		
205-0001/77/M/W2	Screening	14FEB2012	09:00	25.6		47.1		
	Week 4	14MAR2012	09:00	<0.750		187		
	Week 8	13APR2012	09:00	53.3		59.6		
	Week 12	08MAY2012	09:00	53.5		61.2		
	Week 16	08JUN2012	09:00	41.0		67.0		
	Week 20	06JUL2012	09:00	22.4		57.1		
	Week 24	06AUG2012	09:00	70.8		79.8		
	Week 28	31AUG2012	09:00	38.5		55.2		
	Week 32	28SEP2012	09:00	70.3		61.0		

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Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
	Week 36	23OCT2012	09:00	58.1		51.6		
	Week 40	20NOV2012	09:00	56.9		58.8		Uns Continuation

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Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
205-0001/77/M/W2	Week 44	20DEC2012	09:00	43.4		52.2		Uns Continuation
	Week 52	13FEB2013	09:00	52.9		63.0		Uns Continuation
	Week 56	13MAR2013	09:00	95.4		62.0		Uns Continuation
	Week 68	13JUN2013	09:00	51.7		56.3		Uns Continuation
	Week 70	25JUN2013	09:30	67.2		72.9		Uns Continuation
	Week 72	09JUL2013	08:30	45.5		56.0		Uns Continuation
	Week 74	19JUL2013	09:30	44.1		48.9		Uns Continuation
	Week 78	26AUG2013	09:40	47.8		44.1		Uns Continuation

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Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
	Week 80	10SEP2013	09:00	67.7		57.3		Uns Continuation
	Week 82	24SEP2013	09:30	63.0		44.3		Uns Continuation
205-0004/77/F/W2	Screening	12MAR2012	09:00	54.5		53.6		
	Week 4	12APR2012	09:00	1.08		101		Back up sample, no primary sample was received
	Week 8	10MAY2012	09:00	33.4		48.9		
	Week 12	05JUN2012	09:00	31.3		44.9		

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Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
205-0008/76/M/W2	Screening	20APR2012	09:00	56.3		44.7		
	Unscheduled	27APR2012	Unknown	68.8		38.8		Week 1
	Week 4	17MAY2012	09:00	<0.750		579		
205-0012/73/F/W2	Screening	27NOV2012	09:00	68.3		48.8		
	Week 4	27DEC2012	09:00	59.7		76.6		
205-0015/71/M/W2	Screening	07JUN2013	07:30	53.8		27.7		
	Week 2	27JUN2013	09:30	<0.750		372		
	Week 4	12JUL2013	08:30	1.16		463		
	Week 7	02AUG2013	08:00	1.21		704		
	Week 8	09AUG2013	10:30	0.942		800		
205-0016/70/M/W2	Screening	11JUN2013	08:30	18.1		45.3		
	Week 2	02JUL2013	09:30	<0.750		516		
	Week 4	19JUL2013	09:30	<0.750		347		
	Week 12	20SEP2013	10:00	<0.750		291		

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Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
205-0016/70/M/W2	Week 16	17OCT2013	11:00	<0.750		393		
	Week 20	14NOV2013	14:00	<0.750		326		
	Week 24	10DEC2013	10:45	<0.750		374		
	Week 28	10JAN2014	11:00	<0.750		233		
	Week 32	07FEB2014	11:15	<0.750		231		
	Week 36	07MAR2014	10:30	<0.750		256		
	Week 38	21MAR2014	10:30	<0.750		208		Uns Continuation
	Week 40	03APR2014	10:00	<0.750		648		Uns Continuation
	Week 44	29APR2014	09:30	<0.750		654		Uns Continuation
	Week 48	27MAY2014	10:15	<0.750		630		Uns Continuation

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE – ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE – WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
	Week 50	10JUN2014	10:30	1.49		532		Uns Continuation
	Week 52	24JUN2014	10:00	<0.750		720		Uns Continuation
	Week 56	22JUL2014	11:30	<0.750		310		Uns Continuation
	Week 60	11AUG2014	10:15	<0.750		772		Uns Continuation

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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
205-0016/70/M/W2	Week 64	11SEP2014	10:00	1.09		702		Uns Continuation
	Week 68	09OCT2014	10:30	1.20		770		Uns Continuation
	Week 72	06NOV2014	11:00	<0.750		679		Uns Continuation
	Week 76	04DEC2014	11:00	1.17		793		Uns Continuation
	Week 78	18DEC2014	10:00	0.917		632		Uns Continuation
	Week 80	30DEC2014	10:00	0.906		686		Uns Continuation
	Week 84	29JAN2015	10:20	<0.750		521		Uns Continuation
	Week 88	26FEB2015	10:50	<0.750		651		Uns Continuation

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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
	Week 92	26MAR2015	11:00	<0.750		694		Uns Continuation
	Week 96	21APR2015	11:00	<0.750		707		Uns Continuation
	Week 100	21MAY2015	11:00	<0.750		628		Uns Continuation
205-0017/71/M/W2	Screening	02AUG2013	10:00	60.2		59.0		
	Unscheduled	08AUG2013	Unknown	58.4		32.4		Week 1
	Week 4	26AUG2013	10:00	1.16		256		

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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
205-0017/71/M/W2	Week 8	24SEP2013	09:00	2.12		126		
	Week 12	25OCT2013	12:30	66.0		45.4		
	Week 16	22NOV2013	09:30	77.9		38.3		
	Week 20	20DEC2013	09:15	70.9		38.7		
	Week 24	14JAN2014	08:45	44.9		35.7		
205-0020/82/M/W2	Screening	01OCT2013	09:30	70.6		43.5		
	Week 2	17OCT2013	12:30	0.801		277		
	Week 4	31OCT2013	11:30	<0.750		306		
	Week 8	29NOV2013	09:30	58.1		51.0		
	Week 12	23DEC2013	09:00	76.4		43.2		
205-0022/67/M/W2	Screening	25OCT2013	10:00	69.5	62.35	53.2	49.75	
	Screening	25OCT2013	10:00	55.2		46.3		
	Week 2	12NOV2013	11:00	<0.750		527		
205-0024/80/M/W2	Screening	19NOV2013	09:45	69.8		44.4		

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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
205-0024/80/M/W2	Week 2	13DEC2013	09:40	<0.750		418		
	Week 4	23DEC2013	11:00	<0.750		700		
	Week 8	23JAN2014	12:30	<0.750		450		
	Week 12	25FEB2014	12:00	65.4		41.5		
205-0025/63/F/W2	Screening	21NOV2013	12:30	77.7		38.0		
	Week 2	03DEC2013	10:30	<0.750		301		
	Week 4	19DEC2013	10:00	3.57		95.3		
	Week 8	14JAN2014	11:15	26.9		67.0		
	Week 12	14FEB2014	10:30	43.1		36.5		
207-0001/81/F/W2	Screening	08MAR2012	11:30	92.8		56.0		
207-0005/74/M/W2	Screening	21MAY2012	13:30	115	103.1	73.8	68.45	

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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
	Screening	21MAY2012	13:30	91.2		63.1		Screening (collection date not found on visit report, date is between screening and week 1)
207-0006/73/M/W2	Screening	08JUN2012	11:30	68.0		33.2		
	Week 4	09JUL2012	09:30	<0.750		271		

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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
207-0006/73/M/W2	Week 8	06AUG2012	09:40	<0.750		256		
207-0008/66/M/W2	Screening	25JUN2012	12:00	78.5		51.9		
	Week 4	13AUG2012	09:25	<0.750		330		
207-0011/78/M/W2	Screening	09JAN2013	12:45	73.3		43.8		
207-0015/77/M/W2	Screening	08AUG2013	11:20	84.3		36.4		
	Week 2	20AUG2013	09:00	<0.750		423		
	Week 4	03SEP2013	11:45	<0.750		429		
	Week 8	01OCT2013	09:50	<0.750		642		
207-0020/77/M/W2	Screening	11JUN2014	10:20	75.7		25.6		
	Week 2	25JUN2014	09:45	<0.750		366		
	Week 4	09JUL2014	09:50	<0.750		104		
	Week 8	06AUG2014	09:45	71.3		33.5		
207-0021/74/M/W2	Screening	11JUN2014	11:15	70.0		28.6		
	Week 2	26JUN2014	10:35	<0.750		347		

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Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
207-0021/74/M/W2	Week 4	10JUL2014	11:30	<0.750		544		
	Week 8	07AUG2014	11:15	1.03		383		
	Week 12	04SEP2014	11:00	25.4		114		
	Week 16	02OCT2014	11:30	61.8		46.1		
	Week 20	30OCT2014	09:40	86.6		41.7		
	Week 24	28NOV2014	13:00	73.7		30.3		
	Week 28	29DEC2014	10:30	82.3		35.4		
	Week 32	23JAN2015	09:30	92.1		41.1		
207-0022/74/M/W2	Screening	30JUN2014	10:45	48.8		16.2		
	Week 2	17JUL2014	11:05	<0.750		314		
	Week 8	28AUG2014	10:30	59.3		10.5		
208-0001/59/M/W2	Screening	14SEP2012	09:15	75.2		37.6		
	Week 4	11OCT2012	08:30	<0.750		199		
	Week 8	07NOV2012	08:30	21.7		94.3		

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Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
208-0001/59/M/W2	Week 12	05DEC2012	08:50	115		72.3		
	Week 16	02JAN2013	08:20	78.6		26.7		
	Week 20	30JAN2013	08:40	63.6		30.5		
	Week 24	01MAR2013	09:00	92.9		61.7		
	Week 28	27MAR2013	08:45	90.9		37.6		
	Week 32	24APR2013	09:00	81.1		18.7		
	Week 36	22MAY2013	08:30	82.6		63.9		
	Week 40	19JUN2013	08:30	48.7		19.9		Uns Continuation
	Week 44	17JUL2013	08:30	71.8		36.4		Uns Continuation
	Week 48	19AUG2013	08:15	57.3		33.5		Uns Continuation
	Week 52	11SEP2013	08:30	67.0		49.7		Uns Continuation

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Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
	Week 56	09OCT2013	08:15	64.8		22.9		Uns Continuation
	Week 60	06NOV2013	08:30	103		53.8		Uns Continuation
	Week 64	04DEC2013	09:00	73.9		43.2		Uns Continuation

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Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
208-0001/59/M/W2	Week 68	02JAN2014	08:50	76.7		31.9		Uns Continuation
	Week 72	29JAN2014	08:30	89.4		39.4		Uns Continuation
	Week 76	26FEB2014	08:30	58.1		21.8		Uns Continuation
	Week 80	26MAR2014	08:40	64.5		32.9		Uns Continuation
	Week 84	23APR2014	09:00	81.6		34.3		Uns Continuation
	Week 86	07MAY2014	08:10	60.7		29.0		Uns Continuation
	Week 88	21MAY2014	08:30	62.9		20.8		Uns Continuation
	Unscheduled	18JUN2014	08:15	66.0		43.9		Week 92
	Unscheduled	16JUL2014	08:20	66.1		47.9		Week 96

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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
	Week 100	13AUG2014	09:15	97.9		33.2		Uns Continuation
	Week 104	10SEP2014	09:00	80.3		39.2		Uns Continuation
	Week 108	08OCT2014	08:20	64.0		34.6		Uns Continuation
	Week 110	22OCT2014	08:15	75.1		40.3		Uns Continuation
	Week 112	05NOV2014	08:30	52.4		19.3		Retest in sample list from CLS

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE – ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE – WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
208-0001/59/M/W2	Week 116	03DEC2014	09:40	94.2		39.5		Uns Continuation
	Week 120	02JAN2015	08:30	79.9		40.1		Uns Continuation
	Week 124	28JAN2015	08:15	82.8		52.6		Uns Continuation
	Week 128	25FEB2015	08:30	49.6		32.8		Uns Continuation
	Week 132	25MAR2015	08:15	47.1		24.6		Uns Continuation
	Week 136	Unknown	Unknown	85.5		44.8		Uns Continuation
	Week 140	Unknown	Unknown	62.4		24.6		Uns Continuation
208-0002/82/F/W2	Screening	14SEP2012	10:00	49.8		40.2		
	Week 4	11OCT2012	09:00	0.804		144		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE – ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
	Week 8	07NOV2012	08:45	33.8		35.3		
208-0006/69/F/W2	Screening	19AUG2013	09:45	88.8		56.2		
	Week 2	05SEP2013	09:00	<0.750		160		
	Week 4	18SEP2013	09:00	<0.750		273		
	Week 8	16OCT2013	09:15	<0.750		183		

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[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
208-0006/69/F/W2	Week 12	13NOV2013	08:45	82.6		70.9		
208-0007/53/M/W2	Screening	23JUN2014	10:00	190		93.8		
	Week 2	16JUL2014	08:30	<0.750		511		
	Week 4	30JUL2014	08:30	106		69.9		
	Week 8	27AUG2014	08:20	91.9		48.8		
	Week 12	25SEP2014	08:30	112		30.2		
209-0001/66/M/W2	Screening	08NOV2012	10:30	62.7		26.6		
	Week 4	06DEC2012	10:10	0.849		327		
	Week 8	03JAN2013	09:50	38.5		30.4		
	Week 12	31JAN2013	10:15	43.4		20.0		
209-0004/74/M/W2	Screening	28MAR2013	10:15	57.6		31.6		
	Week 4	30APR2013	09:15	<0.750		471		
	Week 8	30MAY2013	09:30	<0.750		391		
	Week 12	25JUN2013	10:45	<0.750		403		

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[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
209-0008/66/M/W2	Screening	26JUN2013	07:45	56.7		40.4		
	Week 4	31JUL2013	09:30	<0.750		170		
	Week 12	24SEP2013	09:00	64.5		34.5		
209-0012/63/M/W2	Screening	26NOV2013	10:10	80.9		79.9		
	Week 2	10DEC2013	10:20	<0.750		477		
	Week 4	23DEC2013	09:00	<0.750		384		
	Week 8	22JAN2014	09:30	114		104		
	Week 12	19FEB2014	09:00	82.6		54.0		
	Week 16	19MAR2014	10:00	109		72.7		
	Week 20	16APR2014	09:00	108		54.6		
	Week 24	15MAY2014	10:00	97.1		46.0		
209-0013/52/M/W2	Screening	10DEC2013	09:00	75.3		52.6		
	Week 4	14JAN2014	09:30	<0.750		188		
	Week 8	12FEB2014	09:35	95.1		57.6		

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[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
209-0013/52/M/W2	Week 12	11MAR2014	11:05	76.5		43.9		
	Week 16	08APR2014	10:40	107		48.8		
	Week 20	07MAY2014	09:30	84.5		47.7		
	Week 24	04JUN2014	10:15	75.5		44.6		
	Week 28	02JUL2014	09:15	92.2		51.1		
	Week 32	29JUL2014	10:15	80.5		51.4		
	Week 36	26AUG2014	09:40	81.2		53.5		
210-0001/67/M/W2	Screening	28AUG2013	09:30	23.8		48.6		
	Week 2	05SEP2013	11:00	<0.750		360		
	Week 4	19SEP2013	09:30	<0.750		474		
	Week 8	17OCT2013	10:00	108		67.2		
	Week 12	14NOV2013	10:15	121		59.0		
	Week 16	12DEC2013	09:45					Empty tube
	Week 20	09JAN2014	09:30	72.3		44.0		

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[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
210-0001/67/M/W2	Week 24	06FEB2014	09:30	85.6		40.7		
210-0002/80/M/W2	Screening	02OCT2013	10:15	96.9		41.8		
	Week 2	16OCT2013	11:00	<0.750		400		
	Week 4	31OCT2013	10:10	<0.750		359		
	Week 8	29NOV2013	10:10	98.8		54.4		
	Week 12	23DEC2013	09:30	109		63.3		
	Week 16	22JAN2014	09:15	88.4		45.1		
	Week 20	19FEB2014	09:30	106		48.6		
	Week 24	19MAR2014	09:15	78.8		44.9		
	Week 32	14MAY2014	09:30	106		53.1		
	Week 36	12JUN2014	09:30	126		51.0		
	Week 40	09JUL2014	09:30	97.9		46.6		Uns Continuation

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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
	Week 44	06AUG2014	09:20	110		64.9		Uns Continuation
210-0007/72/M/W2	Screening	03JUL2014	09:30	62.1		29.5		

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[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
210-0007/72/M/W2	Week 2	16JUL2014	10:15	<0.750		287		
	Week 4	31JUL2014	09:15	<0.750		286		
	Week 8	28AUG2014	09:10	60.8		52.0		
	Week 12	24SEP2014	09:30	54.5		32.8		
	Week 20	27NOV2014	09:45	53.8		33.5		
	Week 24	22DEC2014	10:10	65.5		42.5		
	Week 28	22JAN2015	09:45	68.2		41.8		
	Week 32	19FEB2015	10:40	63.0		34.3		
	Week 36	19MAR2015	09:45	73.3		30.6		
210-0009/49/F/W2	Screening	05NOV2014	09:30	49.6		35.0		
	Week 2	19NOV2014	10:00	0.978		247		
	Week 4	03DEC2014	10:00	<0.750		224		
	Week 8	29DEC2014	09:40	8.70		94.8		
	Week 12	28JAN2015	10:00	58.9		27.3		

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[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
210-0011/73/M/W2	Screening	12NOV2014	09:30	35.9		8.83		
	Week 2	26NOV2014	10:05	<0.750		134		
	Week 4	10DEC2014	10:00	1.11		190		
	Week 8	08JAN2015	10:15	0.889		170		
210-0012/47/F/W2	Screening	11DEC2014	09:30	108		23.4		
	Week 2	22DEC2014	10:00	0.973		239		
	Week 4	08JAN2015	09:35	<0.750		201		
	Week 8	05FEB2015	09:55	51.5		39.6		
	Week 12	05MAR2015	09:40	55.0		25.9		
210-0014/71/F/W2	Screening	15JAN2015	10:15	59.7		79.1		
	Week 2	05FEB2015	10:00	1.34		232		
	Week 4	19FEB2015	10:35	3.56		632		
	Week 8	19MAR2015	09:40	39.2		134		
	Week 12	16APR2015	10:10	57.9		37.1		

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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
251-0001/55/F/W2	Screening	23JUL2012	14:50	81.4		29.3		
	Week 4	21AUG2012	12:00	<0.750		213		Retest in sample list from CLS
	Week 8	18SEP2012	11:30	<0.750		148		
	Week 12	16OCT2012	12:00	1.23		90.2		
252-0002/76/M/W2	Screening	21AUG2012	11:45	57.5	57.3	24.2	24.5	
	Unscheduled	21AUG2012	11:45	57.1		24.8		Screening
	Week 4	Unknown	Unknown	55.0		13.2		
252-0003/68/M/W2	Screening	11DEC2012	14:00	52.5		18.8		
	Week 4	22JAN2013	10:10	<0.750		301		
	Week 8	19FEB2013	10:15	0.784		110		
	Week 12	19MAR2013	09:30	107		76.6		
252-0007/77/M/W2	Screening	11FEB2014	08:25	72.8		23.3		

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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
252-0011/81/M/BL	Screening	18NOV2014	11:20	50.9		14.8		
	Week 2	02DEC2014	08:45	<0.750		125		

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[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
252-0011/81/M/BL	Week 8	13JAN2015	08:15	2.02		127		
	Week 12	10FEB2015	08:25	1.32		175		
	Week 16	10MAR2015	12:00	0.999		125		
	Week 20	07APR2015	09:00	1.29		92.8		
	Week 24	05MAY2015	08:50	26.5		34.9		
253-0002/63/M/W2	Screening	02MAR2012	13:45	64.0		39.6		
	Week 4	30MAR2012	10:10	0.990		210		
	Week 8	27APR2012	11:15	68.2		26.5		
253-0010/76/M/W2	Screening	31MAY2013	10:30	67.2		36.9		
	Week 4	28JUN2013	11:00	<0.750		601		
	Week 8	26JUL2013	11:30	<0.750		403		
	Week 12	23AUG2013	11:00	72.1		83.9		
	Week 16	20SEP2013	10:40	110		44.5		
	Week 20	18OCT2013	10:30	108		46.9		

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[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
253-0010/76/M/W2	Week 24	18NOV2013	10:30	66.2		48.1		
254-0001/69/M/W2	Screening	04MAY2012	12:15	53.0		30.5		
	Week 4	13JUN2012	12:30	<0.750		245		
	Week 8	10JUL2012	13:05	77.6		38.0		
	Week 12	06AUG2012	13:00	80.1		68.9		
257-0001/47/M/A4	Screening	29MAR2012	12:45	63.3		32.0		
	Week 4	26APR2012	14:25	1.77		198		
	Week 8	24MAY2012	10:55	48.5		36.3		
257-0002/56/M/W2	Screening	12APR2012	10:35	93.6		46.3		
257-0007/80/M/W2	Screening	13FEB2013	09:13	54.6	62.1	34.9	39.15	

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[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
	Unscheduled	13FEB2013	09:13	69.6		43.4		Screening (collection date not found on visit report, date is between screening and week 1)
	Unscheduled	21FEB2013	Unknown	73.4		44.1		Week 1
	Week 2	28FEB2013	12:00	<0.750		387		
	Week 4	14MAR2013	11:05	<0.750		493		

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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
257-0007/80/M/W2	Week 8	11APR2013	10:50	<0.750		493		
	Week 12	09MAY2013	11:20	51.1		67.8		
257-0008/80/F/W2	Screening	21MAR2013	13:15	62.8	60.95	27.8	26.85	
	Unscheduled	21MAR2013	13:15	59.1		25.9		Screening (collection date not found on visit report, date is between screening and week 1)
	Week 2	04APR2013	10:28	<0.750		238		
	Week 4	18APR2013	10:05	<0.750		223		
	Week 8	16MAY2013	12:05	<0.750		201		
	Week 12	13JUN2013	12:50	<0.750		349		
257-0010/42/M/BL	Screening	16MAY2013	14:35	57.4	75.2	29.4	28.9	

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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
	Unscheduled	16MAY2013	14:35	93.0		28.4		Screening (collection date not found on visit report, date is between screening and week 1)
	Week 2	30MAY2013	10:19	<0.750		346		
	Week 4	13JUN2013	12:40	<0.750		503		
	Week 8	08JUN2013	14:13	<0.750		276		
	Week 12	05AUG2013	14:12	<0.750		176		

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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
257-0012/75/M/W2	Screening	09MAY2013	11:08	39.4		16.5		
	Week 2	23MAY2013	11:10	1.11		114		
	Week 4	07JUN2013	11:24	2.08		92.3		
257-0015/69/F/BL	Screening	31MAR2014	13:57	40.9		13.8		
257-0017/74/M/A8	Screening	28APR2014	14:20	97.8		59.4		
	Week 2	12MAY2014	14:10	1.56		649		
	Week 4	27MAY2014	15:30	0.987		907		
	Week 8	23JUN2014	15:05	1.45		240		
257-0018/53/M/A6	Screening	17APR2014	11:00	89.5		22.6		
	Week 2	02MAY2014	14:20	<0.750		228		
	Week 4	19MAY2014	14:20	40.8		11.6		
257-0022/60/M/W2	Screening	26NOV2014	11:35	86.6		27.2		
	Week 2	08DEC2014	14:10	1.83		212		
	Week 4	22DEC2014	14:00	3.56		227		

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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
257-0022/60/M/W2	Week 8	19JAN2015	15:20	8.14		140		
	Unscheduled	26JAN2015	Unknown	7.57		147		Week 9
257-0024/75/M/W2	Screening	15DEC2014	13:20	153		50.0		
	Week 2	29DEC2014	13:20	1.54		384		
	Week 4	12JAN2015	13:30	<0.750		153		
	Week 8	09FEB2015	15:34	<0.750		314		
257-0025/69/M/BL	Screening	15DEC2014	14:15	73.2		29.1		
	Week 2	29DEC2014	13:44	1.05		256		
	Week 4	12JAN2015	13:20	1.48		408		
	Week 8	09FEB2015	15:05	<0.750		269		
	Unscheduled	16FEB2015	Unknown	<0.750		225		Week 9
	Week 12	09MAR2015	14:00	<0.750		222		
257-0026/65/M/W2	Screening	12JAN2015	15:10	112		102		
	Week 2	26JAN2015	13:45	1.70		595		

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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
257-0026/65/M/W2	Week 4	09FEB2015	14:45	28.0		135		
	Week 8	09MAR2015	14:00	73.7		52.6		
	Week 12	Unknown	Unknown	69.5		43.2		
257-0027/52/M/A6	Screening	12JAN2015	15:45	138		64.4		
	Week 2	26JAN2015	16:10	0.926		477		
	Week 4	09FEB2015	15:00	<0.750		647		
258-0005/64/M/OTH	Screening	31JUL2013	10:50	44.6		24.1		
	Week 2	21AUG2013	11:20	<0.750		251		
	Week 4	04SEP2013	11:15	<0.750		342		
	Week 8	02OCT2013	11:25	<0.750		203		
258-0007/74/M/W2	Screening	02OCT2013	12:28	69.2		23.9		
	Week 2	18OCT2013	11:58	1.46		248		

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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
	Week 4	01NOV2013	11:32	1.22		189		
258-0008/70/M/W2	Screening	06NOV2013	10:14	113		64.4		

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Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
258-0009/64/M/W2	Screening	16MAY2014	12:09	58.2		19.7		
	Week 2	30MAY2014	10:05	<0.750		336		
	Week 4	11JUN2014	10:05	<0.750		178		
	Week 8	09JUL2014	10:38	<0.750		240		
	Week 12	06AUG2014	10:40	1.22		121		
	Week 16	03SEP2014	10:45	61.0		72.8		
	Week 20	01OCT2014	10:25	67.5		22.7		
	Week 24	29OCT2014	11:43	84.0		45.1		
258-0010/53/M/W2	Screening	30MAY2014	11:12	53.7		15.0		
	Week 2	11JUN2014	11:20	<0.750		276		
	Week 4	25JUN2014	10:10	77.6		16.1		
	Week 8	21JUL2014	10:20	52.5		16.5		
	Week 12	20AUG2014	09:12	51.9		14.5		
	Week 16	17SEP2014	10:20	63.3		20.6		

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Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
258-0010/53/M/W2	Week 20	16OCT2014	09:30	71.0		30.7		
	Week 24	12NOV2014	10:05	86.6		17.0		
258-0012/66/F/W2	Screening	09JUL2014	10:30	83.8		35.8		
	Week 2	23JUL2014	12:20	<0.750		422		
	Week 4	06AUG2014	12:15	103		60.2		
	Week 8	03SEP2014	12:05	78.4		36.3		
	Week 12	01OCT2014	11:20	112		37.6		
258-0015/65/M/W2	Screening	28NOV2014	09:33	138		49.0		
	Week 2	10DEC2014	09:43	<0.750		517		
259-0001/68/F/W2	Screening	24MAY2013	09:15	44.1		34.9		
	Week 2	13JUN2013	13:20	1.02		176		
	Week 4	26JUN2013	14:00	21.5		17.7		
	Week 8	24JUL2013	13:20	31.4		23.4		
	Week 12	21AUG2013	13:50	29.7		15.3		

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Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
259-0001/68/F/W2	Week 20	16OCT2013	13:20	41.2		19.2		
	Week 36	05FEB2014	10:15	34.0		21.4		
	Week 40	05MAR2014	13:00	32.1		17.7		Uns Continuation
	Week 48	30APR2014	10:45	37.5		22.7		Uns Continuation
	Week 52	28MAY2014	10:50	53.3		24.3		Uns Continuation
259-0002/54/F/W2	Screening	04SEP2013	12:45	63.1		21.9		
	Week 2	18SEP2013	11:15	<0.750		140		
	Week 4	02OCT2013	11:56	<0.750		120		
	Week 8	30OCT2013	12:05	75.9		31.0		
	Week 12	27NOV2013	11:30	79.3		32.8		
260-0003/81/M/A7	Screening	22OCT2014	14:00	84.6		34.7		
	Week 2	12NOV2014	11:40	1.28		683		

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Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
	Week 4	26NOV2014	10:50	1.99		881		
	Week 8	22DEC2014	11:30	1.85		751		

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[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE – ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE – WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
260-0003/81/M/A7	Week 12	21JAN2015	11:30	67.6		82.6		
	Week 16	18FEB2015	11:00	77.1		44.2		
	Week 20	18MAR2015	11:00	78.6		41.8		
	Week 24	15APR2015	10:30	93.6		33.9		
	Week 28	13MAY2015	10:30	81.8		59.9		
301-0005/61/M/A2	Screening	17MAY2012	10:00	84.4		30.8		
	Week 4	14JUN2012	10:05	<0.750		369		
	Week 8	12JUL2012	10:00	76.9		34.8		
	Week 12	09AUG2012	09:20	81.4		33.3		
301-0007/55/F/A2	Screening	26DEC2012	09:35	55.0		38.7		
	Week 4	25JAN2013	10:10	<0.750		517		
	Week 8	22FEB2013	09:56	<0.750		539		
301-0009/55/M/A2	Screening	08JAN2013	09:45	63.5		27.8		
	Week 4	31JAN2013	09:55	63.9		28.1		

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[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
301-0009/55/M/A2	Week 8	01MAR2013	09:45	53.5		22.1		
	Week 12	28MAR2013	10:00	85.7		14.1		
302-0002/32/F/A2	Screening	03NOV2011	11:00	39.9		7.48		
	Week 4	29NOV2011	10:50	50.6		10.3		
302-0004/57/M/A2	Screening	04JAN2012	09:15	76.7		23.1		
	Week 4	01FEB2012	09:15	<0.750		357		
	Week 8	28FEB2012	09:15	<0.750		149		
302-0007/76/M/A2	Screening	08FEB2012	08:44	104		51.6		
	Week 4	06MAR2012	09:00	<0.750		608		
	Week 8	03APR2012	09:10	<0.750		339		
	Week 12	01MAY2012	08:35	50.8		94.5		
302-0008/37/M/A2	Screening	23FEB2012	09:12	120		36.5		
	Week 4	20MAR2012	09:30	<0.750		121		
	Week 8	17APR2012	09:20	107		34.0		

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[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
302-0010/45/M/A2	Screening	12APR2012	10:35	103		41.8		
	Week 4	08MAY2012	09:15	<0.750		730		
	Week 8	05JUN2012	09:20	<0.750		700		
	Week 12	03JUL2012	08:55	<0.750		204		
302-0011/52/M/A2	Screening	17APR2012	11:02	120		33.7		
	Week 4	15MAY2012	09:25	<0.750		317		
302-0015/60/M/A2	Screening	11APR2013	08:40	87.3		43.8		
	Week 2	23APR2013	08:50	<0.750		363		
	Week 4	07MAY2013	08:55	<0.750		564		
	Week 8	04JUN2013	09:10	<0.750		490		
	Week 12	02JUL2013	08:40	<0.750		388		

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[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
302-0016/60/M/A2	Screening	11APR2013	09:05	69.4		26.5		Additional sample with visit screening-1 is listed in sample list
	Week 2	23APR2013	09:20	<0.750		221		
	Week 4	07MAY2013	08:50	<0.750		253		

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[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
302-0016/60/M/A2	Week 8	04JUN2013	09:05	70.6		17.7		
	Week 12	02JUL2013	08:40	69.6		24.5		
302-0019/52/M/A2	Screening	09MAY2013	09:15	96.5		42.1		
	Week 2	21MAY2013	09:20	<0.750		502		
	Week 4	04JUN2013	09:15	<0.750		676		
	Week 8	02JUL2013	09:10	4.44		117		
	Week 12	30JUL2013	09:15	90.7		32.4		
302-0022/65/M/A2	Screening	04JUL2013	09:05	76.4		27.3		
	Week 2	16JUL2013	09:30	<0.750		310		
	Week 4	30JUL2013	09:30	<0.750		232		
	Week 8	27AUG2013	09:00	58.5		58.0		
302-0023/68/M/A2	Screening	15SEP2009	Unknown	70.2		25.1		
	Week 2	17SEP2013	08:20	1.77		214		
	Week 4	01OCT2013	09:13	1.18		240		

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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
302-0024/66/F/A2	Screening	04JAN2013	Unknown	89.9		35.1		
	Week 2	01OCT2013	09:08	<0.750		406		
	Week 4	15OCT2013	08:28	<0.750		239		
	Week 8	12NOV2013	08:20	107		47.3		
	Week 12	10DEC2013	08:10	105		37.7		
302-0025/40/M/A2	Screening	07SEP2011	Unknown	88.9		25.1		
	Week 2	29OCT2013	08:15	0.904		607		
302-0026/49/M/A2	Screening	05NOV2013	10:45	126		41.6		
	Week 2	19NOV2013	08:25	<0.750		556		
	Week 4	03DEC2013	08:50	<0.750		714		
	Week 8	31DEC2013	08:40	41.6		126		
	Week 12	28JAN2014	09:35	154		46.3		
	Week 16	25FEB2014	08:55	137		41.7		
	Week 20	25MAR2014	09:00	127		41.8		

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[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
302-0026/49/M/A2	Week 24	22APR2014	09:00	140		33.1		
	Week 28	22MAY2014	09:10	134		39.1		
	Week 32	17JUN2014	09:30	85.5		36.1		
	Week 36	15JUL2014	08:40	118		36.7		
303-0001/50/M/A2	Screening	20JAN2012	09:20	91.8		31.7		
	Week 4	22FEB2012	13:25	51.0		99.6		
	Week 8	21MAR2012	14:30	94.2		35.5		
	Week 12	18APR2012	13:00	71.8		44.1		
303-0003/47/M/A2	Screening	14NOV2012	10:15	63.9		32.9		
	Week 4	19DEC2012	10:30	75.4		37.4		
	Week 8	16JAN2013	10:00	62.0		32.6		
	Week 12	15FEB2013	14:00	69.4		37.8		
303-0004/18/M/A2	Screening	26NOV2012	14:50	104		19.1		
	Week 4	02JAN2013	14:00	<0.750		295		

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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
303-0004/18/M/A2	Week 8	30JAN2013	13:30	1.10		85.2		
	Week 12	27FEB2013	13:50	46.7		14.0		
303-0006/64/M/A2	Screening	27MAR2013	15:10	83.0		24.0		
	Week 4	01MAY2013	13:30	63.8		18.3		
	Week 8	29MAY2013	13:25	45.6		23.4		
303-0007/50/M/A2	Screening	03JUL2013	Unknown	107		19.1		
	Week 2	31JUL2013	13:30	<0.750		291		
	Week 4	14AUG2013	13:30	<0.750		230		
	Week 8	11SEP2013	13:25	63.8		19.5		
304-0001/54/M/A2	Screening	30OCT2012	10:30	52.4		17.5		
	Week 4	27NOV2012	11:00	54.1		39.0		
304-0005/58/M/A2	Screening	30MAY2013	11:16	62.5		32.2		
	Week 2	13JUN2013	08:15	<0.750		143		
	Week 4	26JUN2013	08:30	<0.750		170		

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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
305-0002/57/M/A2	Screening	13FEB2012	09:15	189		38.6		
305-0003/50/M/A2	Screening	26AUG2008	Unknown	106		39.6		
	Week 4	09MAR2012	09:00	<0.750		245		
	Week 8	06APR2012	09:00	114		51.7		
	Week 12	04MAY2012	09:00	79.9		36.5		
	Week 16	01JUN2012	08:45	74.9		42.6		
	Week 20	29JUN2012	08:52	80.9		38.7		
	Week 24	27JUL2012	08:32	110		41.2		
305-0005/48/M/A2	Screening	15FEB2012	11:35	112		15.0		
	Week 4	15MAR2012	09:09	78.7		42.7		
305-0006/65/M/A2	Screening	07MAR2012	09:20	77.8		37.3		
	Week 4	28MAR2012	12:15	<0.750		362		
	Week 8	25APR2012	12:30	101		42.3		
	Week 12	23MAY2012	12:09	86.0		38.8		

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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
305-0006/65/M/A2	Week 16	19JUN2012	12:25	141		53.5		
	Week 20	18JUL2012	12:40	174		62.5		
	Week 24	15AUG2012	12:40	101		52.0		
305-0009/45/F/A2	Screening	11APR2012	09:30	87.9		60.8		
	Week 4	01MAY2012	11:50	<0.750		853		
	Week 8	30MAY2012	11:53	0.812		974		
	Week 12	27JUN2012	12:20	<0.750		731		
	Week 16	25JUL2012	12:50	<0.750		941		
	Week 20	22AUG2012	13:00	1.85		1010		
	Week 24	19SEP2012	13:05	<0.750		944		
305-0010/64/F/A2	Screening	16APR2012	11:20	93.3		41.2		
	Week 4	08MAY2012	12:40	<0.750		223		
	Week 8	05JUN2012	13:35	17.0		82.0		
	Week 12	04JUL2012	13:00	58.9		36.3		

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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
305-0011/68/M/A2	Screening	20APR2012	12:00	51.3		35.3		
	Week 4	18MAY2012	08:20	1.41		316		
	Week 8	15JUN2012	07:50	41.4		15.8		
	Week 12	13JUL2012	07:20	37.8		16.7		
	Week 16	10AUG2012	07:50	66.6		29.1		
305-0012/62/F/A2	Screening	03MAY2012	15:10	101		60.2		
	Week 4	25MAY2012	08:20	<0.750		762		
	Week 8	22JUN2012	08:20	<0.750		831		
	Week 12	20JUL2012	09:02	<0.750		431		
	Week 16	17AUG2012	07:42	<0.750		381		
	Week 20	14SEP2012	08:11	<0.750		345		
	Week 24	12OCT2012	07:56	0.774		203		
	Week 28	09NOV2012	07:55	<0.750		212		
	Week 32	07DEC2012	07:40	<0.750		190		

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[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
305-0012/62/F/A2	Week 36	04JAN2013	07:55	<0.750		184		
305-0014/61/F/A2	Screening	04JUL2012	08:00	69.0		32.4		
	Week 4	31JUL2012	11:30	<0.750		569		
	Week 8	28AUG2012	12:22	<0.750		582		
	Week 12	25SEP2012	12:09	<0.750		604		
305-0019/35/M/A2	Screening	05SEP2012	10:33	42.9		17.7		
	Week 4	02OCT2012	11:55	2.42		404		
	Week 8	30OCT2012	12:33	41.8		20.3		
305-0023/54/M/A2	Screening	02JAN2013	09:45	60.1		51.9		
	Week 4	29JAN2013	12:10	<0.750		393		
	Week 8	26FEB2013	12:09	49.8		45.7		
	Week 12	29MAR2013	07:40	52.4		39.0		
	Week 16	25APR2013	08:10	40.5		48.7		
305-0025/77/F/A2	Screening	15JAN2013	14:40	132		61.3		

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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
305-0025/77/F/A2	Week 4	15FEB2013	12:15	132		51.3		
	Week 8	12MAR2013	11:45	120		39.1		
	Week 12	09APR2013	10:50	121		34.0		
305-0026/45/M/A2	Screening	11MAR2002	Unknown	107		34.9		
	Week 4	19MAR2013	12:40	<0.750		616		
	Week 8	16APR2013	13:00	<0.750		225		
	Week 12	14MAY2013	13:05	118		66.2		
	Week 20	09JUL2013	13:05	75.5		37.7		
	Week 24	06AUG2013	13:00	64.8		32.6		
305-0028/73/F/A2	Screening	13MAR2013	14:00	70.0		20.3		
	Week 4	03APR2013	13:00	<0.750		311		
	Week 8	30APR2013	13:22	<0.750		116		
	Week 12	29MAY2013	12:50	50.8		15.1		
305-0030/61/M/A2	Screening	28MAR2013	10:00	66.8		41.3		

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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
305-0030/61/M/A2	Week 4	23APR2013	12:00	<0.750		595		
305-0031/29/M/A2	Screening	26MAR2013	17:58	37.8		17.6		
	Week 4	26APR2013	09:33	<0.750		248		
305-0034/53/M/A2	Screening	26JUN2013	15:15	65.4		21.3		
	Week 2	10JUL2013	13:05	0.920		218		
	Week 4	22JUL2013	11:20	0.992		203		
305-0036/38/M/A2	Screening	27AUG2013	15:03	69.1		31.9		
	Week 2	12SEP2013	08:01	1.35		427		
	Week 4	26SEP2013	08:30	15.7		102		
	Week 8	24OCT2013	08:15	111		44.9		
	Week 12	19NOV2013	09:32	62.6		22.7		
305-0037/50/M/A2	Screening	17OCT2013	15:07	115		49.3		
	Week 4	14NOV2013	09:00	0.823		505		
	Week 8	12DEC2013	09:07	60.9		135		

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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
305-0037/50/M/A2	Week 12	09JAN2014	09:20	59.8		32.9		
305-0039/35/M/A2	Screening	22NOV2013	15:25	43.8		19.4		
	Week 2	05DEC2013	10:46	<0.750		233		
	Week 4	19DEC2013	10:50	<0.750		208		
305-0040/61/M/A2	Screening	11NOV2013	08:57	104		72.9		
	Week 2	19NOV2013	12:50	<0.750		234		
305-0043/70/M/A2	Screening	27JUN2014	09:00	118		38.0		
	Week 2	08JUL2014	12:40	1.07		497		
	Week 4	22JUL2014	13:00	<0.750		951		
	Week 8	19AUG2014	13:00	<0.750		867		
	Week 12	16SEP2014	10:51	0.810		554		
305-0044/67/M/A2	Screening	01JUL2014	16:30	66.3		60.9		
	Week 2	15JUL2014	12:30	<0.750		597		
	Week 4	29JUL2014	12:35	<0.750		843		

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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
305-0044/67/M/A2	Week 8	26AUG2014	12:50	<0.750		997		
	Week 12	26SEP2014	13:00	<0.750		429		
305-0045/65/M/A2	Screening	06OCT2014	08:06	59.1		42.7		
	Week 2	24OCT2014	08:00	<0.750		313		
	Week 4	07NOV2014	07:43	<0.750		283		
305-0047/58/M/A2	Screening	24DEC2014	09:30	124		64.9		
	Week 2	31DEC2014	14:00	<0.750		381		
	Week 4	14JAN2015	12:55	<0.750		596		
305-0048/55/M/A2	Screening	10FEB2015	15:20	234		146		
	Week 2	06MAR2015	09:30	<0.750		461		
	Week 4	20MAR2015	12:50	<0.750		547		
	Week 8	14APR2015	12:30	<0.750		531		
	Week 12	12MAY2015	13:07	57.8		64.4		
306-0001/56/M/A2	Screening	13FEB2012	08:30	85.8		28.4		

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Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
306-0001/56/M/A2	Week 4	09MAR2012	13:30	108		39.0		
	Week 8	06APR2012	13:30	115		45.4		
	Week 12	04MAY2012	09:00	132		40.2		
306-0002/73/M/A2	Screening	09FEB2012	09:30	76.5		45.4		
	Week 4	06MAR2012	09:30	0.835		515		
	Week 8	03APR2012	08:30	47.3		71.1		
	Week 12	30APR2012	15:00	103		54.9		
306-0005/69/F/A2	Screening	22FEB2012	10:30	79.7		43.7		
	Week 4	16MAR2012	09:00	<0.750		566		
	Week 8	13APR2012	09:00	64.3		55.9		
306-0006/43/M/A2	Screening	13MAR2012	10:00	91.3	80.6	32.0	30.1	
	Screening	13MAR2012	10:00	69.9		28.2		
	Week 4	10APR2012	13:00	<0.750		676		
306-0007/56/M/A2	Screening	01MAR2012	10:30	123		30.6		

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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
306-0007/56/M/A2	Week 4	26MAR2012	13:30	<0.750		267		
306-0008/40/M/A2	Screening	07MAR2012	10:30	39.4		18.0		
	Week 4	02APR2012	09:00	<0.750		211		
	Week 8	30APR2012	09:00	2.49		155		
306-0011/47/M/A2	Screening	13MAR2012	13:30	66.4		36.1		
	Week 4	05APR2012	10:00	1.06		281		
	Week 8	03MAY2012	10:00	53.0		30.3		
	Week 12	30MAY2012	10:00	38.8		23.4		
306-0012/61/M/A2	Screening	29MAR2012	10:06	107		44.1		
	Week 4	25APR2012	10:30	<0.750		494		
	Week 8	21MAY2012	09:00	<0.750		293		
	Week 12	19JUN2012	09:00	84.6		34.0		
	Week 16	17JUL2012	09:40	81.2		22.1		
	Week 20	13AUG2012	09:35	76.8		27.1		

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Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
306-0012/61/M/A2	Week 24	11SEP2012	09:15	77.8		46.8		
306-0014/47/M/A2	Screening	13APR2012	11:00	77.8		34.5		
	Week 4	11MAY2012	08:30	<0.750		203		
306-0017/49/M/A2	Screening	09JUL2012	09:00	72.4		35.7		
	Week 4	02AUG2012	09:00	<0.750		398		
306-0019/78/M/A2	Screening	20AUG2012	09:10	102		44.8		
	Week 4	13SEP2012	10:00	2.23		493		
	Week 8	08OCT2012	08:20	60.8		62.5		
	Week 12	05NOV2012	08:20	43.0		34.8		
306-0020/63/M/A2	Screening	27SEP2012	08:20	123		51.0		
	Week 4	25OCT2012	09:00	0.769		461		
	Week 8	22NOV2012	09:00	<0.750		239		
	Week 12	20DEC2012	09:30	95.0		36.9		
306-0023/68/M/A2	Screening	20NOV2012	09:00	70.1		26.8		

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Pharmacodynamic Analysis Results
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Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
306-0023/68/M/A2	Week 4	18DEC2012	11:00	1.01		476		
306-0026/58/M/A2	Screening	24JAN2013	10:00	44.5		29.8		
	Week 4	25FEB2013	13:50	1.63		85.7		
	Week 8	28MAR2013	09:00	49.5		31.2		
	Week 12	25APR2013	08:30	53.2		22.3		
	Week 16	23MAY2013	09:00	106		45.0		
	Week 20	20JUN2013	09:30	90.5		36.7		
	Week 24	18JUL2013	09:00	84.6		37.4		
	Week 28	15AUG2013	09:00	91.9		38.1		
	Week 32	12SEP2013	09:00	121		43.1		
	Week 36	08OCT2013	08:30	123		35.9		
306-0027/67/M/A2	Screening	06FEB2013	13:00	55.6		26.3		
	Week 4	13MAR2013	10:00	<0.750		442		
	Week 8	10APR2013	09:30	<0.750		453		

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Pharmacodynamic Analysis Results
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Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
306-0027/67/M/A2	Week 12	08MAY2013	09:30	<0.750		215		
	Week 16	05JUN2013	09:30	44.7		49.4		
	Week 20	03JUL2013	09:30	51.7		43.5		
	Week 24	31JUL2013	10:00	36.8		41.3		
	Week 28	28AUG2013	10:00	48.5		45.8		
	Week 32	25SEP2013	09:00	44.8		36.1		
	Week 36	23OCT2013	09:00	57.1		32.3		
	Week 40	20NOV2013	09:30	62.8		40.9		
	Week 44	18DEC2013	09:30	81.2		52.7		
	Week 48	15JAN2014	09:30	90.3		53.0		
	Week 52	12FEB2014	09:00	84.2		40.3		
	Week 56	12MAR2014	09:30	72.2		40.4		
	Week 60	09APR2014	09:30	56.1		35.1		
	Week 64	07MAY2014	09:40	68.0		31.7		

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[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
306-0027/67/M/A2	Week 68	06JUN2014	09:40	80.7		23.4		
	Week 72	02JUL2014	09:30	71.3		36.9		
306-0030/63/M/A2	Screening	12APR2013	11:30	67.3		27.2		
	Week 4	14MAY2013	09:00	<0.750		178		
306-0031/40/M/A2	Screening	07MAY2013	11:00	69.4		30.8		
	Week 4	05JUN2013	09:30	1.11		286		
	Week 8	03JUL2013	09:30	82.0		34.3		
306-0034/65/M/A2	Screening	20JUN2013	10:30	48.8		65.4		
	Week 2	08JUL2013	13:30	0.917		178		
	Week 4	25JUL2013	13:30	28.2		49.9		
306-0035/48/M/A2	Screening	27JUN2013	10:00	72.7		22.2		
	Week 2	15JUL2013	08:30	1.13		146		
	Week 4	29JUL2013	08:40	71.4		27.9		
	Week 8	26AUG2013	09:00	77.2		17.3		

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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
306-0036/73/M/A2	Screening	02JUL2013	10:00	38.9		12.7		
	Week 2	16JUL2013	10:00	0.975		234		
	Week 4	30JUL2013	08:40	0.897		213		
	Week 8	27AUG2013	08:30	42.5		17.3		
306-0038/66/M/A2	Screening	09AUG2013	13:30	111		86.3		
	Week 2	28AUG2013	09:00	<0.750		307		
	Week 4	11SEP2013	08:30	<0.750		253		
	Week 8	09OCT2013	08:30	79.5		57.4		
	Week 12	06NOV2013	08:30	93.6		36.3		
306-0039/62/M/A2	Screening	09AUG2013	13:30	78.4		18.1		
	Week 2	27AUG2013	09:00	1.97		229		
	Week 4	10SEP2013	09:00	0.989		447		
	Week 8	08OCT2013	08:30	0.901		249		
	Week 12	05NOV2013	08:30	0.832		177		

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Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
306-0040/44/F/A2	Screening	17SEP2013	10:00	74.4		53.7		
	Week 2	01OCT2013	08:30	1.01		336		
	Week 4	15OCT2013	10:00	0.817		231		
	Week 8	12NOV2013	09:30	83.0		35.3		
	Week 12	12DEC2013	10:00	55.3		37.6		
	Week 16	07JAN2014	09:30	69.9		25.2		
	Week 20	07FEB2014	12:00	26.6		28.4		
	Week 24	04MAR2014	10:30	33.0		21.7		
306-0041/62/M/A2	Screening	18OCT2013	10:30	83.8		24.8		
	Week 2	08NOV2013	09:30	<0.750		368		
	Week 4	22NOV2013	09:30	<0.750		638		
	Week 8	20DEC2013	08:30	0.806		665		
	Week 12	17JAN2014	09:00	<0.750		528		
	Week 16	11FEB2014	09:30	<0.750		316		

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Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
306-0043/56/M/A2	Screening	08MAY2014	10:30	106		35.5		
	Week 2	29MAY2014	09:30	0.919		259		
	Week 4	09JUN2014	09:20	74.1		47.5		
	Week 8	10JUL2014	09:00	118		44.7		
	Week 12	04AUG2014	09:00	89.6		33.0		
307-0002/61/M/A2	Screening	31OCT2011	10:30	82.0		34.0		
	Week 4	25NOV2011	11:05	73.2		21.3		
	Week 8	22DEC2011	10:25	59.6		12.5		
	Week 12	19JAN2012	13:26	39.9		12.3		
307-0003/68/M/A2	Screening	04NOV2011	08:00	56.8	83.4	45.8	44	Collected on 04Nov2011, screening in sample list
	Screening	08NOV2011	08:00	110		42.2		Collected on 08Nov2011

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Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
	Week 4	29NOV2011	09:10	<0.750		610		
	Week 8	27DEC2011	10:45	<0.750		421		
	Week 12	27JAN2012	08:45	94.2		61.8		

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Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
307-0003/68/M/A2	Week 16	21FEB2012	08:46	104		51.9		
	Week 20	20MAR2012	08:14	77.2		53.0		
	Week 24	16APR2012	09:50	96.2		58.4		
	Week 28	15MAY2012	10:25	53.3		30.3		
	Week 32	14JUN2012	10:25	77.0		39.6		
	Week 36	10JUL2012	10:25	85.4		56.6		
307-0004/60/M/A2	Screening	08NOV2011	09:09	83.2		26.4		
	Week 4	29NOV2011	09:20	<0.750		569		
	Week 8	27DEC2011	08:35	<0.750		530		
307-0008/58/M/A2	Screening	13DEC2011	08:30	124		47.9		
	Week 4	10JAN2012	08:54	26.5		171		
	Week 8	07FEB2012	08:40	115		52.1		
	Week 12	08MAR2012	08:40	164		69.9		
307-0011/75/M/A2	Screening	31JAN2012	11:55	85.4	73.15	22.8	17.75	

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Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
307-0011/75/M/A2	Screening	31JAN2012	11:55	60.9		12.7		
	Week 4	29FEB2012	08:54	55.2		27.6		
307-0014/61/M/A2	Screening	14FEB2012	09:13	89.6		49.6		
	Week 4	08MAR2012	08:30	<0.750		209		
	Week 8	05APR2012	13:30	141		71.2		
	Week 12	03MAY2012	13:40	112		51.5		
	Week 16	31MAY2012	13:23	131		51.3		
	Week 20	28JUN2012	13:28	166		71.3		
	Week 24	26JUL2012	09:09	105		44.8		
307-0018/70/M/A2	Screening	11JUN2012	09:40	80.6		30.8		
	Week 4	05JUL2012	14:00	<0.750		445		
	Week 8	03AUG2012	10:30	77.5		29.6		
	Week 12	30AUG2012	09:45	97.4		33.1		
	Week 16	27SEP2012	08:52	87.3		35.0		

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Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
307-0018/70/M/A2	Week 20	25OCT2012	08:50	71.0		26.7		
	Week 24	22NOV2012	09:20	77.4		30.2		
	Week 28	20DEC2012	09:07	81.1		25.8		
	Week 32	17JAN2013	08:42	80.3		24.3		
	Week 36	14FEB2013	09:18	83.9		30.5		
	Week 40	14MAR2013	18:34	89.9		29.7		
	Week 44	11APR2013	08:55	79.0		27.4		
	Week 48	09MAY2013	09:25	88.4		32.1		
307-0020/68/F/A2	Screening	14AUG2012	10:20	113		29.0		
	Week 4	04SEP2012	11:15	1.51		613		
	Week 8	02OCT2012	11:10	3.10		96.2		
	Week 12	30OCT2012	10:08	41.7		19.3		
307-0022/59/M/A2	Screening	21NOV2012	09:25	89.9		31.6		
	Week 4	17DEC2012	10:10	<0.750		436		

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307-0022/59/M/A2	Week 8	14JAN2013	08:31	73.1		34.2		
	Week 12	14FEB2013	09:53	59.6		26.3		
307-0025/68/M/A2	Screening	13DEC2012	10:00	108		39.2		
	Week 4	10JAN2013	09:55	<0.750		588		
	Week 8	05FEB2013	12:00	80.5		83.2		
	Week 12	07MAR2013	09:40	104		40.5		
	Week 16	03APR2013	09:50	104		42.3		
	Week 20	02MAY2013	09:15	130		42.2		
	Week 24	30MAY2013	10:10	147		55.1		
307-0026/65/M/A2	Screening	25DEC2012	10:00	85.8		30.9		
	Week 4	15JAN2013	09:00	<0.750		277		
	Week 8	14FEB2013	09:10	108		32.0		
	Week 12	12MAR2013	09:50	65.9		22.2		
	Week 16	09APR2013	08:20	103		39.9		

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307-0026/65/M/A2	Week 20	07MAY2013	08:32	128		32.5		
	Week 24	04JUN2013	11:05	130		32.5		
307-0030/53/M/A2	Screening	01MAR2013	09:35	91.3		26.4		
	Week 4	25MAR2013	09:36	<0.750		368		
	Week 8	22APR2013	12:07	<0.750		190		
307-0031/60/M/A2	Screening	12MAR2013	11:55	64.9		37.6		
	Week 4	03APR2013	09:15	<0.750		624		
	Week 8	02MAY2013	09:25	87.5		45.6		
	Week 12	30MAY2013	10:26	114		46.6		
	Week 16	27JUN2013	09:15	120		50.0		
	Week 20	25JUL2013	10:30	127		48.2		
	Week 24	22AUG2013	10:25	124		60.0		
	Week 28	17SEP2013	11:57	80.7		36.0		
	Week 32	17OCT2013	09:18	92.5		50.2		

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Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
307-0031/60/M/A2	Week 36	14NOV2013	09:40	86.1		37.5		
307-0032/74/F/A2	Screening	09APR2013	13:40	72.2		35.8		
	Week 2	18APR2013	13:30	0.836		202		
	Week 4	02MAY2013	13:20	1.28		221		
307-0037/61/M/A2	Screening	30SEP2013	09:53	105		51.4		
	Week 2	11OCT2013	08:54	<0.750		618		
	Week 4	24OCT2013	13:13	<0.750		445		
307-0039/51/M/A2	Screening	31OCT2013	11:14	129		67.0		
	Week 2	13NOV2013	09:25	<0.750		844		
	Week 4	27NOV2013	09:15	<0.750		1370		
	Week 8	23DEC2013	09:05	<0.750		305		
	Week 12	21JAN2014	10:13	124		71.7		
307-0040/65/M/A2	Screening	22MAY2014	09:35	64.1		21.9		
	Week 2	03JUN2014	13:45	<0.750		273		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE – ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE – WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
307-0040/65/M/A2	Week 4	17JUN2014	13:40	<0.750		132		
307-0043/54/M/A2	Screening	20JUN2014	11:10	74.8		31.2		
	Week 2	02JUL2014	08:55	0.832		401		
	Week 4	15JUL2014	08:59	<0.750		371		
	Week 8	12AUG2014	09:04	70.9		39.4		
	Week 12	09SEP2014	09:30	74.5		37.9		
	Week 16	08OCT2014	09:04	35.7		20.4		
307-0044/53/M/A2	Screening	26SEP2013	Unknown	73.9		24.6		
	Week 2	04JUL2014	09:36	0.925		319		
307-0045/48/M/A2	Screening	06JAN2012	Unknown	69.8		31.0		
	Week 2	14JUL2014	10:22	<0.750		373		
	Week 4	28JUL2014	11:15	<0.750		382		
	Week 8	25AUG2014	09:55	1.05		244		
	Week 12	22SEP2014	10:43	<0.750		185		

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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
307-0046/46/M/A2	Screening	08JUL2014	13:12	68.7		32.2		
	Week 2	24JUL2014	10:40	0.756		141		
308-0003/54/M/A2	Screening	13NOV2010	Unknown	83.7		33.4		
	Week 4	19FEB2013	09:05	<0.750		170		
	Week 8	19MAR2013	09:10	94.2		36.2		
	Week 12	16APR2013	09:30	83.8		33.6		
	Week 16	14MAY2013	09:25	105		37.9		
	Week 20	11JUN2013	09:30	80.2		31.3		
	Week 24	09JUL2013	09:05	97.5		32.1		
	Week 28	06AUG2013	09:00	81.3		35.4		
	Week 32	03SEP2013	09:00	86.7		37.3		
	Week 36	01OCT2013	12:20	69.0		58.4		
308-0005/68/F/A2	Screening	24APR2013	11:00	165		36.1		
	Week 4	21MAY2013	09:05	<0.750		337		

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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
308-0005/68/F/A2	Week 8	18JUN2013	08:55	<0.750		257		
	Week 12	16JUL2013	09:00	80.9		48.5		
309-0001/46/M/A2	Screening	29MAY2012	13:00	77.1		33.9		
	Week 4	02JUL2012	16:00	11.4		99.3		
	Week 8	30JUL2012	15:35	93.0		30.8		
	Week 12	27AUG2012	16:10	92.3		32.0		
309-0002/56/M/A2	Screening	04JUN2012	10:35	97.5		35.3		
309-0003/52/F/A2	Screening	11JUN2012	10:50	102		46.8		
	Week 4	11JUL2012	10:30	<0.750		640		
	Week 8	08AUG2012	10:10	<0.750		629		
	Week 12	05SEP2012	10:30	<0.750		204		
309-0004/55/M/A2	Screening	14JUN2012	11:50	71.0		47.5		
309-0008/38/M/A2	Screening	08FEB2013	11:50	101		24.6		
	Week 4	14MAR2013	09:45	106		20.6		

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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
309-0008/38/M/A2	Week 8	11APR2013	09:30	91.4		21.1		
	Week 12	09MAY2013	09:30	89.1		22.0		
309-0010/47/M/A2	Screening	07MAR2013	Unknown	108		57.6		
	Week 4	15APR2013	12:35	0.877		238		
	Week 8	13MAY2013	13:10	4.22		153		
	Week 12	10JUN2013	11:10	117		65.8		
	Week 16	08JUL2013	09:20	93.1		72.7		
	Week 20	05AUG2013	10:20	97.7		56.1		
	Week 24	02SEP2013	09:15	107		65.3		
	Week 28	30SEP2013	10:25	116		64.7		
	Week 32	28OCT2013	10:05	97.5		63.9		
	Week 36	25NOV2013	09:30	75.2		90.5		
	Week 40	23DEC2013	09:58	91.0		73.1		
	Week 44	20JAN2014	11:20	116		61.8		

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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
309-0010/47/M/A2	Week 48	17FEB2014	09:40	129		78.7		
	Week 52	17MAR2014	09:45	115		69.1		
	Week 56	14APR2014	09:30	112		60.8		
	Week 60	12MAY2014	09:50	114		57.0		
	Week 64	09JUN2014	10:50	88.1		73.6		
	Week 68	07JUL2014	09:44	83.6		54.4		
	Week 72	04AUG2014	09:50	98.0		63.0		
	Week 76	01SEP2014	10:15	140		90.0		
	Week 80	29SEP2014	10:12	166		102		
	Week 84	27OCT2014	09:55	89.1		74.0		
309-0011/59/M/A2	Screening	28MAR2013	15:10	72.4		31.5		
	Week 2	15APR2013	14:30	<0.750		268		
	Week 4	29APR2013	14:50	<0.750		411		
	Week 8	27MAY2013	14:15	<0.750		291		

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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
309-0011/59/M/A2	Week 12	24JUN2013	15:40	<0.750		120		
309-0012/82/M/A2	Screening	13MAY2013	12:00	67.3		58.3		
	Week 2	30MAY2013	09:20	<0.750		437		
	Week 4	13JUN2013	10:05	<0.750		334		
	Week 8	11JUL2013	09:50	72.5		52.4		
	Week 12	08AUG2013	10:05	52.9		48.3		
309-0015/62/M/A2	Screening	18JUN2013	13:35	49.7		21.3		
	Week 2	01JUL2013	09:40	<0.750		195		
	Week 4	15JUL2013	09:30	60.2		21.6		
	Week 8	12AUG2013	10:50	61.2		17.1		
	Week 12	09SEP2013	10:49	59.4		12.4		
309-0016/72/F/A2	Screening	26AUG2013	11:20	119		67.1		
	Week 2	12SEP2013	09:50	<0.750		390		
	Week 4	26SEP2013	10:00	1.20		472		

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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
309-0016/72/F/A2	Week 8	24OCT2013	09:05	<0.750		194		
	Week 12	21NOV2013	09:28	93.3		45.3		
309-0017/73/F/A2	Screening	20NOV2013	12:50	101		67.9		
	Week 2	09DEC2013	11:20	<0.750		503		
	Week 4	23DEC2013	11:15	<0.750		888		
	Week 8	20JAN2014	11:00	<0.750		977		
	Week 12	17FEB2014	11:30	<0.750		629		
309-0018/82/M/A2	Screening	03JUN2014	12:30	59.1		41.9		
	Week 2	23JUN2014	09:40	1.05		340		
	Week 4	07JUL2014	12:10	1.17		300		
	Week 8	04AUG2014	10:44	68.2		39.9		
	Week 12	01SEP2014	09:40	88.9		45.5		
309-0021/54/F/A2	Screening	04JUL2014	12:15	134		70.9		
	Week 2	24JUL2014	10:35	1.84		531		

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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
309-0021/54/F/A2	Week 4	07AUG2014	11:50	<0.750		530		
	Week 8	04SEP2014	09:55	128		53.3		
309-0025/49/M/A2	Screening	12AUG2014	13:35	47.4		10.1		
	Week 2	01SEP2014	11:00	27.5		183		
309-0026/41/M/A2	Screening	09SEP2014	14:00	41.8		7.31		
	Week 2	29SEP2014	10:25	<0.750		81.2		
	Week 4	13OCT2014	09:45	0.915		211		
	Week 8	10NOV2014	11:10	1.18		85.4		
	Week 12	08DEC2014	11:15	33.0		19.0		
	Week 16	05JAN2015	12:20	35.2		27.8		
309-0028/62/M/A2	Screening	22OCT2014	12:00	62.6		51.0		
	Week 2	10NOV2014	09:45	1.05		366		
	Week 4	24NOV2014	11:10	1.28		592		
	Week 8	22DEC2014	08:40	0.958		473		

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Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
309-0028/62/M/A2	Week 12	19JAN2015	09:00	0.780		244		
	Week 16	16FEB2015	09:10	<0.750		231		
	Week 20	16MAR2015	08:50	0.766		164		
	Week 24	13APR2015	09:32	0.783		114		
309-0030/33/M/A2	Screening	04DEC2014	13:30	64.5		22.9		
	Week 2	22DEC2014	10:45	1.09		258		
	Week 4	05JAN2015	11:25	72.5		29.5		
	Week 8	02FEB2015	10:10	34.3		46.8		
309-0031/34/M/A2	Screening	18DEC2014	13:25	51.3		18.4		
	Week 2	31DEC2014	10:55	1.15		270		
	Week 4	15JAN2015	10:50	1.14		239		
	Week 8	12FEB2015	10:40	0.988		125		
309-0032/63/M/A2	Screening	26DEC2014	12:20	68.8		38.2		
	Week 2	15JAN2015	12:00	1.25		284		

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Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
309-0032/63/M/A2	Week 4	29JAN2015	10:20	0.778		278		
	Week 8	26FEB2015	09:55	75.9		50.3		
	Week 12	26MAR2015	09:40	212		117		
309-0033/78/F/A2	Screening	16JAN2015	12:30	117		63.0		
	Week 2	05FEB2015	10:55	0.864		605		
	Week 4	17FEB2015	13:10	<0.750		438		
	Week 8	17MAR2015	16:10	1.08		489		
	Week 12	16APR2015	11:20	<0.750		388		
	Week 16	14MAY2015	10:55	<0.750		253		
310-0001/61/M/A2	Screening	12JUN2012	14:25	76.1		38.2		
	Week 4	10JUL2012	13:10	3.49		694		
	Week 8	07AUG2012	13:35	<0.750		540		
310-0002/55/M/A2	Screening	28JUN2012	10:25	111		38.9		
	Week 4	31JUL2012	13:10	<0.750		460		

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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
310-0003/61/M/A2	Screening	23JAN2013	10:00	91.6		39.3		
	Week 4	27FEB2013	08:50	<0.750		676		
	Week 8	27MAR2013	09:30	<0.750		547		
	Week 12	24APR2013	09:15	<0.750		129		
310-0008/49/M/A2	Screening	11JUN2013	09:30	88.1		35.9		
	Week 2	26JUN2013	09:00	<0.750		273		
310-0012/73/M/A2	Screening	01NOV2013	08:40	90.6		75.9		
	Week 2	14NOV2013	09:00	<0.750		705		
	Week 4	26NOV2013	14:29	<0.750		648		
	Week 8	26DEC2013	09:08	0.785		866		
	Week 12	23JAN2014	09:05	<0.750		769		
	Week 16	18FEB2014	13:30	65.0		155		
	Week 20	18MAR2014	13:30	91.4		57.1		
310-0013/54/M/A2	Screening	22AUG2014	07:59	47.5		37.1		

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[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

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310-0013/54/M/A2	Week 2	10SEP2014	08:13	1.38		270		
	Week 4	24SEP2014	08:10	1.65		206		
	Week 8	22OCT2014	07:49	49.8		42.1		
311-0002/60/M/A2	Screening	08AUG2013	09:10	87.7		36.7		
	Week 2	21AUG2013	09:30	<0.750		453		
	Week 4	04SEP2013	11:40	<0.750		150		
	Week 8	02OCT2013	10:10	83.7		37.4		
311-0007/55/M/A2	Screening	11NOV2013	14:00	101		35.2		
	Week 2	25NOV2013	09:30	1.01		448		
	Week 4	09DEC2013	10:30	1.83		480		
	Week 8	08JAN2014	14:15	1.76		188		
311-0008/71/M/A2	Screening	14MAY2014	15:00	80.9		12.6		
	Week 2	28MAY2014	14:07	1.11		181		
	Week 4	11JUN2014	11:27	0.924		154		

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311-0008/71/M/A2	Week 8	08JUL2014	08:45	98.7		33.0		
401-0003/36/M/A7	Screening	24JUN2013	10:20	70.7		17.4		
	Week 2	02JUL2013	13:07	1.61		385		
	Week 4	17JUL2013	09:46	<0.750		186		
	Week 8	13AUG2013	10:21	0.771		199		
401-0005/58/M/A7	Screening	10OCT2013	08:14	120		44.8		
	Week 2	22OCT2013	09:04	1.15		362		
	Week 4	05NOV2013	08:05	1.33		493		
	Week 8	06DEC2013	12:24	116		37.6		
402-0003/75/M/A7	Screening	30APR2013	14:00	105		69.3		
	Week 2	07MAY2013	12:00	<0.750		519		
	Week 4	21MAY2013	12:30	<0.750		723		
	Week 8	19JUN2013	11:52	<0.750		836		
	Week 12	16JUL2013	12:00	<0.750		739		

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402-0003/75/M/A7	Week 16	13AUG2013	15:00	<0.750		704		
	Week 20	10SEP2013	12:00	<0.750		682		
	Week 24	08OCT2013	12:30	0.945		595		
402-0006/71/M/A7	Screening	25APR2013	10:20	97.9		38.4		
	Week 2	09MAY2013	10:54	<0.750		343		
	Week 4	28MAY2013	11:30	<0.750		577		
	Week 8	25JUN2013	11:06	<0.750		525		
	Week 12	22JUL2013	11:26	36.3		74.2		
402-0008/43/M/A7	Screening	08MAY2013	14:30	107		23.0		
	Week 2	28MAY2013	12:00	<0.750		347		
402-0009/70/M/A7	Screening	09MAY2013	13:20	55.9		43.2		
	Week 2	23MAY2013	08:30	<0.750		353		
	Week 4	07JUN2013	08:42	<0.750		453		
	Week 8	04JUL2013	08:00	<0.750		337		

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402-0011/64/M/A7	Screening	14MAY2013	10:40	74.4		32.8		
	Week 2	31MAY2013	10:00	<0.750		418		
	Week 4	13JUN2013	09:20	<0.750		660		
	Week 8	Unknown	Unknown	1.45		343		
402-0017/50/M/A7	Screening	11JUN2013	11:20	51.4		29.6		
	Week 2	24JUN2013	12:00	<0.750		358		
	Week 4	08JUL2013	12:30	<0.750		348		
402-0018/48/M/A7	Screening	12JUN2013	11:20	88.1		35.4		
	Week 2	01JUL2013	14:00	<0.750		499		
	Week 4	15JUL2013	12:00	<0.750		647		
	Week 8	12AUG2013	12:00	36.3		111		
	Week 12	09SEP2013	12:30	97.9		40.4		
402-0019/54/M/A7	Screening	01JUL2013	14:00	88.2		35.0		
	Week 2	08JUL2013	12:00	0.901		354		

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402-0019/54/M/A7	Week 4	22JUL2013	12:00	43.9		76.8		
	Week 8	19AUG2013	14:00	90.8		44.7		
	Week 12	16SEP2013	13:00	83.5		30.7		
402-0021/64/M/A7	Screening	13AUG2013	13:30	61.3		34.4		
	Week 2	20AUG2013	12:00	<0.750		392		
	Week 4	03SEP2013	12:30	<0.750		462		
	Week 8	01OCT2013	12:30	105		56.1		
	Week 12	29OCT2013	11:50	113		46.8		
	Week 16	26NOV2013	12:20	124		55.1		
	Week 20	24DEC2013	11:50	79.0		36.1		
	Week 24	21JAN2014	11:50	117		38.1		
	Week 28	18FEB2014	12:00	114		45.4		
	Week 32	18MAR2014	11:49	86.9		31.4		
	Week 36	15APR2014	12:00	95.1		41.5		

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402-0021/64/M/A7	Week 40	13MAY2014	11:30	86.7		34.3		
	Week 44	10JUN2014	12:00	83.7		39.4		
	Week 48	08JUL2014	12:30	93.5		44.9		
	Week 52	05AUG2014	11:30	74.5		36.6		
	Week 56	02SEP2014	11:30	103		50.8		
402-0024/57/M/A7	Screening	23AUG2013	10:10	78.3		47.1		
	Week 2	03SEP2013	12:00	<0.750		558		
	Week 4	17SEP2013	12:30	<0.750		572		
	Week 8	15OCT2013	11:40	115		47.4		
	Week 12	12NOV2013	11:50	63.4		34.1		
402-0025/58/M/A7	Screening	25SEP2013	13:30	90.8		34.7		
	Week 2	04OCT2013	09:40	0.937		490		
	Week 4	17OCT2013	09:00	1.31		535		
	Week 8	14NOV2013	09:10	75.6		36.4		

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402-0025/58/M/A7	Week 12	12DEC2013	09:38	96.2		33.3		
402-0027/52/M/A7	Screening	25SEP2013	15:10	94.0		35.6		
	Week 2	10OCT2013	08:40	1.33		246		
	Week 4	23OCT2013	12:30	1.37		350		
	Week 8	Unknown	Unknown	38.1		104		
402-0028/60/M/A7	Screening	26SEP2013	15:10	94.1		43.8		
	Week 2	10OCT2013	11:00	1.49		315		
	Week 4	22OCT2013	12:30	1.73		490		
	Week 8	26NOV2013	11:30	55.0		83.7		
402-0031/65/M/A7	Screening	05NOV2013	14:30	97.8		53.8		
	Week 2	21NOV2013	08:00	1.25		487		
	Week 4	06DEC2013	08:00	111		39.0		
	Week 8	02JAN2014	08:00	108		52.0		
	Week 12	29JAN2014	08:00	102		51.3		

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402-0033/63/F/A7	Screening	29NOV2013	16:00	86.4		34.3		
	Week 2	16DEC2013	12:00	0.768		213		
	Week 4	30DEC2013	12:10	0.945		410		
	Week 8	27JAN2014	13:00	8.39		51.6		
402-0035/44/M/A7	Screening	24DEC2013	12:00	118		28.7		
	Week 2	31DEC2013	12:00	1.86		454		
	Week 4	14JAN2014	12:00	<0.750		200		
403-0001/55/M/A7	Screening	20MAY2013	15:41	77.8		32.3		
	Week 2	29MAY2013	08:45	0.759		392		
	Week 4	12JUN2013	08:38	<0.750		182		
403-0002/52/M/A7	Screening	11JUN2013	15:23	49.3		31.1		
	Week 2	19JUN2013	09:03	<0.750		403		
	Week 4	03JUL2013	09:30	61.9		31.0		
	Week 8	31JUL2013	08:14	63.6		32.8		

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403-0005/50/F/A7	Screening	15JUL2013	15:13	87.5		28.4		
	Week 2	22JUL2013	10:17	<0.750		253		
403-0006/66/M/A7	Screening	25JUL2013	09:45	52.6		26.9		
	Week 2	07AUG2013	09:36	0.751		333		
	Week 4	22AUG2013	08:53	1.61		297		
	Week 8	16SEP2013	10:36	39.5		16.4		
	Week 12	17OCT2013	08:35	49.7		13.4		
403-0007/64/M/	Screening	16AUG2013	11:01	83.1		42.3		
	Week 2	27AUG2013	12:32	1.45		355		
	Week 4	11SEP2013	13:56	1.22		467		
	Week 8	08OCT2013	11:10	1.64		262		
	Week 12	07NOV2013	11:58	1.19		245		
404-0001/71/M/A7	Screening	08JUL2013	08:30	63.2		24.8		
	Week 2	29JUL2013	09:30	<0.750		244		

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404-0001/71/M/A7	Week 4	12AUG2013	09:30	<0.750		265		
404-0002/56/F/A7	Screening	22AUG2013	14:30	54.5		19.5		
	Week 2	29AUG2013	13:40	<0.750		150		
	Week 4	12SEP2013	09:20	0.908		92.0		
405-0002/46/M/A7	Screening	10APR2013	17:30	85.0		23.7		
	Week 2	24APR2013	14:30	<0.750		205		
405-0004/38/M/A7	Screening	19APR2013	11:03	107		35.3		
	Week 2	29APR2013	10:07	<0.750		480		
	Week 4	15MAY2013	12:23	<0.750		864		
	Week 8	10JUN2013	09:00	<0.750		629		
	Week 12	10JUL2013	Unknown	1.09		258		
405-0006/62/M/A7	Screening	23APR2013	10:30	98.5		43.2		
	Week 2	08MAY2013	Unknown	<0.750		227		
	Week 4	22MAY2013	10:30	1.47		298		

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[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
405-0007/53/M/A7	Screening	23APR2013	16:35	134		39.0		
	Week 2	14MAY2013	09:40	<0.750		310		
	Week 4	28MAY2013	10:40	119		39.9		
	Week 8	25JUN2013	10:25	89.5		36.5		
	Week 12	23JUL2013	11:25	104		42.8		
	Week 16	20AUG2013	11:05	114		42.4		
	Week 20	Unknown	Unknown	95.8		26.7		
405-0009/50/M/A7	Screening	07MAY2013	11:30	104		32.7		
	Week 2	21MAY2013	10:06	<0.750		410		
	Week 4	05JUN2013	12:45	1.20		378		
	Week 8	03JUL2013	13:10	81.1		33.5		
405-0010/39/M/A7	Screening	23MAY2013	13:10	119		35.2		
	Week 2	31MAY2013	10:35	<0.750		375		
	Week 4	11JUN2013	10:10	<0.750		449		

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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
405-0010/39/M/A7	Week 8	08JUL2013	10:10	1.59		512		
	Week 12	06AUG2013	10:17	1.95		196		
405-0011/63/M/A7	Screening	08MAY2013	19:12	115		40.3		
	Week 2	20MAY2013	09:40	<0.750		406		
	Week 4	03JUN2013	10:00	<0.750		469		
	Week 8	01JUL2013	09:32	1.29		231		
	Week 12	29JUL2013	08:52	68.1		51.8		
	Week 16	26AUG2013	08:55	110		50.0		
	Week 20	23SEP2013	08:45	174		58.7		
	Week 24	21OCT2013	08:45	148		60.9		
405-0013/45/M/A7	Screening	13MAY2013	12:05	62.2		36.2		
	Week 2	20MAY2013	09:53	<0.750		215		
	Week 4	10JUN2013	09:50	<0.750		153		
	Week 8	08JUL2013	09:15	67.6		34.8		

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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
405-0013/45/M/A7	Week 12	05AUG2013	09:07	72.1		27.9		
	Week 16	02SEP2013	10:00	59.0		23.1		
405-0014/35/M/A7	Screening	23MAY2013	16:50	103		27.2		
	Week 2	05JUN2013	12:40	<0.750		246		
	Week 4	19JUN2013	13:00	1.52		102		
405-0016/41/M/A7	Screening	27MAY2013	09:30	106		25.6		
	Week 2	03JUN2013	09:20	<0.750		209		
	Week 4	17JUN2013	09:15	<0.750		116		
405-0018/70/F/A7	Screening	07JUN2013	15:30	47.6		15.5		
	Week 2	21JUN2013	09:40	<0.750		140		
405-0020/69/M/A7	Screening	19JUN2013	15:00	86.9		55.8		
	Week 2	26JUN2013	10:40	1.97		595		
	Week 4	10JUL2013	11:05	2.07		740		
	Week 8	07AUG2013	10:40	1.50		830		

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Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
405-0020/69/M/A7	Week 12	04SEP2013	09:25	<0.750		705		
	Week 16	30SEP2013	09:45	<0.750		590		
	Week 20	30OCT2013	10:50	0.928		605		
	Week 24	27NOV2013	11:20	<0.750		632		
	Week 28	23DEC2013	09:15	<0.750		1060		
	Week 32	22JAN2014	10:25	0.756		745		
	Week 36	19FEB2014	09:55	<0.750		773		
	Week 40	19MAR2014	11:00	1.62		911		
	Week 44	14APR2014	10:30	1.08		869		
	Week 48	14MAY2014	09:55	1.12		1040		
405-0021/47/M/A7	Screening	17JUN2013	13:20	115		20.1		
	Week 2	26JUN2013	12:25	1.81		266		
	Week 4	10JUL2013	11:50	146		59.6		
	Week 8	07AUG2013	11:40	1.58		189		

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Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
405-0021/47/M/A7	Week 12	04SEP2013	11:40	1.66		166		
	Week 16	02OCT2013	11:55	<0.750		160		
	Week 20	30OCT2013	11:05	62.2		82.5		
	Week 24	27NOV2013	12:00	71.8		81.8		
	Week 28	23DEC2013	09:07	1.85		133		
	Week 32	22JAN2014	10:25	28.7		94.8		
	Week 36	17FEB2014	09:40	14.7		127		
	Week 40	17MAR2014	09:25	68.2		56.0		
	Week 44	18APR2014	10:30	60.4		35.7		
	Week 48	14MAY2014	11:50	1.52		121		
	Week 52	09JUN2014	09:35	1.21		99.8		
	Week 56	14JUL2014	09:00	104		27.2		
405-0022/65/M/A7	Screening	04JUL2013	12:30	69.1	72.85	34.5	34.35	
	Screening	04JUL2013	12:30	76.6		34.2		

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Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
405-0022/65/M/A7	Week 2	10JUL2013	11:10	2.29		289		
	Week 4	22JUL2013	10:48	1.67		117		
	Week 8	21AUG2013	10:53	65.5		37.6		
	Week 12	16SEP2013	10:00	108		41.1		
	Week 16	14OCT2013	10:00	90.9		41.2		
	Week 20	13NOV2013	10:20	65.4		37.6		
	Week 24	11DEC2013	10:55	71.1		36.7		
405-0023/46/M/A7	Screening	17JUN2013	08:35	115		38.4		
	Week 2	24JUN2013	09:35	1.02		321		
	Week 4	08JUL2013	09:40	1.72		322		
	Week 8	05AUG2013	09:25	19.6		110		
	Week 12	02SEP2013	09:53	72.3		26.5		
405-0025/47/M/A7	Screening	24JUN2013	10:30	107		30.7		
	Week 2	03JUL2013	13:30	1.86		295		

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Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
405-0025/47/M/A7	Week 4	17JUL2013	11:45	35.4		107		
405-0028/67/M/A7	Screening	17JUL2013	11:07	165		30.8		
	Week 2	29JUL2013	08:56	0.786		316		
	Week 4	14AUG2013	10:50	0.791		428		
	Week 8	11SEP2013	10:49	<0.750		254		
	Week 12	07OCT2013	08:50	<0.750		169		
405-0030/35/M/A7	Screening	17JUL2013	16:38	62.3		21.0		
	Week 2	05AUG2013	08:45	<0.750		356		
	Week 4	19AUG2013	08:45	<0.750		646		
	Week 8	16SEP2013	09:15	0.848		318		
405-0032/69/M/A7	Screening	19JUL2013	14:25	75.5		13.8		
	Week 2	29JUL2013	08:50	0.964		449		
	Week 4	12AUG2013	08:35	<0.750		376		
	Week 8	09SEP2013	10:30	<0.750		371		

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Pharmacodynamic Analysis Results
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Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
405-0032/69/M/A7	Week 12	08OCT2013	08:43	88.3		57.2		
	Week 16	04NOV2013	08:40	96.2		22.8		
	Week 20	02DEC2013	08:40	74.2		21.8		
	Week 24	30DEC2013	08:40	104		52.4		
	Week 28	27JAN2014	08:32	75.2		23.4		
	Week 32	24FEB2014	08:35	69.9		23.9		
	Week 36	24MAR2014	08:30	97.3		43.3		
	Week 40	21APR2014	08:50	75.8		22.1		
	Week 44	19MAY2014	08:40	75.4		24.4		
	Week 48	16JUN2014	08:40	92.3		46.4		
	Week 52	14JUL2014	08:45	135		37.3		
	Week 56	12AUG2014	08:40	73.7		26.7		
	Week 60	05SEP2014	08:50	70.5		32.3		
405-0033/43/M/A7	Screening	29JUL2013	11:20	187		35.2		

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Pharmacodynamic Analysis Results
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Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
405-0033/43/M/A7	Week 2	14AUG2013	11:25	<0.750		481		
	Week 4	28AUG2013	11:40	<0.750		596		
	Week 8	25SEP2013	12:00	<0.750		577		
	Week 12	23OCT2013	11:45	<0.750		693		
405-0034/61/M/A7	Screening	29JUL2013	09:58	139		54.5		
	Week 2	14AUG2013	09:42	0.802		462		
	Week 4	28AUG2013	10:00	0.762		297		
	Week 8	25SEP2013	09:55	112		57.5		
	Week 12	23OCT2013	10:00	105		51.4		
405-0035/66/M/A7	Screening	04MAY2010	Unknown	138		42.3		
	Week 2	26AUG2013	08:50	<0.750		634		
	Week 4	11SEP2013	11:40	<0.750		608		
	Week 8	11OCT2013	09:03	<0.750		348		
405-0039/73/M/A7	Screening	13AUG2012	Unknown	75.6		24.7		

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Pharmacodynamic Analysis Results
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Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
405-0039/73/M/A7	Week 2	23SEP2013	08:35	1.23		351		
	Week 4	07OCT2013	08:43	1.66		181		
	Week 8	04NOV2013	08:38	119		33.0		
	Week 12	29NOV2013	08:30	80.7		26.0		
405-0040/65/M/A7	Screening	09SEP2013	12:12	142		49.6		
	Week 2	30SEP2013	09:40	0.933		431		
	Week 4	14OCT2013	09:55	167		64.4		
	Week 8	11NOV2013	09:05	154		41.0		
	Week 12	09DEC2013	08:40	132		37.7		
405-0042/53/M/A7	Screening	24SEP2013	Unknown	121		54.2		
	Week 2	14OCT2013	09:45	<0.750		308		
	Week 4	30OCT2013	10:55	<0.750		200		
	Week 8	27NOV2013	11:10	79.2		50.3		
405-0043/49/M/A7	Screening	16SEP2013	11:53	138		36.0		

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(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
405-0043/49/M/A7	Week 2	02OCT2013	14:40	<0.750		513		
	Week 4	17OCT2013	12:15	<0.750		756		
	Week 8	14NOV2013	12:05	0.959		178		
405-0044/56/M/A7	Screening	25SEP2013	13:35	101		33.2		
	Week 2	02OCT2013	12:48	<0.750		424		
	Week 4	18OCT2013	11:40	<0.750		479		
	Week 8	13NOV2013	11:40	72.8		66.6		
501-0001/59/M/A1	Screening	13NOV2013	07:20	107		34.4		
	Week 2	20NOV2013	06:30	1.13		445		
	Week 4	04DEC2013	07:00	0.795		494		
	Week 8	02JAN2014	06:00	<0.750		224		
501-0002/36/F/A1	Screening	29NOV2013	07:00	90.0		28.9		
	Week 2	09DEC2013	08:50	<0.750		279		
	Week 4	23DEC2013	08:30	0.838		327		

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[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
501-0002/36/F/A1	Week 8	20JAN2014	08:30	56.6		30.4		
	Week 12	18FEB2014	07:00	75.2		22.3		
501-0005/80/M/A1	Screening	17JAN2014	07:00	110		45.6		
	Week 2	29JAN2014	08:00	<0.750		321		
	Week 4	13FEB2014	09:10	<0.750		574		
	Week 8	14MAR2014	08:20	<0.750		932		
	Week 12	11APR2014	08:30	<0.750		802		
	Week 16	10MAY2014	09:50	1.68		958		
	Week 20	06JUN2014	07:58	2.76		985		
	Week 24	03JUL2014	08:30	1.26		853		
	Week 28	01AUG2014	08:15	1.55		914		
	Week 32	29AUG2014	07:10	1.05		296		
	Week 36	30SEP2014	08:30	0.979		841		
	Week 40	23OCT2014	08:30	1.28		942		

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Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
501-0005/80/M/A1	Week 44	20NOV2014	08:38	0.960		860		
	Week 48	18DEC2014	08:45	1.04		1170		
	Week 52	15JAN2015	08:37	0.839		721		
	Week 56	10FEB2015	08:46	0.857		861		
	Week 60	12MAR2015	08:45	0.983		1090		
	Week 64	10APR2015	08:20	0.770		758		
	Week 68	07MAY2015	10:55	0.756		568		
	Week 72	04JUN2015	07:45	<0.750		800		
501-0006/60/M/A1	Screening	12FEB2014	09:00	106		53.4		
	Week 2	20FEB2014	08:30	0.814		494		
	Week 4	06MAR2014	08:30	<0.750		662		
	Week 8	03APR2014	07:30	<0.750		430		
	Week 12	28APR2014	08:00	80.4		78.9		
501-0007/43/M/A1	Screening	03MAR2014	11:30	113		45.5		

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Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
501-0007/43/M/A1	Week 2	10MAR2014	09:55	<0.750		372		
	Week 4	24MAR2014	10:15	0.829		639		
	Week 8	21APR2014	07:20	<0.750		832		
	Week 12	19MAY2014	09:50	2.77		714		
501-0008/76/F/A1	Screening	15APR2014	07:45	95.6		35.5		
	Week 2	23APR2014	08:30	<0.750		398		
	Week 4	09MAY2014	09:15	2.42		641		
	Week 8	04JUN2014	07:30	<0.750		718		
	Week 12	01JUL2014	09:05	1.83		318		
501-0009/62/M/A1	Screening	17JUL2014	06:00	116		71.3		
	Week 2	25JUL2014	08:00	0.951		1100		
	Week 4	08AUG2014	08:00	1.80		1470		
	Week 8	04JUN2014	07:30	0.809		1090		
	Week 12	30SEP2014	06:00	0.802		1270		

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Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
501-0010/65/M/A1	Screening	04SEP2014	07:40	98.0		34.8		
	Week 2	16SEP2014	07:00	0.974		466		
	Week 4	28SEP2014	07:30	1.91		641		
	Week 8	29OCT2014	09:15	1.34		870		
	Week 12	27NOV2014	08:00	2.40		152		
502-0002/65/M/A1	Screening	09JAN2014	07:40	83.4		30.3		
503-0001/32/M/A1	Screening	09DEC2013	15:30	84.2		23.4		
	Week 2	16DEC2013	09:23	<0.750		196		
	Week 4	31DEC2013	12:10	<0.750		268		
503-0004/49/M/A1	Screening	11MAR2014	10:30	83.3		37.7		
	Week 2	18MAR2014	09:30	<0.750		276		
503-0006/54/M/A1	Screening	06AUG2014	11:20	73.5		41.0		
	Week 2	13AUG2014	08:46	1.35		194		
	Week 4	27AUG2014	08:30	0.870		155		

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Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
503-0006/54/M/A1	Week 8	25SEP2014	08:40	71.5		31.4		
	Week 12	22OCT2014	08:54	89.8		35.5		
	Week 16	19NOV2014	Unknown	113		51.2		
	Week 20	17DEC2014	Unknown	84.5		51.2		
	Week 24	15JAN2015	15:20	105		40.6		
	Week 28	09FEB2015	Unknown	86.0		58.2		
503-0007/57/M/A1	Screening	28OCT2014	16:00	122		34.1		
	Week 2	04NOV2014	09:55	0.754		444		
	Week 4	18NOV2014	Unknown	<0.750		519		
	Week 8	16DEC2014	09:36	<0.750		652		
	Week 12	13JAN2015	09:30	0.913		582		
503-0008/50/M/A1	Screening	30OCT2014	16:50	82.2		44.1		
	Week 2	05NOV2014	09:25	1.05		289		
	Week 4	19NOV2014	09:45	0.873		478		

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503-0009/57/M/A1	Screening	19NOV2014	15:42	60.2		23.9		
	Week 2	26NOV2014	15:21	1.09		337		
504-0001/47/M/A1	Screening	17FEB2014	10:36	116		27.5		
	Week 2	25FEB2014	10:15	<0.750		318		
	Week 4	11MAR2014	10:40	<0.750		394		
	Week 8	08APR2014	09:35	105		41.3		
	Week 12	06MAY2014	09:25	179		50.4		
	Week 16	03JUN2014	09:15	133		41.9		
504-0007/32/M/A1	Screening	11OCT2014	14:26	65.1		24.1		
	Week 2	17OCT2014	08:50	2.12		316		
505-0001/70/M/A1	Screening	13AUG2014	08:00	101		31.5		
	Week 2	02SEP2014	07:50	2.39		306		
	Week 4	16SEP2014	08:15	2.71		268		
506-0002/54/M/A1	Screening	12MAY2014	06:30	98.5		31.3		

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Pharmacodynamic Analysis Results
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506-0002/54/M/A1	Week 2	19MAY2014	08:30	4.00		371		
	Week 4	04JUN2014	08:45	1.42		185		
	Week 8	02JUL2014	08:55	76.4		36.2		
	Week 12	30JUL2014	08:40	87.8		36.3		
	Week 16	27AUG2014	08:40	58.9		36.6		
	Week 20	24SEP2014	08:55	65.9		31.9		
	Week 24	22OCT2014	08:45	71.1		31.0		
	Week 28	19NOV2014	08:25	81.1		38.5		
	Week 32	17DEC2014	08:50	61.6		34.1		
	Week 36	14JAN2015	09:10	69.6		30.7		
	Week 40	11FEB2015	08:40	57.2		16.6		
	Week 44	11MAR2015	08:20	51.1		29.2		
	Week 48	08APR2015	09:00	50.6		27.9		
506-0003/66/M/A1	Screening	10SEP2014	08:30	120		58.1		

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506-0003/66/M/A1	Week 2	17SEP2014	09:20	2.93		576		
	Week 4	30SEP2014	09:20	2.37		767		
506-0004/49/M/A1	Screening	27OCT2014	08:10	81.2		17.6		
	Week 2	05NOV2014	08:50	1.46		158		
	Week 4	19NOV2014	08:35	7.34		166		
	Week 8	17DEC2014	08:55	64.2		29.2		
508-0001/36/M/A1	Screening	31DEC2013	09:00	89.0		40.9		Week 2 in sample list
	Week 2	15JAN2014	09:50	<0.750		422		Screening in sample list
	Week 4	27JAN2014	09:40	<0.750		723		
508-0003/49/F/A1	Screening	13MAR2014	09:50	12.2		15.0		
	Week 2	25MAR2014	09:50	0.840		152		
	Week 4	08APR2014	11:08	<0.750		64.0		

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509-0001/45/M/A1	Screening	28APR2014	11:00	27.4		18.5		
	Week 2	07MAY2014	10:20	0.816		239		

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509-0001/45/M/A1	Week 4	21MAY2014	10:05	0.868		237		
	Week 8	17JUN2014	10:10	32.3		16.6		
	Week 12	15JUL2014	10:45	37.5		14.4		
509-0002/51/M/A1	Screening	22MAY2014	10:10	55.4		21.7		
	Week 2	04JUN2014	10:20	<0.750		340		
510-0002/50/M/A1	Screening	22MAY2014	09:10	108		27.6		
	Week 2	28MAY2014	08:30	<0.750		333		
	Week 4	11JUN2014	08:30	86.8		29.9		
	Week 8	09JUL2014	08:20	90.2		40.0		
510-0004/72/M/A1	Screening	30JUL2014	08:30	92.7		35.6		
	Week 2	06AUG2014	08:30	0.796		288		
	Week 4	20AUG2014	07:30	<0.750		487		
	Week 8	17SEP2014	14:10	0.843		248		
	Week 12	15OCT2014	07:30	118		37.7		

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(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
511-0001/35/M/A1	Screening	18JAN2014	08:00	60.2		29.4		
	Week 2	28JAN2014	07:35	0.905		452		
	Week 4	11FEB2014	08:15	1.08		776		
511-0002/49/M/A1	Screening	07MAR2014	06:30	57.2		36.7		
	Week 2	18MAR2014	08:10	0.936		419		
	Week 4	01APR2014	09:20	0.935		836		
	Week 8	29APR2014	09:00	<0.750		794		
	Week 12	27MAY2014	09:00	<0.750		867		
	Week 16	24JUN2014	08:55	<0.750		859		
	Week 20	22JUL2014	08:49	<0.750		886		
	Week 24	19AUG2014	08:20	<0.750		428		
512-0001/59/M/A1	Screening	25FEB2014	10:21	64.4		25.9		
	Week 2	11MAR2014	09:15	<0.750		325		
	Week 4	25MAR2014	08:45	<0.750		584		

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[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
512-0001/59/M/A1	Week 8	22APR2014	08:32	1.29		721		
	Week 12	20MAY2014	09:18	0.760		594		
	Week 16	18JUN2014	09:26	<0.750		693		
513-0001/28/M/A1	Screening	10APR2014	08:02	51.6		14.0		
	Week 2	18APR2014	09:14	0.832		268		
	Week 4	04MAY2014	09:44	<0.750		207		
513-0004/46/M/A1	Screening	18JUN2014	10:18	45.9		20.7		
	Week 2	25JUN2014	09:02	<0.750		226		
	Week 4	08JUL2014	08:58	<0.750		112		
513-0005/61/M/A1	Screening	30OCT2014	11:11	157		41.0		
	Week 2	06NOV2014	09:26	<0.750		381		
	Week 4	20NOV2014	09:10	96.2		48.2		
	Week 8	18DEC2014	09:25	57.3		28.3		
	Week 12	14JAN2015	09:40	81.6		33.7		

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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
515-0001/64/M/A1	Screening	14FEB2014	09:30	76.5		50.6		
	Week 2	26FEB2014	15:15	<0.750		410		
	Week 4	12MAR2014	15:10	<0.750		635		
	Week 8	09APR2014	15:10	<0.750		252		
	Week 12	07MAY2014	15:10	95.4		45.3		
515-0003/69/M/A1	Screening	13MAY2014	10:20	130		28.5		
	Week 2	20MAY2014	09:36	<0.750		450		
	Week 4	05JUN2014	10:00	<0.750		875		
	Week 9	11JUL2014	Unknown	91.9		33.1		
	Week 12	29JUL2014	09:30	73.9		29.6		
515-0004/52/M/A1	Screening	27MAY2014	14:20	146		57.7		
	Week 2	05JUN2014	09:15	<0.750		525		
	Week 4	16JUN2014	09:30	<0.750		830		
	Week 8	14JUL2014	09:50	<0.750		337		

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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
515-0004/52/M/A1	Week 12	11AUG2014	10:00	72.0		70.7		
	Week 16	09SEP2014	10:00	73.0		43.6		
515-0006/47/M/A1	Screening	05AUG2014	09:00	72.5		24.4		
	Week 2	11AUG2014	09:00	<0.750		321		
	Week 4	26AUG2014	09:03	<0.750		560		
	Week 8	22SEP2014	09:40	<0.750		400		
	Week 12	20OCT2014	10:10	8.41		113		
515-0007/39/M/A1	Screening	17SEP2014	09:30	102		40.7		
	Week 2	22SEP2014	09:48	0.821		433		
	Week 4	08OCT2014	10:10	115		52.8		
515-0008/60/M/A1	Screening	27NOV2014	08:53	103		29.0		
	Week 2	03DEC2014	09:40	<0.750		359		
	Week 4	17DEC2014	10:30	<0.750		538		
	Week 8	14JAN2015	09:40	<0.750		342		

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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
515-0008/60/M/A1	Week 12	09FEB2015	09:05	0.929		206		
516-0001/45/M/A1	Screening	07AUG2014	09:20	144		35.3		
	Week 2	15AUG2014	09:10	1.87		626		
	Week 4	29AUG2014	08:48	1.84		857		
	Week 8	26SEP2014	08:40	1.55		688		
	Week 12	24OCT2014	08:10	1.21		410		
	Week 16	21NOV2014	09:15	<0.750		493		
	Week 20	19DEC2014	08:50	<0.750		701		
	Week 24	16JAN2015	09:00	0.800		723		
517-0001/42/M/A1	Screening	18DEC2013	09:41	79.6		19.5		
	Week 2	30DEC2013	08:45	1.13		283		
	Week 4	13JAN2014	09:05	1.32		222		
517-0002/43/M/A1	Screening	24MAR2014	08:55	95.9		28.8		
	Week 2	02APR2014	09:12	1.44		346		

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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
517-0002/43/M/A1	Week 4	15APR2014	09:25	1.45		628		
	Week 8	13MAY2014	08:43	1.18		404		
	Week 12	10JUN2014	09:10	2.19		162		
	Week 16	08JUL2014	09:00	1.94		152		
	Week 20	05AUG2014	09:00	68.2		75.7		
	Week 24	02SEP2014	08:54	91.1		57.6		
517-0005/46/M/	Screening	22MAY2014	11:33	79.3		21.5		
517-0006/67/F/A1	Screening	12AUG2014	08:40	116		24.7		
	Week 2	27AUG2014	09:15	3.34		381		
	Week 4	10SEP2014	09:08	0.759		868		
	Week 8	08OCT2014	09:15	105		42.3		
	Week 12	05NOV2014	09:30	108		32.3		
	Week 16	03DEC2014	09:15	120		40.0		
	Week 20	30DEC2014	09:17	124		40.3		

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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
517-0006/67/F/A1	Week 24	28JAN2015	09:30	141		19.4		
	Week 28	25FEB2015	09:35	119		38.4		
	Week 32	25MAR2015	09:05	132		42.6		
	Week 36	22APR2015	09:10	107		42.2		
517-0007/66/M/A1	Screening	12AUG2014	09:20	63.3		21.3		
	Week 2	27AUG2014	08:55	0.864		313		
	Week 4	12SEP2014	09:10	1.38		388		
517-0008/59/M/A1	Screening	15AUG2014	08:40	93.1		29.6		
	Week 2	29AUG2014	11:30	1.28		547		
	Week 4	12SEP2014	09:20	1.01		721		
517-0009/23/M/A1	Screening	11SEP2014	10:05	109		30.4		
	Week 2	24SEP2014	09:31	9.72		433		
	Week 4	08OCT2014	10:15	0.880		157		
	Week 8	05NOV2014	09:35	1.87		156		

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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
517-0009/23/M/A1	Week 12	03DEC2014	11:10	94.9		49.9		

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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
101-0002/70/M/OTH	Screening	08JUN2011	Unknown	27.7		28.5		
	Week 4	19AUG2011	13:43	28.7		21.7		
	Week 8	20SEP2011	08:08	70.9		26.1		
	Week 12	18OCT2011	07:47	25.5		30.0		
101-0004/78/F/A2	Screening	02AUG2011	08:40	46.4		41.3		
	Week 4	26AUG2011	10:55	26.9		33.6		
	Week 8	23SEP2011	11:52	46.9		27.5		
	Week 12	21OCT2011	12:51	97.9		51.1		
	Week 16	18NOV2011	14:51	50.4		39.6		
	Week 20	15DEC2011	16:05	55.4		46.9		
	Week 28	10FEB2012	11:45	35.1		28.1		
	Week 32	09MAR2012	10:23	86.1		40.3		
	Week 36	10APR2012	15:25	62.8		44.9		

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Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
101-0004/78/F/A2	Week 40	11MAY2012	11:52	60.8		34.1		Uns Continuation
	Week 44	08JUN2012	12:31	67.0		32.9		Uns Continuation
	Week 48	06JUL2012	11:14	37.7		32.1		Uns Continuation
	Week 52	03AUG2012	11:01	44.0		37.8		Uns Continuation
	Week 56	31AUG2012	09:55	70.0		40.7		
	Week 60	28SEP2012	14:30	43.5		37.0		Uns Continuation
101-0010/43/M/BL	Screening	13SEP2011	07:43	59.0		20.5		
101-0014/61/M/W2	Screening	03MAY2012	Unknown	74.6		36.0		
	Week 4	27JAN2012	10:07	74.3		33.8		
	Week 8	24FEB2012	11:16	60.7		27.8		

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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
	Week 12	23MAR2012	07:52	84.0		26.7		
101-0015/65/M/A4	Screening	06JAN2012	16:14	49.4		62.9		
	Week 4	31JAN2012	13:01	60.0		57.1		
	Week 8	28FEB2012	14:56	86.3		64.5		

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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
101-0015/65/M/A4	Week 12	27MAR2012	15:20	62.5		45.9		
101-0017/60/M/W2	Screening	06APR2011	Unknown	46.0		16.5		
	Week 4	13MAR2012	10:09	55.5		15.5		
	Week 8	10APR2012	12:29	58.1		17.8		
	Week 12	08MAY2012	12:50	59.1		17.9		
101-0020/86/M/W2	Screening	13MAR2012	Unknown	40.0	42.7	48.0	45.2	Collected on 13Mar2012
	Screening	13MAR2012	Unknown	45.4		42.4		Collected on 13Mar2012
	Week 4	03APR2012	08:15	30.1		39.5		
	Week 8	01MAY2012	07:47	15.1		37.5		
	Week 12	05JUN2012	08:58	43.1		44.2		
	Week 16	03JUL2012	07:15	34.5		40.5		
	Week 20	31JUL2012	07:27	41.9		51.9		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE – ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE – WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
	Week 24	28AUG2012	07:35	35.7		56.2		
101-0027/72/M/W2	Screening	22MAY2012	11:02	14.0		4.73		

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[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
101-0027/72/M/W2	Week 4	15JUN2012	09:08	13.6		8.27		
101-0031/69/F/W2	Screening	06DEC2010	Unknown	88.2		29.7		
	Week 4	07AUG2012	10:23	56.1		35.0		
	Week 8	04SEP2012	12:51	60.8		29.8		
	Week 12	Unknown	Unknown	61.4		25.4		
101-0034/44/M/OTH	Screening	22NOV2013	Unknown	81.8		34.2		
	Week 4	02OCT2012	17:34	78.6		71.2		
101-0035/37/M/A6	Screening	26OCT2012	Unknown	108		27.4		
101-0043/69/M/W1	Screening	22OCT2013	15:53	83.1		37.3		
	Week 2	29OCT2013	11:18	65.1		42.1		
	Week 4	19NOV2013	08:54	63.6		35.6		
	Week 8	10DEC2013	08:56	78.7		33.8		

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[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
	Week 12	14JAN2014	08:01	66.9		45.3		
101-0051/70/F/W2	Screening	23JAN2014	Unknown	123		75.6		

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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
101-0051/70/F/W2	Week 2	03FEB2014	13:45	139		81.8		
	Week 4	17FEB2014	13:31	61.2		74.6		
102-0006/66/M/BL	Screening	05DEC2013	09:45	64.7		21.9		
	Week 2	17DEC2013	10:06	65.2		26.3		
	Week 4	02JAN2014	09:53	83.5		33.2		
	Week 8	29JAN2014	09:22	95.2		32.8		
	Week 12	26FEB2014	09:25	52.1		23.4		
102-0007/61/M/W2	Screening	23DEC2013	09:25	85.5		28.6		
	Week 2	09JAN2014	11:45	90.1		25.7		
	Week 4	23JAN2014	10:24	50.4		28.3		
	Unscheduled	27FEB2014	Unknown	70.4		27.7		Week 9
	Week 12	20MAR2014	10:12	56.7		31.6		
103-0002/74/M/W2	Screening	29OCT2009	Unknown	66.8		32.6		
	Week 4	02JAN2013	10:48	58.6		33.7		

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[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
103-0002/74/M/W2	Week 8	30JAN2013	10:00	72.4		30.3		
	Week 12	27FEB2013	10:15	90.2		33.5		
	Week 16	27MAR2013	10:00	1.01		198		
	Week 20	24APR2013	10:00	79.9		50.3		
103-0006/57/M/W2	Screening	06NOV2014	10:30	81.0		43.0		
	Week 2	25NOV2014	10:30	80.5		43.7		
	Week 4	11DEC2014	08:30	76.3		41.2		
	Week 8	06JAN2015	09:25	79.2		37.0		
104-0002/80/M/W2	Screening	30APR2012	09:10	77.5	68.8	51.7	45.2	

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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
	Unscheduled	30APR2012	09:10	60.1		38.7		Screening (collection date not found on visit report, date is between screening and week 1)
	Week 4	29MAY2012	10:25	70.5		48.0		
	Week 8	25JUN2012	09:05	84.5		36.6		
	Week 12	23JUL2012	08:55	61.6		54.5		
	Week 16	20AUG2012	08:55	68.1		46.5		

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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
104-0002/80/M/W2	Week 20	17SEP2012	09:55	83.4		64.8		
	Week 24	15OCT2012	11:02	77.1		42.2		
	Week 28	12NOV2012	09:50	70.5		34.4		
	Week 32	10DEC2012	10:10	67.2		41.7		
	Week 36	07JAN2013	09:33	69.6		38.3		
104-0007/89/M/A1	Screening	30JUN2015	Unknown	108		50.2		
	Week 2	12AUG2013	09:52	81.1		51.6		
	Week 4	26AUG2013	08:42	89.3		48.6		
	Week 8	23SEP2013	09:50	82.9		48.3		
	Week 12	21OCT2013	09:40	95.3		56.7		
	Week 16	18NOV2013	09:00	90.0		49.6		
	Week 20	16DEC2013	09:45	82.8		44.1		
	Week 22	02JAN2014	09:05	145		52.8		
	Week 24	13JAN2014	09:05	124		62.0		

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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
104-0007/89/M/A1	Week 28	10FEB2014	09:35	<0.750		518		
	Week 32	10MAR2014	09:05	<0.750		168		
	Week 34	27MAR2014	09:21	52.7		91.7		
	Week 36	09APR2014	09:25	84.0		66.5		
	Week 40	05MAY2014	09:24	111		56.7		Uns Continuation
	Week 42	19MAY2014	09:33	144		74.3		Uns Continuation
	Week 44	02JUN2014	09:30	106		55.9		Uns Continuation
	Week 48	02JUL2014	09:50	92.9		46.9		Uns Continuation
	Week 50	14JUL2014	09:39	99.8		55.9		Uns Continuation
	Week 52	28JUL2014	09:44	111		50.3		Uns Continuation

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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
	Week 54	13AUG2014	10:00	88.3		46.2		Uns Continuation
	Week 56	25AUG2014	09:35	101		41.8		Uns Continuation
	Week 58	08SEP2014	09:30	115		42.9		Uns Continuation
	Week 60	22SEP2014	09:15	115		56.2		Uns Continuation

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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
104-0007/89/M/A1	Week 62	08OCT2014	09:54	88.9		56.1		Uns Continuation
	Week 64	20OCT2014	10:05	105		52.6		Uns Continuation
	Week 66	03NOV2014	09:35	107		43.4		Uns Continuation
	Week 68	17NOV2014	09:40	136		63.9		Uns Continuation
	Week 70	01DEC2014	09:20	142		64.7		Uns Continuation
	Week 72	15DEC2014	09:49	103		54.4		Uns Continuation
	Week 74	29DEC2014	09:33	111		53.7		Uns Continuation
	Week 74	29DEC2014	09:33	90.9		52.7		Uns Continuation

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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
	Week 76	12JAN2015	10:43	125		45.1		Uns Continuation
	Week 78	26JAN2015	09:48	126		57.5		Uns Continuation
	Week 80	09FEB2015	09:54	132		56.4		Uns Continuation
	Week 82	26FEB2015	08:43	117		62.7		Uns Continuation
	Week 86	25MAR2015	10:18	100		59.6		Uns Continuation
	Week 88	06APR2015	09:52	91.4		38.3		Uns Continuation

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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
104-0007/89/M/A1	Week 90	20APR2015	09:45	100		46.9		Uns Continuation
	Week 92	04MAY2015	09:40	90.7		41.5		Uns Continuation
	Week 94	20MAY2015	09:23	116		51.8		Uns Continuation
105-0003/57/M/W2	Screening	31OCT2013	Unknown	65.9		27.2		
	Week 2	12NOV2013	10:45	61.4		35.0		
	Week 4	26NOV2013	11:05	83.4		37.7		
	Week 8	27DEC2013	11:35	94.0		46.8		
	Week 12	24JAN2014	10:15	93.9		48.4		
	Week 16	21FEB2014	10:30	71.6		34.3		
	Week 20	18MAR2014	10:20	90.4		48.6		
	Week 24	15APR2014	10:20	115		50.0		
	Week 28	16MAY2014	11:34	65.8		44.5		

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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
	Week 32	12JUN2014	10:40	87.8		42.8		
	Week 36	08JUL2014	12:00	80.6		44.5		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
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[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
105-0003/57/M/W2	Week 40	08AUG2014	11:00	88.7		41.4		Uns Continuation
	Week 44	05SEP2014	09:50	97.1		40.5		Uns Continuation
	Week 48	30SEP2014	13:10	76.4		37.0		Uns Continuation
105-0006/60/F/BL	Screening	17DEC2014	Unknown	62.1		29.8		
	Week 2	06JAN2015	10:15	77.5		31.8		
	Week 4	20JAN2015	10:45	65.9		22.2		
	Week 8	19FEB2015	11:35	37.6		19.4		
	Week 12	17MAR2015	08:30	62.7		34.8		
	Week 16	15APR2015	10:30	71.7		28.7		
108-0003/85/M/W2	Screening	14NOV2012	15:00	52.4		58.2		
	Week 4	10DEC2012	09:35	37.5		58.9		
109-0002/63/M/W2	Screening	20MAR2013	13:10	83.1		32.2		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE – ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
	Week 2	29MAR2013	12:52	114		37.2		
	Week 4	12APR2013	08:30	104		32.6		

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[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
109-0002/63/M/W2	Week 8	10MAY2013	09:00	107		35.6		
	Week 12	07JUN2013	09:10	94.7		30.9		
	Week 16	05JUN2013	10:28	103		36.0		
	Week 20	02AUG2013	08:40	116		36.1		
	Week 24	30AUG2013	08:35	86.8		38.0		
109-0005/64/F/W2	Screening	24JUL2013	12:25	45.3		45.4		
	Week 2	07AUG2013	15:00	103		76.6		
	Week 4	21AUG2013	13:15	47.7		51.0		
109-0012/21/F/W2	Screening	07MAY2012	Unknown	75.5		25.4		
	Week 2	01OCT2014	13:54	71.3		20.5		
	Week 4	14OCT2014	11:45	91.1		28.8		
	Week 8	11NOV2014	12:25	67.2		24.2		
109-0014/50/F/W2	Screening	12JAN2015	16:00	108		30.6		
	Week 2	04FEB2015	14:24	71.4		31.4		

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[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
109-0014/50/F/W2	Week 4	18FEB2015	15:25	57.5		31.0		
111-0003/37/M/A1	Screening	02JAN2013	10:40	75.3		24.9		
	Week 4	31JAN2013	13:20	154		47.0		
	Week 8	28FEB2013	10:35	38.9		18.4		
112-0010/56/F/W2	Screening	27NOV2013	11:15	32.1	34.45	19.1	18.9	
	Screening	27NOV2013	11:15	36.8		18.7		
	Week 2	13DEC2013	07:45	27.6		24.1		
	Week 4	27DEC2013	07:28	51.1		29.3		
	Week 8	24JAN2014	10:55	56.5		27.6		
	Week 12	21FEB2014	11:10	30.0		19.0		
113-0007/74/M/W2	Screening	17DEC2013	Unknown	87.9		32.2		
	Week 2	05FEB2014	09:20	99.7		20.8		
	Week 4	20FEB2014	09:20	84.7		27.2		
	Week 8	19MAR2014	08:58	101		25.4		

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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
113-0007/74/M/W2	Week 12	18APR2014	08:30	89.2		22.3		
	Week 16	16MAY2014	08:17	96.9		22.1		
	Week 20	10JUN2014	12:35	67.9		20.1		
113-0015/58/F/BL	Screening	20NOV2014	14:54	115		92.6		
	Week 2	05DEC2014	08:20	89.2		41.6		
114-0001/25/F/OTH	Screening	24JUL2012	15:20	74.1		39.7		
	Week 4	21AUG2012	11:50	68.6		43.9		
114-0004/54/F/A1	Screening	30JAN2013	11:35	62.6		41.3		
	Week 4	27FEB2013	11:10	141		52.5		
	Week 8	27MAR2013	09:35	85.7		46.4		
115-0005/60/M/W2	Screening	08MAR2013	11:31	66.6		19.6		
115-0006/62/M/W2	Screening	04APR2013	13:02	92.5		27.2		

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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
	Week 2	18APR2013	14:10	108		36.4		
	Week 4	02MAY2013	10:25	94.6		38.1		

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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
115-0006/62/M/W2	Week 8	30MAY2013	13:10	94.2		41.7		
	Week 12	27JUN2013	07:38	81.7		37.1		
115-0007/57/M/W2	Screening	10APR2013	13:20	65.1		22.7		
	Week 2	25APR2013	09:45	47.7		17.8		
	Week 4	09MAY2013	08:20	101		30.9		
115-0010/54/M/A4	Screening	27MAR2014	Unknown	71.8		39.9		
	Week 2	21APR2014	10:50	67.3		46.8		
	Week 4	05MAY2014	08:47	81.4		40.0		
	Week 8	02JUN2014	10:38	76.2		34.4		
121-0003/65/M/BL	Screening	03JUN2013	Unknown	122		33.3		
	Week 2	09JUL2014	07:00	112		50.1		
	Week 4	23JUL2014	08:00	58.5		29.3		
	Week 8	20AUG2014	08:35	79.1		37.1		
201-0002/76/M/W2	Screening	11APR2008	Unknown	99.3		62.3		

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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
201-0002/76/M/W2	Week 4	05APR2012	08:00	142		80.7		
	Week 12	31MAY2012	08:00	69.9		47.4		
	Week 16	28JUN2012	08:30	91.8		66.7		
	Week 20	26JUL2012	08:30	84.5		60.7		
	Week 24	23AUG2012	08:15	54.5		55.6		
	Week 28	20SEP2012	08:30	63.8		61.2		
	Week 32	18OCT2012	08:30	53.3		40.7		
	Week 36	15NOV2012	08:00	67.2		57.9		
	Week 40	12DEC2012	08:00	57.2		53.5		Uns Continuation
	Week 44	10JAN2013	08:00	94.0		53.2		Uns Continuation
	Week 48	07FEB2013	08:00	72.5		49.5		Uns Continuation
201-0006/71/M/W2	Screening	05JUL2012	08:10	129		47.4		

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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
	Week 4	02AUG2012	08:30	129		64.0		
	Week 8	30AUG2012	08:30	116		49.5		

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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
201-0006/71/M/W2	Week 12	27SEP2012	08:30	112		74.1		
	Week 16	25OCT2012	08:30	152		74.2		
	Week 20	22NOV2012	08:05	130		50.5		
	Week 24	18DEC2012	08:10	120		42.8		
201-0007/71/M/W2	Screening	16JUL2012	08:00	106		59.1		
	Week 8	12SEP2012	08:30	83.6		61.2		
	Week 12	11OCT2012	08:00	96.2		50.0		
	Week 16	08NOV2012	08:00	83.3		49.3		
	Week 20	06DEC2012	07:50	81.1		52.9		
	Week 24	03JAN2013	08:00	99.2		72.5		
	Week 32	28FEB2013	08:00	149		98.2		
	Week 36	28MAR2013	07:50	101		70.2		
201-0009/64/M/W2	Screening	13JUN2013	08:30	83.1		58.2		
	Week 2	27JUN2013	08:20	75.6		56.3		

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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
201-0009/64/M/W2	Week 4	11JUL2013	08:30	76.6		46.1		
	Week 8	08AUG2013	07:50	72.0		58.0		
	Week 12	05SEP2013	09:05	40.9		116		
	Week 16	03OCT2013	08:00	81.7		49.6		
	Week 20	31OCT2013	08:10	79.6		59.1		
	Week 24	28NOV2013	07:45	93.2		77.6		
	Week 36	20FEB2014	08:30	90.3		59.0		
	Week 38	06MAR2014	08:30	77.3		50.7		Uns Continuation
	Week 40	20MAR2014	08:15	109		91.7		Uns Continuation
	Week 42	03APR2014	08:15	85.6		78.3		Uns Continuation
	Week 44	17APR2014	08:40	69.1		69.4		Uns Continuation

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
	Week 46	30APR2014	08:15	73.0		58.6		Uns Continuation
	Week 48	15MAY2014	08:00	85.3		59.7		Uns Continuation
	Week 50	29MAY2014	08:10	61.4		57.1		Uns Continuation

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE – ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE – WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
201-0009/64/M/W2	Week 52	12JUN2014	08:15	73.6		69.1		Uns Continuation
	Week 54	26JUN2014	08:00	74.9		65.4		Uns Continuation
	Week 56	11JUL2014	08:00	84.2		80.2		Uns Continuation
	Week 58	24JUL2014	08:00	77.2		68.6		Uns Continuation
	Week 60	07AUG2014	08:00	70.8		49.5		Uns Continuation
	Week 64	04SEP2014	08:00	67.0		49.5		Uns Continuation
	Week 68	01OCT2014	08:00	92.9		59.9		Uns Continuation
	Week 72	30OCT2014	08:00	87.1		62.5		Uns Continuation

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE – ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE – WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
	Week 76	27NOV2014	08:00	83.5		68.2		Uns Continuation
	Week 84	21JAN2015	08:30	93.3		89.0		Uns Continuation
	Week 88	19FEB2015	08:10	83.6		69.2		Uns Continuation
	Week 92	19MAR2015	07:50	103		101		Uns Continuation
	Week 96	16APR2015	07:50	82.4		71.8		Uns Continuation
	Week 100	14MAY2015	07:50	80.7		69.0		Uns Continuation

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE – ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE – WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
201-0010/81/F/W2	Screening	20JUN2013	08:00	55.0		66.2		
	Week 2	04JUL2013	08:00	72.0		70.6		
	Week 4	17JUL2013	08:40	64.2		73.6		
	Week 12	12SEP2013	07:50	74.5		70.0		
201-0014/73/M/W2	Screening	11JUL2013	08:50	78.3		50.9		
	Week 2	24JUL2013	08:25	65.2		45.9		
	Week 4	08AUG2013	08:25	75.1		49.3		
	Week 8	05SEP2013	08:50	72.3		45.0		
	Week 12	03OCT2013	08:15	66.7		30.8		
201-0015/49/M/W2	Screening	01AUG2013	09:05	54.0		43.7		
	Week 4	29AUG2013	09:05	57.7		31.3		
	Week 8	26SEP2013	08:35	66.0		31.7		
	Week 12	24OCT2013	08:00	123		49.1		
	Week 16	21NOV2013	08:15	84.0		38.3		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE – ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
201-0015/49/M/W2	Week 20	19DEC2013	08:20	67.8		33.6		
	Week 24	16JAN2014	08:30	66.7		29.5		
	Week 28	13FEB2014	08:30	59.8		34.1		
	Week 32	13MAR2014	08:00	73.9		32.8		
201-0022/80/F/W2	Screening	09MAY2014	09:30	98.2		41.9		
	Week 2	21MAY2014	08:00	126		42.9		
	Week 4	05JUN2014	08:00	105		46.0		
	Week 8	03JUL2014	08:30	106		47.1		
	Week 12	31JUL2014	08:20	99.0		50.6		
	Week 16	28AUG2014	08:30	90.9		48.8		
	Week 20	25SEP2014	08:00	97.4		52.5		
	Week 24	23OCT2014	08:00	116		47.8		
203-0004/81/M/W2	Screening	22MAR2012	08:00	45.8		47.3		
	Week 4	19APR2012	08:00	59.2		43.6		

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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
203-0004/81/M/W2	Week 8	22MAY2012	08:00	39.7		26.6		
	Week 12	28JUN2012	08:00	38.4		31.1		
	Week 16	26JUL2012	08:00	37.1		36.6		
	Week 24	20SEP2012	08:30	51.9		46.3		
	Week 28	18OCT2012	08:00	41.9		30.4		
	Week 32	15NOV2012	08:00	44.4		33.8		
	Week 36	13DEC2012	08:00	47.1		36.7		
203-0006/76/M/W2	Screening	30MAR2012	08:00	66.0		38.1		
	Week 4	04MAY2012	08:00	42.8		38.2		
	Week 8	30MAY2012	08:30	50.5		53.1		
203-0007/59/M/W2	Screening	28MAY2012	08:30	78.9		65.8		
	Week 4	06JUL2012	08:00	63.3		52.8		
	Week 8	01AUG2012	08:00	72.9		55.2		
203-0009/73/M/W2	Screening	30AUG2012	08:00	72.2		58.1		

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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
203-0009/73/M/W2	Week 4	08OCT2012	08:00	60.7		40.8		
	Week 8	15NOV2012	08:00	52.1		37.5		
	Week 12	20DEC2012	08:00	54.1		39.8		
	Week 16	25JAN2013	08:00	60.6		46.0		
	Week 20	27FEB2013	08:00	58.6		15.9		
	Week 24	04APR2013	08:00	74.8		45.8		
	Week 28	13MAY2013	08:00	71.0		48.7		
	Week 32	27JUN2013	08:00	91.7		49.2		
	Week 36	01AUG2013	08:00	77.0		46.0		
	Week 38	22AUG2013	08:00	87.1		49.4		Uns Continuation
	Week 40	12SEP2013	08:00	74.1		34.7		Uns Continuation
	Week 42	27SEP2013	09:00	87.9		34.2		Uns Continuation

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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
	Week 44	14OCT2013	08:00	89.4		52.0		Uns Continuation
	Week 46	31OCT2013	09:00	75.1		46.5		Uns Continuation

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[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE – ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE – WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
203-0010/74/M/W2	Screening	17SEP2012	08:00	62.0		37.4		
	Week 4	18OCT2012	08:00	39.6		33.2		
	Week 8	15NOV2012	08:00	22.1		32.9		
	Week 12	13DEC2012	08:00	52.5		29.0		
	Week 16	17JAN2013	08:00	50.8		40.1		
	Week 20	15FEB2013	08:00	43.5		38.5		
	Week 24	21MAR2013	08:00	46.0		35.9		
	Week 28	17APR2013	08:00	36.9		41.2		
	Week 32	17MAY2013	08:00	35.6		33.7		
	Week 36	20JUN2013	08:00	32.0		31.7		
	Week 40	25JUL2013	08:00	45.8		35.9		Uns Continuation
	Week 46	12SEP2013	08:00	41.1		33.2		Uns Continuation

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE – ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
	Week 48	26SEP2013	09:00	38.8		38.7		Uns Continuation
	Week 48	26SEP2013	09:00	42.0		37.1		Uns Continuation

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
203-0010/74/M/W2	Week 50	17OCT2013	09:00	30.7		38.1		Uns Continuation
	Week 50	17OCT2013	09:00	30.8		32.0		Uns Continuation
	Week 52	30OCT2013	09:00	44.9		35.8		Uns Continuation
	Week 52	30OCT2013	09:00	48.0		33.4		Uns Continuation
	Week 54	15NOV2013	08:00	47.2		36.9		Uns Continuation
	Week 56	02DEC2013	09:00	43.4		35.1		Uns Continuation
	Week 58	20DEC2013	08:00	57.4		35.7		Uns Continuation
	Week 60	09JAN2014	08:00	39.9		31.5		Uns Continuation

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE – ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
	Week 62	24JAN2014	09:00	57.9		36.4		Uns Continuation
	Week 64	10FEB2014	09:00	34.2		35.3		Uns Continuation
	Week 66	24FEB2014	08:00	51.0		39.8		Uns Continuation
	Week 70	28MAR2014	09:00	31.3		34.3		Uns Continuation
	Week 72	17APR2014	08:30	35.4		36.0		Uns Continuation
	Week 74	02MAY2014	09:00	42.9		38.8		Uns Continuation

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[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE – ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE – WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
203-0010/74/M/W2	Week 76	19MAY2014	08:00	32.7		35.5		Uns Continuation
	Week 78	05JUN2014	09:00	32.6		33.0		Uns Continuation
	Week 80	19JUN2014	09:00	47.0		35.4		Uns Continuation
	Week 82	04JUL2014	08:30	38.7		31.3		Uns Continuation
	Week 84	17JUL2014	09:00	25.7		35.6		Uns Continuation
	Week 86	31JUL2014	09:00	24.0		35.7		Uns Continuation
	Week 90	04SEP2014	09:00	40.5		37.7		Uns Continuation
	Week 92	22SEP2014	09:00	47.7		38.1		Uns Continuation

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE – ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE – WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

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Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
	Week 96	24OCT2014	09:00	39.3		36.4		Uns Continuation
203-0014/73/M/W2	Screening	10JAN2014	08:00	77.7		33.8		
	Week 2	30JAN2014	08:00	68.4		35.3		
	Week 4	13FEB2014	09:00	49.9		34.6		
	End of Treatment	06MAR2014	09:00	65.9		35.1		Week 8 (7 days after week 7 visit)
203-0016/57/M/W2	Screening	28JAN2014	09:00	97.7		62.0		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE – ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE – WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
203-0016/57/M/W2	Week 2	11FEB2014	09:00	87.6		52.7		
	Week 4	27FEB2014	09:00	98.7		52.4		
	Week 8	31MAR2014	08:30	98.0		40.4		
	Week 12	02MAY2014	09:00	75.2		36.7		
	Week 16	03JUN2014	09:00	81.6		43.3		
	Week 20	03JUL2014	09:00	73.2		44.0		
	Week 24	31JUL2014	09:00	84.6		53.5		
203-0019/68/M/W2	Unscheduled	Unknown	Unknown	29.8		43.1		Week 1
	Screening	12MAY2014	09:00	69.5		41.5		
	Week 2	30MAY2014	09:00	40.9		39.7		
	Week 4	13JUN2014	09:00	43.2		33.8		
204-0003/64/M/W2	Screening	27JUN2013	13:50	127		36.7		
	Week 4	22JUL2013	09:30	97.6		36.2		
	Week 8	26AUG2013	09:55	138		45.4		

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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
204-0003/64/M/W2	Week 12	26SEP2013	08:20	109		65.2		
204-0004/76/F/W2	Screening	04SEP2013	10:20	65.9		33.3		
	Week 2	24SEP2013	09:15	66.1		31.5		
	Week 4	11OCT2013	09:58	43.9		30.8		
	Week 8	14NOV2013	08:30	36.2		23.7		
	Week 12	12DEC2013	09:25	37.9		29.9		
205-0002/71/M/W2	Screening	14FEB2012	09:00	40.3		27.7		Retest in sample list from CLS
	Week 4	16MAR2012	09:00	32.1		34.9		
	Unscheduled	30MAR2012	09:00	36.5		27.2		Week 6
	Week 8	13APR2012	09:00	30.4		20.8		
	Week 12	08MAY2012	09:00	43.6		29.7		

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Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
205-0003/79/M/W2	Unscheduled	Unknown	Unknown	61.4		54.7		Week 1 (collection date not found on visit report, date is between week 1 and week2)
	Screening	16MAR2012	09:00	49.2		57.3		
	Week 4	17APR2012	09:00	74.9		54.9		

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Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
205-0003/79/M/W2	Week 8	15MAY2012	09:00	59.4		43.7		
	Week 12	12JUN2012	09:00	58.5		67.7		
	Week 16	10JUL2012	09:00	28.7		51.2		
	Week 20	14AUG2012	09:00	34.5		65.8		
	Week 24	11SEP2012	09:00	25.9		54.8		
	Week 28	09OCT2012	09:00	56.1		54.1		Back up sample, no primary sample was received
	Week 32	06NOV2012	09:00	64.5		45.4		
	Week 36	04DEC2012	09:00	36.8		49.9		
205-0005/71/M/W2	Screening	12MAR2012	09:00	33.4		34.3		
	Week 4	12APR2012	09:00	31.1		27.6		
	Week 8	10MAY2012	09:00	27.7		27.5		

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Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
	Week 12	05JUN2012	09:00	28.3		18.7		
205-0014/70/M/W2	Screening	07JUN2013	07:30	27.5		30.5		
	Week 2	28JUN2013	09:30	37.4		21.2		

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Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
205-0014/70/M/W2	Week 4	26JUL2013	10:30	36.6		18.2		
	Week 5	02AUG2013	10:30	38.8		21.1		
205-0023/72/M/W2	Screening	29OCT2013	13:30	61.5	63.85	43.7	42.4	
	Screening	29OCT2013	13:30	66.2		41.1		
	Week 2	15NOV2013	09:15	77.5		47.9		
	Week 4	29NOV2013	08:30	82.5		48.8		
	Week 8	23DEC2013	09:30	76.6		41.8		
	Week 12	21JAN2014	08:45	97.3		50.4		
205-0026/61/F/W2	Screening	02MAR2012	Unknown	103	84.15	48.7	43.45	

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	Screening	02MAR2012	Unknown	65.3		38.2		Screening (collection date not found on visit report, date is between screening and week 1)
	Week 2	17FEB2015	10:00	56.9		43.9		
	Week 4	03MAR2015	10:30	54.0		36.1		
	Week 8	31MAR2015	10:00	49.8		41.6		
	Week 12	28APR2015	11:00	63.6		38.9		

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Pharmacodynamic Analysis Results
(Safety Population)

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Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
205-0028/73/F/W2	Screening	19JAN2015	12:00	75.9		29.6		
	Week 2	03FEB2015	10:30	64.6		24.0		
207-0002/71/M/W2	Screening	08MAR2012	12:30	77.0		68.7		
	Week 4	12APR2012	09:40	88.5		72.6		
	Week 8	10MAY2012	09:40	87.4		60.0		
	Week 12	07JUN2012	09:30	53.4		44.9		
207-0007/71/M/W2	Screening	18JUN2012	10:30	88.1		102		
	Week 4	23JUL2012	10:00	74.7		82.1		
	Week 8	20AUG2012	10:55	94.7		76.7		
207-0012/66/M/W2	Screening	12MAR2013	08:30	68.9		42.7		
	Week 4	11APR2013	09:50	42.7		36.9		
	Week 8	09MAY2013	08:30	42.5		42.9		
	Week 12	06JUN2013	08:45	48.0		50.6		
	Week 16	04JUL2013	08:45	54.5		54.9		

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207-0012/66/M/W2	Week 20	01AUG2013	09:15	74.4		46.7		
	Week 24	30AUG2013	08:30	48.6		48.6		
	Week 28	04OCT2013	08:50	70.2		41.3		
	Week 32	31OCT2013	08:50	76.6		46.0		
	Week 36	29NOV2013	09:30	63.7		56.8		
	Week 42	10JAN2014	11:30	55.0		52.2		Uns Continuation
	Week 44	24JAN2014	09:45	69.3		65.9		Uns Continuation
	Week 46	06FEB2014	10:30	109		75.0		Uns Continuation
207-0016/82/F/W2	Screening	30SEP2013	10:00	94.4		44.4		
	Week 4	31OCT2013	10:40	97.9		39.1		
	Week 8	28NOV2013	09:40	90.8		37.5		
	Week 12	27DEC2013	09:30	108		47.1		

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Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
207-0017/81/F/W2	Screening	22NOV2013	10:00	44.3		30.4		
	Week 2	05DEC2013	10:45	61.3		51.2		

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207-0017/81/F/W2	Week 4	19DEC2013	10:00	35.9		44.0		
	Week 8	17JAN2014	10:50	62.9		28.3		
	Week 12	13FEB2014	12:30	52.8		18.0		
207-0019/55/M/W2	Screening	27MAY2014	13:15	34.7		15.9		
	Week 2	10JUN2014	10:20	48.1		15.6		
209-0006/68/M/W2	Screening	18APR2013	09:45	60.3		28.0		
	Week 2	07MAY2013	09:30	78.2		38.2		
	Week 4	21MAY2013	09:30	98.8		30.9		
	Week 8	18JUN2013	10:45	93.3		24.5		
	Week 12	24JUL2013	08:00	54.4		27.0		
	Week 16	20AUG2013	10:00	65.3		22.9		
	Week 20	20SEP2013	09:30	64.5		23.5		
	Week 24	15OCT2013	10:30	57.7		25.2		
	Week 28	14NOV2013	11:00	58.8		31.8		

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Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
209-0006/68/M/W2	Week 32	10DEC2013	09:30	55.4		30.2		
	Week 36	07JAN2014	09:15	56.3		23.6		
209-0011/69/M/W2	Screening	21NOV2013	10:50	95.8		35.3		
	Week 2	10DEC2013	11:30	72.3		35.1		
	Week 4	23DEC2013	09:00	68.2		35.4		
	Week 8	22JAN2014	09:50	61.1		25.8		
	Week 12	19FEB2014	09:30	85.5		28.6		
209-0014/79/M/W2	Screening	04MAR2014	10:05	95.8		64.3		
	Week 2	26MAR2014	10:15	96.3		55.8		
	Week 4	08APR2014	11:00	92.7		55.5		
	Week 8	07MAY2014	10:20	92.2		71.7		
	Week 12	04JUN2014	10:30	95.2		47.2		
	Week 16	02JUL2014	09:00	95.9		55.7		
	Week 20	29JUL2014	10:00	82.7		55.3		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE – ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
209-0014/79/M/W2	Week 24	26AUG2014	10:10	79.2		68.1		
	End of Treatment	23SEP2014	09:00	72.0		52.0		Week 28 (4 weeks after week 24 visit)
210-0003/74/M/W2	Screening	30OCT2013	10:00	79.5	91.75	44.3	46.25	
	Screening	30OCT2013	10:00	104		48.2		
	Week 2	14NOV2013	10:30	68.3		41.3		
	Week 4	28NOV2013	11:15	55.4		33.2		
210-0004/71/M/W2	Screening	02JAN2014	09:45	61.9		40.0		
	Week 2	15JAN2014	09:40	79.4		41.5		
	Week 4	29JAN2014	09:30	74.2		42.0		
	Week 8	26FEB2014	09:35	74.4		33.9		
	Week 12	26MAR2014	10:00	63.4		34.0		
210-0005/53/M/W2	Screening	13FEB2014	09:20	85.0		28.7		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE – ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
	Week 2	27FEB2014	09:30	95.9		33.0		
	Week 4	13MAR2014	11:30	79.5		31.3		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE – ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE – WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
210-0005/53/M/W2	Week 8	10APR2014	09:15	76.3		29.7		
	Week 12	07MAY2014	09:10	58.2		31.0		
210-0006/45/M/W2	Screening	18JUN2014	10:45	103		34.4		
	Week 2	02JUL2014	09:20	112		28.9		
	Week 4	16JUL2014	10:15	119		37.1		
	Week 8	14AUG2014	09:30	105		47.3		
	Week 12	10SEP2014	10:20	157		63.7		
251-0002/69/M/W2	Screening	06AUG2013	11:00	34.7		18.1		
	Week 2	20AUG2013	11:30	33.4		13.8		
	Week 4	03SEP2013	11:45	38.1		15.6		
	Week 8	01OCT2013	11:30	31.9		13.8		
251-0003/68/M/W2	Screening	29OCT2013	09:36	53.6	68.8	22.9	22.3	
	Screening	29OCT2013	09:36	84.0		21.7		
	Week 2	12NOV2013	09:00	77.0		27.8		

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[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE – ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
251-0003/68/M/W2	Week 4	26NOV2013	09:15	62.0		28.4		
	Week 12	21JAN2014	10:00	95.4		23.0		
	Week 16	18FEB2014	10:00	69.4		20.1		
	Week 20	18MAR2014	10:30	74.6		26.3		
	Week 24	15APR2014	11:00	60.6		20.6		
252-0001/65/M/A3	Screening	30MAY2008	Unknown	55.5		46.7		
	Week 4	29MAY2012	11:25	45.7		31.8		
	Week 8	26JUN2012	11:35	48.2		41.5		
252-0004/50/M/A1	Screening	21MAY2013	11:20	63.6		28.2		
	Week 2	04JUN2013	11:00	103		32.9		
	Week 4	18JUN2013	11:30	84.6		23.5		
	Unscheduled	16JUL2013	10:35	67.6		24.5		Week 8
252-0006/64/M/W2	Screening	25JUL2013	Unknown	91.3		43.3		
	Week 2	08OCT2013	08:25	56.7		17.6		

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[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE – ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
252-0006/64/M/W2	Week 4	22OCT2013	08:30	108		39.1		
	Week 8	19NOV2013	08:30	82.8		16.1		
	Week 12	17DEC2013	08:30	81.5		37.9		
	Week 16	14JAN2014	08:20	92.0		43.2		
	Week 20	11FEB2014	08:00	93.2		42.9		
	Week 24	11MAR2014	08:00	104		45.3		
252-0008/76/M/W2	Screening	20MAY2014	11:30	53.5		15.4		
	Week 2	03JUN2014	11:05	56.4		12.9		
	Week 4	17JUN2014	11:25	59.4		19.9		
	Week 8	15JUL2014	11:15	52.1		12.1		
	Week 12	12AUG2014	12:40	48.0		13.2		
252-0010/56/F/W2	Screening	28OCT2014	10:40	128		37.4		
	Week 2	11NOV2014	11:10	71.6		24.3		
	Week 4	25NOV2014	10:10	90.6		28.6		

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[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
252-0010/56/F/W2	Week 8	23DEC2014	10:03	73.3		26.7		
	Week 12	20JAN2015	10:45	85.0		30.5		
253-0003/75/M/W2	Screening	25MAY2012	11:30	36.1		13.7		
	Week 4	06JUL2012	11:44	44.4		16.4		
	Week 8	03AUG2012	11:35	60.0		20.6		
	Week 12	31AUG2012	11:20	64.8		60.9		
	Week 16	28SEP2012	11:20	49.7		15.2		
	Week 20	26OCT2012	11:30	59.8		35.2		
	Week 24	23NOV2012	11:30	38.0		14.0		
	Week 28	21DEC2012	11:30	57.4		36.4		
	Week 32	18JAN2013	12:00	36.2		14.2		
	Week 36	15FEB2013	11:20	48.2		17.9		
253-0004/79/M/W2	Screening	04SEP2012	14:30	105		50.8		
	Week 4	28SEP2012	10:20	61.4		43.7		

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[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE – ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE – WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
253-0004/79/M/W2	Week 8	26OCT2012	10:30	51.8		14.5		
	Week 12	23NOV2012	10:00	88.2		46.5		
253-0005/74/F/W2	Screening	03MAR2011	Unknown	73.3		35.7		
253-0006/63/M/A3	Screening	16NOV2012	Unknown	63.3		32.6		
	Week 4	18JAN2013	12:00	136		53.6		
	Week 8	15FEB2013	11:45	136		53.0		
	Week 12	15MAR2013	11:30	117		60.5		
	Week 16	12APR2013	11:05	131		56.7		
	Week 20	10MAY2013	10:00	114		43.9		
253-0011/67/M/W2	Screening	25SEP2014	10:00	77.1		41.3		
	Week 2	13OCT2014	10:10	72.5		51.3		
	Week 4	27OCT2014	10:30	73.3		37.5		
	Week 8	24NOV2014	10:20	78.5		42.9		
	Week 12	22DEC2014	10:00	63.2		44.4		

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[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE – ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
253-0011/67/M/W2	Week 16	19JAN2015	11:00	76.8		32.7		
	Week 20	16FEB2015	09:50	104		58.5		
	Week 24	16MAR2015	10:50	64.5		33.2		
	Week 28	13APR2015	09:40	74.3		39.7		
	Week 32	11MAY2015	09:58	61.7		30.1		
253-0012/67/M/W2	Screening	24NOV2014	12:10	95.2		33.6		
	Week 2	15DEC2014	09:40	72.6		17.8		
	Week 4	29DEC2014	09:30	47.7		18.6		
257-0005/66/M/W2	Screening	11DEC2012	09:50	55.8	53	57.7	51.15	

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[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
	Unscheduled	11DEC2012	09:50	50.2		44.6		Screening (collection date not found on visit report, date is between screening and week 1)
	Week 4	24JAN2013	11:56	36.9		43.7		
	Unscheduled	28FEB2013	Unknown	35.2		33.7		Week 9
	Week 12	21MAR2013	10:35	33.0		26.3		
257-0013/63/M/W2	Screening	23MAY2013	12:10	60.6		21.8		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE – ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE – WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
257-0013/63/M/W2	Week 2	07JUN2013	11:53	46.5		11.2		
	Week 4	20JUN2013	11:45	54.5		17.9		
257-0020/72/M/A1	Screening	21OCT2014	14:10	60.3		26.9		
	Week 2	03NOV2014	15:30	67.6		32.2		
	Week 4	17NOV2014	13:43	59.1		25.8		
258-0002/69/F/W2	Screening	08APR2013	10:00	40.4	39	34.6	29.3	
	Unscheduled	08APR2013	10:00	37.6		24.0		Screening (collection date not found on visit report, date is between screening and week 1)
	Week 2	17APR2013	11:50	37.1		28.7		
	Week 4	01MAY2013	11:00	38.6		31.0		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE – ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE – WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
	Week 8	29MAY2013	11:08	35.3		31.9		
	Week 12	26JUN2013	11:30	49.9		40.4		
	Week 16	24JUL2013	09:45	33.5		30.5		
	Week 20	21AUG2013	10:26	72.9		32.4		
	Week 24	18SEP2013	10:34	39.5		24.4		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
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[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
258-0002/69/F/W2	Week 28	16OCT2013	10:46	57.6		30.6		
	Week 36	11DEC2013	12:13	35.4		23.5		
258-0003/67/F/W2	Screening	09MAY2013	11:30	72.9		30.3		
	Week 4	05JUN2013	11:25	68.6		27.4		
	Week 8	03JUL2013	11:05	59.8		28.6		
	Week 12	31JUL2013	11:24	57.7		27.0		
	Week 16	30AUG2013	10:07	71.4		29.5		
	Week 24	23OCT2013	10:25	72.5		34.5		
258-0004/65/M/W2	Screening	13MAY2013	11:20	103		50.9		
	Week 2	29MAY2013	Unknown	83.9		34.2		
258-0006/69/M/W2	Screening	02OCT2013	10:50	44.5		33.8		
	Week 2	25OCT2013	10:41	36.6		17.9		
	Week 4	08NOV2013	10:45	42.4		18.4		
258-0013/59/M/W2	Screening	05NOV2014	10:05	90.4		54.2		

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[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
258-0013/59/M/W2	Week 2	19NOV2014	10:21	100		69.4		
	Week 4	03DEC2014	10:40	87.0		52.4		
	Week 8	29DEC2014	11:25	100		55.2		
	Week 12	28JAN2015	12:00	77.3		53.0		
259-0003/73/M/W2	Unscheduled	09JUN2014	13:50	63.9		59.0		Screening
	Week 2	18JUN2014	11:55	78.2		54.0		
	Week 4	02JUL2014	11:15	88.2		62.0		
	Week 8	30JUL2014	12:05	87.0		74.4		
	Week 12	27AUG2014	11:40	79.8		68.9		
	Week 16	24SEP2014	11:55	81.9		55.9		
	Week 20	22OCT2014	11:10	84.4		81.0		
	Week 24	19NOV2014	11:00	93.8		67.9		
	Week 28	17DEC2014	11:30	79.6		75.9		
	Week 32	14JAN2015	11:10	84.3		58.6		

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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
259-0003/73/M/W2	Week 40	11MAR2015	11:14	67.2		58.4		Uns Continuation
	Week 44	08APR2015	11:40	73.5		52.8		Uns Continuation
	Week 48	06MAY2015	10:50	53.4		61.5		Uns Continuation
259-0004/52/M/W2	Screening	16JUL2014	10:45	76.7		42.9		
	Unscheduled	23JUL2014	Unknown	84.7		42.3		Week 1 (2 days after week 1 visit)
	Week 2	30JUL2014	12:40	104		47.6		
	Week 4	13AUG2014	11:25	64.9		46.1		
260-0002/66/M/W2	Screening	18SEP2013	15:15	87.7		29.2		
	Week 2	09OCT2013	14:15	111		29.7		
	Week 4	23OCT2013	14:15	104		28.4		

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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
301-0001/47/F/A2	Screening	27OCT2011	10:05	91.7		37.3		
	Week 4	22NOV2011	09:25	73.4		37.8		
	Week 8	20DEC2011	09:25	111		40.7		
	Week 12	17JAN2012	11:50	102		35.0		

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[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
301-0003/61/F/A2	Screening	23FEB2012	11:40	57.1		42.3		
	Week 4	22MAR2012	10:40	43.0		45.8		
	Week 8	19APR2012	11:10	42.0		20.2		
	Week 12	17MAY2012	11:10	55.0		34.0		
301-0008/53/M/A2	Screening	26DEC2012	09:50	57.3		20.3		
	Week 4	25JAN2013	09:50	48.2		18.2		
	Week 8	22FEB2013	09:50	87.0		19.2		
	Week 12	22MAR2013	10:35	60.5		13.7		
302-0006/49/M/A2	Screening	04JAN2012	09:30	83.5		22.5		
	Week 4	31JAN2012	09:45	70.2		22.0		
	Week 8	28FEB2012	09:40	71.7		27.2		
302-0009/73/M/A2	Screening	11APR2012	09:02	108		55.3		
	Week 4	08MAY2012	09:03	112		56.2		
	Week 8	05JUN2012	09:12	112		53.5		

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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
302-0012/62/M/A2	Screening	18APR2012	08:30	133		59.3		
	Week 4	15MAY2012	08:15	102		53.7		
	Week 8	12JUN2012	10:22	117		42.7		
	Week 12	10JUL2012	08:23	99.2		33.7		
302-0013/62/M/A2	Screening	21MAR2013	09:55	80.5		28.3		
	Week 2	02APR2013	08:35	88.1		30.4		
	Week 4	16APR2013	08:05	95.8		25.6		
	Week 8	14MAY2013	08:10	134		37.7		
302-0020/52/M/A2	Screening	16MAY2013	09:00	100		23.0		
	Week 2	28MAY2013	09:25	95.6		23.8		
	Week 4	11JUN2013	09:00	94.7		19.5		
302-0021/75/F/A2	Screening	06JUN2013	10:25	71.0		34.3		
	Week 2	18JUN2013	09:50	66.2		39.0		
	Week 4	02JUL2013	09:30	89.7		46.7		

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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
302-0021/75/F/A2	Week 8	30JUL2013	09:45	70.0		24.0		
	Week 12	27AUG2013	09:10	94.0		39.3		
	Week 16	24SEP2013	09:45	78.7		32.9		
	Week 20	22OCT2013	10:15	75.2		38.7		
	Week 24	19NOV2013	09:20	67.8		37.0		
304-0003/56/F/A2	Screening	11MAR2013	11:50	99.8		47.0		
	Week 4	03APR2013	10:00	97.5		40.3		
	Week 8	02MAY2013	10:00	92.8		42.3		
	Week 12	30MAY2013	09:02	91.1		44.7		
304-0004/69/M/A2	Screening	30MAY2013	13:00	74.6		40.8		
	Week 2	11JUN2013	11:40	46.8		8.71		
	Week 4	25JUN2013	08:02	59.5		21.6		
304-0007/72/M/A2	Screening	07NOV2013	11:20	95.2		51.6		
	Week 2	20NOV2013	09:30	77.6		38.0		

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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
304-0007/72/M/A2	Week 4	04DEC2013	10:00	88.2		39.8		
	Week 8	02JAN2014	10:00	102		42.3		
	Week 12	28JAN2014	09:48	76.3		47.4		
305-0004/79/M/A2	Screening	14FEB2012	16:50	147		47.6		
	Week 4	15MAR2012	08:07	88.2		66.4		
	Week 8	12APR2012	09:00	72.8		44.5		
	Week 12	10MAY2012	08:16	82.3		46.5		
305-0007/67/M/A2	Screening	10SEP2009	Unknown	101		38.0		
	Week 4	30MAR2012	08:00	89.8		45.9		
	Week 8	27APR2012	08:00	153		50.3		
	Week 12	25MAY2012	07:40	115		41.8		
	Week 16	22JUN2012	07:32	136		48.0		
	Week 20	20JUL2012	07:55	167		65.6		
	Week 24	17AUG2012	07:38	138		58.5		

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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
305-0015/84/M/A2	Screening	04JUL2012	11:50	88.4		79.2		
	Week 4	26JUL2012	07:13	50.5		57.2		
	Week 8	21AUG2012	12:47	80.3		52.2		
	Week 12	20SEP2012	08:14	40.4		47.9		
305-0016/78/M/A2	Screening	04JUL2012	16:10	63.8		38.2		
	Week 4	01AUG2012	12:40	72.8		33.0		
	Week 8	28AUG2012	09:05	82.3		26.9		
	Week 12	25SEP2012	12:40	98.5		39.0		
305-0021/83/F/A2	Screening	16NOV2012	16:34	45.5		23.2		
	Week 4	11DEC2012	12:58	53.3		16.2		
	Week 8	08JAN2013	12:10	73.8		16.2		
	Week 12	05FEB2013	13:00	39.6		14.6		
305-0024/68/M/A2	Screening	14JAN2013	10:30	50.5		24.5		
	Week 4	08FEB2013	08:00	44.7		31.8		

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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
305-0024/68/M/A2	Week 8	05MAR2013	13:15	51.6		29.6		
	Week 12	03APR2013	13:10	50.2		26.0		
305-0033/37/F/A2	Screening	25JUN2013	15:20	87.8		26.6		
	Week 2	09JUL2013	15:05	69.4		21.7		
	Week 4	23JUL2013	15:00	99.5		32.8		
	Week 8	20AUG2013	15:25	86.3		43.5		
	Week 12	17SEP2013	16:00	76.2		29.2		
305-0035/60/M/A2	Screening	27AUG2013	15:30	72.1		50.4		
	Week 2	04SEP2013	12:55	64.3		49.5		
	Week 4	18SEP2013	11:40	50.3		46.7		
	Week 8	16OCT2013	12:00	70.5		41.9		
	Week 12	13NOV2013	12:25	58.0		47.8		
	Week 16	11DEC2013	12:50	68.3		43.9		
	Week 20	08JAN2014	12:53	98.5		53.1		

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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
305-0035/60/M/A2	Week 24	05FEB2014	12:20	59.1		42.5		
305-0046/60/M/A2	Screening	03NOV2014	12:20	52.3		40.0		
	Week 2	14NOV2014	13:00	71.3		36.0		
	Week 4	28NOV2014	13:21	67.0		46.7		
	Week 8	26DEC2014	13:15	68.9		52.9		
	Week 12	23JAN2015	12:50	51.5		52.1		
	Week 16	17FEB2015	13:05	62.1		61.2		
	Week 20	20MAR2015	12:40	52.5		32.3		
	Week 24	14APR2015	12:50	60.1		53.3		
306-0004/46/M/A2	Screening	09FEB2012	Unknown	141		25.8		
	Week 4	13MAR2012	09:00	108		23.0		
306-0010/69/M/A2	Screening	18APR2006	Unknown	126		28.5		
	Week 4	11APR2012	11:00	104		30.3		
	Week 8	09MAY2012	10:30	78.8		27.7		

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[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE – ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
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Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
306-0010/69/M/A2	Week 12	06JUN2012	10:00	70.2		20.5		
306-0013/42/M/A2	Screening	09APR2012	09:30	55.2		24.4		
	Week 4	07MAY2012	10:00	51.8		22.4		
	Week 8	04JUN2012	09:00	46.0		25.2		
306-0015/73/M/A2	Screening	15MAY2012	10:30	77.4		42.1		
	Week 4	07JUN2012	09:00	117		47.8		
306-0016/58/M/A2	Screening	21JUN2012	09:00	77.7		26.1		
	Week 4	16JUL2012	09:20	115		35.6		
	Week 8	13AUG2012	09:05	63.4		13.1		
	Week 12	11SEP2012	08:20	114		35.3		
306-0022/56/M/A2	Screening	22MAR2012	Unknown	81.9		40.2		
	Week 4	04DEC2012	09:00	88.7		45.2		
	Week 8	02JAN2013	08:50	96.4		49.9		
	Week 12	29JAN2013	08:50	90.7		40.6		

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[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE – ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE – WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
306-0022/56/M/A2	Week 16	26FEB2013	08:20	82.7		39.8		
	Week 20	26MAR2013	08:30	99.0		52.0		
	Week 24	23APR2013	08:20	72.4		45.3		
306-0028/53/M/A2	Screening	18MAR2013	13:30	114		38.8		
	Week 4	18APR2013	09:00	126		54.5		
	Week 8	16MAY2013	09:30	124		71.7		
	Week 12	13JUN2013	09:30	112		56.7		
306-0045/60/F/A1	Screening	11JUN2014	12:30	117		47.2		
	Week 2	25JUN2014	13:00	86.6		29.2		
	Week 4	08JUL2014	13:00	75.8		39.5		
	Week 8	05AUG2014	13:00	112		50.6		
	Week 12	02SEP2014	13:00	121		63.6		
307-0006/72/M/A2	Screening	25NOV2011	09:09	104		26.5		
307-0009/53/M/A2	Screening	28DEC2011	09:45	34.0		2.46		

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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
307-0009/53/M/A2	Week 4	27JAN2012	09:15	20.9		1.94		
307-0012/42/M/A2	Screening	31JAN2012	09:00	66.7		12.8		
307-0015/75/M/A2	Screening	18APR2012	08:43	86.1		53.2		
	Week 4	16MAY2012	08:45	80.2		47.2		
	Week 8	13JUN2012	09:25	91.9		46.0		
	Week 12	11JUL2012	10:50	70.6		44.1		
	Week 16	08AUG2012	09:57	72.4		36.1		
	Week 20	05SEP2012	09:30	80.0		50.4		
	Week 24	04OCT2012	10:50	79.7		42.1		
307-0021/68/M/A2	Screening	14AUG2012	09:30	101		55.7		
	Week 4	13SEP2012	08:57	105		45.1		
	Week 8	09OCT2012	08:35	91.7		31.2		
	Week 12	08NOV2012	09:18	78.3		28.0		
	Week 16	06DEC2012	09:20	65.2		29.9		

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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
307-0028/69/F/A2	Screening	09JAN2013	09:49	78.5		30.5		
	Week 4	04FEB2013	09:35	102		36.4		
	Week 8	04MAR2013	09:34	80.6		25.6		
	Week 12	01APR2013	09:32	74.4		30.1		
307-0034/48/M/A2	Screening	08AUG2013	11:48	92.2		35.2		
	Week 2	20AUG2013	10:25	85.3		40.5		
	Week 4	03SEP2013	10:24	91.6		40.8		
	Week 8	01OCT2013	09:10	70.8		34.4		
	Week 12	29OCT2013	09:35	73.6		39.6		
307-0036/76/M/A2	Screening	27SEP2013	08:06	82.3		43.4		
	Week 2	08OCT2013	10:50	153		55.9		
	Week 4	24OCT2013	08:33	114		45.2		
	Week 8	21NOV2013	09:20	142		57.6		
	Week 12	18DEC2013	09:09	79.2		47.1		

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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
307-0042/55/M/A2	Screening	10JUN2014	10:35	80.2		29.8		
	Week 2	26JUN2014	10:55	73.6		34.7		
	Week 4	10JUL2014	09:22	106		31.8		
	Week 8	07AUG2014	09:40	115		38.7		
	Week 12	04SEP2014	10:50	90.0		41.4		
	Week 16	02OCT2014	09:37	135		56.7		
	Week 20	30OCT2014	09:28	124		49.5		
	Week 24	27NOV2014	10:37	125		37.0		
308-0002/36/F/A2	Screening	27DEC2012	09:15	55.9		22.4		
	Week 4	22JAN2013	11:30	70.6		20.7		
	Week 8	19FEB2013	12:30	55.8		19.7		
	Week 12	19MAR2013	12:30	40.8		17.5		
308-0004/52/M/A2	Screening	31JAN2013	11:10	96.0		47.5		
	Week 4	26FEB2013	12:30	119		42.8		

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Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
308-0004/52/M/A2	Week 8	26MAR2013	12:30	128		56.7		
	Week 12	23APR2013	12:10	132		58.0		
308-0006/64/M/A2	Screening	12OCT2007	Unknown	62.9		36.7		
	Week 2	21MAY2013	09:20	92.0		31.2		
	Week 4	04JUN2013	13:20	51.8		23.7		
	Week 8	02JUL2013	13:05	80.5		29.4		
308-0008/47/M/A2	Screening	11JUL2013	14:10	95.3		42.8		
	Week 2	30JUL2013	12:40	82.3		32.4		
	Week 4	13AUG2013	09:15	77.0		28.3		
	Week 8	10SEP2013	09:10	54.9		19.5		
	Week 12	08OCT2013	09:00	60.6		19.4		
308-0009/61/M/A2	Screening	11JUL2013	13:40	90.4		24.3		
	Week 2	25JUL2013	14:30	66.1		31.4		
	Week 4	08AUG2013	11:10	54.5		8.72		

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Pharmacodynamic Analysis Results
(Safety Population)

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Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
308-0009/61/M/A2	Week 8	05SEP2013	13:30	49.1		10.3		
309-0006/56/M/A2	Screening	19NOV2012	12:15	108		54.9		
	Week 4	17DEC2012	10:45	123		58.0		
	Week 8	14JAN2013	11:20	122		48.3		
	Week 12	08FEB2013	10:00	116		38.5		
	Week 16	11MAR2013	09:40	126		46.4		
	Week 20	08APR2013	10:50	130		45.2		
	Week 24	06MAY2013	09:20	149		51.1		
	Week 28	03JUN2013	10:20	139		57.0		
	Week 32	01JUL2013	09:10	149		47.5		
	Week 36	29JUL2013	09:50	112		55.7		
309-0007/58/M/A2	Screening	19MAY2011	Unknown	51.8		24.3		
	Week 4	07JAN2013	11:30	67.7		26.6		
	Week 8	04FEB2013	09:40	52.1		26.3		

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Pharmacodynamic Analysis Results
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Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
309-0007/58/M/A2	Week 12	04MAR2013	09:20	40.5		19.8		
309-0013/45/M/A2	Screening	11DEC2012	Unknown	101		43.1		
	Week 2	27JUN2013	10:10	119		45.5		
	Week 4	11JUL2013	09:35	121		57.3		
	Week 8	08AUG2013	09:30	85.3		38.9		
	Week 12	05SEP2013	09:15	94.8		46.3		
309-0014/39/M/A2	Screening	14JUN2013	12:30	82.4		22.3		
	Week 2	27JUN2013	09:50	86.4		24.7		
	Week 4	11JUL2013	09:51	103		23.9		
	Week 8	08AUG2013	09:35	102		20.6		
	Week 12	05SEP2013	10:05	82.5		19.6		
309-0019/68/M/A2	Screening	17JUN2014	12:30	102		42.3		
	Week 2	01JUL2014	11:00	80.7		37.2		
	Week 4	15JUL2014	10:50	77.0		34.2		

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309-0019/68/M/A2	Week 8	12AUG2014	13:10	86.0		28.9		
	Week 12	09SEP2014	11:20	76.8		36.8		
	Week 16	07OCT2014	11:15	108		48.0		
	Week 20	04NOV2014	11:20	106		54.9		
	Week 24	01DEC2014	11:20	113		47.2		
	Week 28	29DEC2014	10:40	121		49.1		
	Week 32	28JAN2015	09:10	141		43.3		
	Week 36	24FEB2015	11:00	129		44.5		
	Week 40	24MAR2015	11:25	135		40.5		
	Week 44	22APR2015	09:30	120		38.2		
	Week 48	19MAY2015	11:20	124		44.5		
309-0027/49/M/A2	Screening	22OCT2014	12:20	80.7		44.4		
	Week 2	10NOV2014	10:45	117		32.6		
	Week 4	24NOV2014	10:55	177		57.8		

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Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
309-0027/49/M/A2	Week 8	22DEC2014	10:16	114		40.7		
	Week 12	19JAN2015	10:14	91.5		43.2		
309-0029/50/M/A2	Screening	18NOV2014	13:00	94.8		53.1		
	Week 2	08DEC2014	10:30	87.9		53.6		
	Week 4	22DEC2014	10:25	99.3		37.0		
	Week 8	19JAN2015	09:35	103		45.3		
310-0004/50/F/A2	Screening	25JAN2013	09:40	52.4		24.4		
	Week 4	27FEB2013	09:00	51.6		16.8		
	Week 8	27MAR2013	08:50	49.1		19.8		
	Week 12	24APR2013	11:10	30.8		16.9		
310-0005/58/M/A2	Screening	13MAR2013	14:00	90.4		35.9		
	Week 2	03APR2013	10:45	101		36.4		
	Week 4	17APR2013	11:00	101		36.4		
	Week 8	15MAY2013	09:40	115		42.5		

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Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
310-0005/58/M/A2	Week 12	10JUN2013	09:30	111		38.1		
310-0006/50/F/A2	Screening	24APR2013	08:50	126		45.7		
	Week 2	08MAY2013	08:40	76.6		33.8		
	Week 4	22MAY2013	09:20	78.0		42.2		
	Week 8	19JUN2013	08:30	84.3		42.3		
	Week 12	17JUL2013	11:25	132		40.9		
	Week 16	14AUG2013	09:00	79.8		54.3		
	Week 20	11SEP2013	10:00	85.5		59.5		
	Week 24	09OCT2013	09:50	78.5		42.1		
	Week 28	06NOV2013	10:50	89.1		57.9		
	Week 32	02DEC2013	11:00	69.6		44.6		
310-0007/74/M/A2	Screening	03JUN2013	14:30	49.8		12.2		
	Week 2	20JUN2013	10:30	56.8		10.6		
	Week 4	04JUL2013	11:00	90.0		17.2		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
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[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
310-0007/74/M/A2	Week 8	01AUG2013	10:45	97.2		16.3		
	Week 12	30AUG2013	11:00	97.8		19.6		
	Week 16	26SEP2013	10:45	133		47.5		
	Week 20	24OCT2013	11:00	76.5		19.1		
	Week 24	21NOV2013	10:50	95.6		20.9		
	Week 28	19DEC2013	10:55	119		29.4		
	Week 32	16JAN2014	09:40	96.2		43.9		
	Week 36	13FEB2014	11:00	71.1		17.2		
	Week 40	11MAR2014	11:00	58.7		17.1		
	Week 44	08APR2014	11:10	62.6		16.1		
310-0009/46/M/A2	Screening	31JUL2013	09:30	80.9		51.8		
	Week 2	14AUG2013	10:45	70.0		42.5		
	Week 4	28AUG2013	10:45	72.7		53.8		
	Week 8	25SEP2013	10:30	40.2		28.7		

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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
310-0010/34/F/A2	Screening	15AUG2013	14:20	61.8		33.0		
	Week 2	02SEP2013	10:00	66.7		39.6		
	Week 4	16SEP2013	08:20	59.3		36.7		
310-0011/52/M/A2	Screening	17OCT2013	12:40	72.0		44.8		
	Week 2	31OCT2013	12:20	98.3		51.1		
	Week 4	14NOV2013	12:15	82.4		42.3		
	Week 8	09DEC2013	08:40	96.0		40.1		
310-0014/64/M/A2	Screening	17SEP2014	08:37	85.6		38.1		
	Week 2	01OCT2014	08:03	47.6		44.7		
	Week 4	15OCT2014	07:05	66.6		57.4		
	Week 8	10NOV2014	07:01	56.6		65.7		
311-0003/44/M/A2	Screening	18SEP2013	10:10	103		48.8		
	Week 2	02OCT2013	14:20	92.1		44.9		
	Week 4	16OCT2013	09:00	116		37.8		

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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
311-0003/44/M/A2	Week 8	13NOV2013	10:10	99.5		42.1		
	Week 12	10DEC2013	08:00	84.4		38.6		
311-0004/68/M/A2	Screening	26SEP2013	09:00	61.7		19.6		
	Week 2	07OCT2013	08:55	51.2		19.6		
311-0005/58/M/A2	Screening	07OCT2013	14:00	88.3		27.0		
	Week 2	28OCT2013	14:00	143		25.6		
	Week 4	11NOV2013	14:00	130		40.4		
	Week 8	09DEC2013	13:30	76.6		34.7		
311-0006/73/F/A2	Screening	04NOV2013	15:00	98.5		53.6		
	Week 2	12NOV2013	10:00	66.7		74.9		
	Week 4	26NOV2013	09:45	49.6		69.4		
	Week 8	24DEC2013	08:30	65.5		54.7		
311-0009/51/F/A2	Screening	01JUL2014	16:10	94.2		37.8		
	Week 2	22JUL2014	09:25	109		32.9		

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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
311-0009/51/F/A2	Week 4	05AUG2014	14:40	79.6		38.2		
	Week 8	02SEP2014	12:00	63.5		24.1		
	Week 12	30SEP2014	09:47	97.0		44.3		
311-0010/47/M/A2	Screening	26AUG2014	08:55	64.1		41.0		
	Week 2	09SEP2014	14:00	71.6		45.2		
	Week 4	23SEP2014	14:30	77.6		38.5		
	Week 8	21OCT2014	13:25	47.9		28.3		
	Week 12	18NOV2014	09:45	66.2		40.0		
	Week 16	17DEC2014	11:00	46.9		39.8		
	Week 20	14JAN2015	10:50	74.2		28.5		
	Week 24	12FEB2015	13:10	38.9		46.9		
	Week 28	11MAR2015	13:32	57.2		29.6		
	Week 32	09APR2015	13:30	70.2		28.9		
	Week 36	07MAY2015	13:20	36.5		38.7		

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Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
311-0011/46/M/A2	Screening	28OCT2014	09:20	103		68.8		
	Week 2	05NOV2014	14:30	41.9		36.1		
	Week 4	19NOV2014	09:15	80.4		60.3		
	Week 8	17DEC2014	12:10	139		45.8		
311-0012/55/M/A2	Screening	20JAN2015	09:56	77.5		44.3		
	Week 2	05FEB2015	13:46	112		37.0		
	Week 4	17FEB2015	14:49	55.8		48.3		
	Week 8	19MAR2015	13:57	96.9		51.7		
	Week 12	16APR2015	11:27	32.6		52.5		
	Week 16	14MAY2015	14:00	72.7		41.0		
401-0001/70/M/A7	Screening	03JUN2013	09:30	192		12.0		
	Week 2	Unknown	Unknown	55.0		14.6		
401-0002/55/M/A7	Screening	12JUN2013	11:30	112		28.8		
	Week 2	27JUN2013	10:15	201		39.7		

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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
402-0001/35/M/A7	Screening	15APR2013	14:30	77.6		57.7		
	Week 2	29APR2013	13:00	74.4		53.9		
	Week 4	13MAY2013	12:40	84.4		62.4		
	Week 8	10JUN2013	12:00	70.5		55.3		
402-0002/58/M/A7	Screening	23APR2013	15:00	172		78.1		
	Week 2	30APR2013	14:12	167		74.9		
	Week 4	14MAY2013	13:00	114		53.7		
	Week 8	11JUN2013	12:30	116		54.0		
	Week 12	09JUL2013	12:00	157		49.6		
402-0005/70/M/A7	Screening	09MAY2013	09:30	129		48.0		
	Week 2	16MAY2013	09:40	135		59.5		
	Week 4	28MAY2013	09:30	145		60.8		
	Week 8	27JUN2013	09:10	137		51.2		
	Week 12	23JUL2013	08:20	126		71.5		

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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
402-0010/50/M/A7	Screening	10MAY2013	11:30	56.1		18.6		
	Week 2	27MAY2013	13:20	79.7		17.5		
	Week 4	10JUN2013	12:00	53.3		17.0		
	Week 8	Unknown	Unknown	41.7		10.4		
402-0022/60/F/A7	Screening	09AUG2013	09:30	80.1		22.0		
	Week 2	30AUG2013	09:00	77.1		16.1		
	Week 4	12SEP2013	08:10	37.7		11.9		
	Week 8	10OCT2013	09:10	69.8		18.5		
	Week 12	11NOV2013	08:11	56.6		10.7		
402-0023/57/M/A7	Screening	22AUG2013	14:20	97.3		42.9		
	Week 2	10SEP2013	12:10	95.0		22.2		
	Week 4	24SEP2013	12:30	64.6		27.4		
	Week 8	22OCT2013	12:20	79.6		29.1		
	Week 12	19NOV2013	12:00	101		43.0		

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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
402-0029/49/M/A7	Screening	06NOV2013	14:40	51.0		26.3		
	Week 2	18NOV2013	12:30	61.1		33.0		
	Week 4	02DEC2013	11:40	59.8		35.1		
	Week 8	30DEC2013	12:00	28.7		24.8		
402-0032/49/F/A7	Screening	28NOV2013	14:10	90.2		44.0		
	Week 2	12DEC2013	10:00	95.2		33.3		
	Week 4	26DEC2013	09:50	128		44.2		
	Week 8	23JAN2014	10:00	92.9		41.6		
	Week 12	20FEB2014	10:00	101		37.7		
402-0034/43/F/A7	Screening	11DEC2013	11:20	112		41.0		
	Week 2	26DEC2013	10:00	90.6		38.3		
	Week 4	09JAN2014	10:00	82.8		33.8		
	Week 8	07FEB2014	10:30	103		40.1		
	Week 12	06MAR2014	10:00	129		48.4		

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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
402-0034/43/F/A7	Week 16	03APR2014	10:00	96.7		31.7		
	Week 20	02MAY2014	10:00	102		29.8		
	Week 24	29MAY2014	10:00	96.1		35.9		
403-0004/37/M/A7	Screening	03JUL2013	08:34	88.4		34.0		
	Week 2	17JUL2013	10:11	87.2		34.2		
	Week 4	31JUL2013	09:08	87.5		31.7		
	Week 8	28AUG2013	12:28	79.0		37.6		
	Week 12	25SEP2013	09:32	97.7		36.0		
404-0003/53/M/A7	Screening	02SEP2013	08:30	71.3		23.4		
	Week 2	17SEP2013	07:30	43.8		13.1		
404-0004/61/F/A7	Screening	08OCT2013	11:00	52.3		31.7		
	Week 2	21OCT2013	12:05	92.0		51.9		
	Week 4	04NOV2013	12:00	70.9		40.8		
	Week 8	02DEC2013	11:45	70.3		38.2		

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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
405-0001/55/M/A7	Screening	22APR2013	08:55	83.0		31.0		
	Week 2	29APR2013	08:45	90.2		19.9		
	Week 4	15MAY2013	13:20	100		18.2		
	Week 8	10JUN2013	08:35	85.1		21.2		
	Week 12	10JUL2013	10:10	100		42.0		
405-0005/35/M/A6	Screening	19APR2013	13:40	88.1		33.3		
	Week 2	29APR2013	09:00	106		29.6		
	Week 4	15MAY2013	11:05	80.7		33.5		
	Week 8	10JUN2013	09:00	106		28.0		
	Week 12	10JUL2013	09:05	102		31.8		
	Week 16	07AUG2013	09:25	95.5		21.7		
	Week 20	04SEP2013	09:20	97.8		29.7		
	Week 24	02OCT2013	09:05	106		31.8		
	Week 28	30OCT2013	09:10	68.2		24.2		

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Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
405-0005/35/M/A6	Week 32	27NOV2013	09:20	87.5		21.9		
	Week 32	27NOV2013	09:20	104		27.8		
405-0012/72/M/A7	Screening	09MAY2013	15:51	153		94.4		
	Week 2	22MAY2013	11:35	119		68.0		
	Week 4	05JUN2013	10:25	166		79.8		
	Week 8	01JUL2013	09:00	120		65.0		
	Week 12	29JUL2013	08:40	122		57.8		
	Week 16	26AUG2013	09:00	112		56.8		
	Week 20	23SEP2013	08:50	123		63.0		
	Week 24	21OCT2013	09:00	130		65.4		
405-0019/61/M/A7	Screening	17JUN2013	10:50	148		68.6		
	Week 2	01JUL2013	10:10	140		61.0		
	Week 4	15JUL2013	09:15	150		79.2		
405-0024/69/M/A7	Screening	19JUN2013	17:25	105		37.8		

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[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
405-0024/69/M/A7	Week 2	10JUL2013	10:20	88.7		44.3		
405-0026/67/M/A7	Screening	27JUN2013	15:20	117		39.8		
	Week 2	17JUL2013	11:40	105		44.5		
	Week 4	31JUL2013	12:35	76.1		36.2		
	Week 8	28AUG2013	11:27	110		47.9		
	Week 12	25SEP2013	11:47	79.4		43.9		
405-0036/70/M/A7	Screening	17APR2012	Unknown	78.9		26.5		
	Week 2	28AUG2013	08:50	96.5		41.5		
	Week 4	13SEP2013	09:20	79.9		29.8		
	Week 8	14OCT2013	08:45	113		32.0		
	Week 12	11NOV2013	08:45	65.6		25.1		
405-0041/57/M/A7	Screening	11SEP2013	14:40	122		43.1		
	Week 2	16SEP2013	09:45	136		37.8		
	Week 4	02OCT2013	10:30	142		43.1		

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Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
405-0041/57/M/A7	Week 8	28OCT2013	08:35	150		39.1		
	Week 12	25NOV2013	08:40	174		47.8		
	Week 16	23DEC2013	08:30	151		47.9		
	Week 20	22JAN2014	12:10	96.5		35.4		
	Week 24	17FEB2014	08:35	140		36.2		
	Week 28	12MAR2014	13:58	120		42.3		
	Week 32	11APR2014	10:30	103		36.0		
	Week 36	09MAY2014	10:35	89.9		31.3		
501-0003/22/M/A1	Screening	10DEC2013	09:00	82.4		21.4		
	Week 2	17DEC2013	10:00	41.8		22.0		
	Week 4	31DEC2013	09:00	52.6		29.1		
	Week 8	28JAN2014	08:17	58.8		30.5		
	Week 12	25FEB2014	08:20	52.3		35.9		
501-0004/26/M/A1	Screening	17DEC2013	06:00	79.4		32.1		

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Listing 16.2.6.9
Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
501-0004/26/M/A1	Week 2	25DEC2013	08:30	68.6		33.5		
	Week 4	09JAN2014	08:00	74.9		34.1		
	Week 8	07FEB2014	08:35	82.5		35.9		
	Week 12	05MAR2014	08:00	66.8		33.3		
501-0011/61/M/A1	Screening	25SEP2014	10:10	95.5		36.0		
	Week 2	29SEP2014	08:00	78.4		37.7		
	Week 4	23OCT2014	10:40	86.0		37.3		
	Week 8	12NOV2014	08:30	82.2		29.7		
	Week 12	10DEC2014	08:30	81.4		35.5		
502-0001/70/M/A1	Screening	23DEC2013	08:30	98.9		45.9		
	Week 2	20DEC2013	08:20	133		52.3		
	Week 4	03JAN2014	08:20	144		55.4		
502-0003/48/M/A1	Screening	13JAN2014	08:00	136		36.8		
	Week 2	22JAN2014	09:20	140		38.8		

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Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
502-0003/48/M/A1	Week 4	07FEB2014	08:30	132		40.7		
	Week 8	07MAR2014	09:30	146		33.7		
	Week 12	04APR2014	08:40	145		34.7		
503-0002/71/F/A1	Screening	20FEB2014	09:00	78.6		24.7		
	Week 2	27FEB2014	09:00	86.0		46.2		
	Week 4	13MAR2014	10:00	79.7		51.3		
	Week 8	10APR2014	09:30	127		60.9		
	Week 12	08MAY2014	08:50	79.1		49.8		
	Week 16	03JUN2014	08:35	103		33.9		
	Week 20	01JUL2014	08:40	94.1		47.7		
	Week 24	29JUL2014	08:35	72.3		40.6		
	Week 28	26AUG2014	09:01	86.0		48.9		
	Week 32	23SEP2014	08:15	84.2		54.5		
	Week 36	21OCT2014	09:00	1.13		165		

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Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
503-0003/47/F/A1	Screening	07MAR2014	18:15	53.9		22.9		
	Week 2	13MAR2014	10:00	44.3		15.7		
	Week 4	27MAR2014	12:00	43.7		15.5		
503-0005/72/M/A1	Screening	25MAR2014	09:50	75.4		31.1		
	Week 2	01APR2014	09:00	77.8		37.4		
	Week 4	15APR2014	09:00	84.6		38.4		
	Week 8	13MAY2014	08:30	58.7		23.3		
	Week 12	10JUN2014	08:30	87.6		33.4		
	Week 16	08JUL2014	09:25	121		34.5		
	Week 20	05AUG2014	09:10	109		36.5		
	Week 24	02SEP2014	08:15	84.2		32.6		
	Week 28	29SEP2014	08:30	91.8		32.0		
	Week 32	28OCT2014	08:35	76.1		26.5		
	Week 36	25NOV2014	Unknown	1.06		424		

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(Safety Population)

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Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
503-0005/72/M/A1	Week 40	23DEC2014	09:30	132		40.7		
	Week 44	21JAN2015	09:15	83.3		37.0		
	Week 48	15FEB2015	Unknown	90.7		28.6		
504-0003/53/M/A1	Screening	13MAR2014	15:15	88.2		41.7		
	Week 2	20MAR2014	10:40	85.6		34.4		
	Week 4	03APR2014	08:30	74.7		28.0		
504-0005/41/F/A1	Screening	02SEP2014	14:15	120		18.0		
	Week 2	10SEP2014	09:40	73.5		14.5		
	Week 4	24SEP2014	09:35	83.1		12.9		
504-0006/51/M/A1	Screening	04SEP2014	15:30	91.1		21.3		
506-0001/43/M/A1	Screening	15APR2014	06:30	74.6		27.8		
	Week 2	22APR2014	10:30	72.5		25.4		
	Week 4	06MAY2014	09:10	67.5		23.5		
506-0005/24/M/A1	Screening	21DEC2014	09:45	60.3		12.1		

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Pharmacodynamic Analysis Results
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Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
506-0005/24/M/A1	Week 2	31DEC2014	09:15	44.1		17.6		
507-0001/51/M/A1	Screening	23JUL2014	16:30	135		27.7		
	Week 2	31JUL2014	09:30	89.7		30.5		
	Week 4	14AUG2014	09:20	49.4		27.6		
	Week 8	11SEP2014	09:10	81.2		22.3		
	Week 12	09OCT2014	09:40	52.4		14.9		
507-0002/44/M/A1	Screening	29JUL2014	10:55	70.8		45.9		
	Week 2	05AUG2014	10:00	75.1		43.6		
	Week 4	20AUG2014	08:45	178		74.4		
	Week 8	16SEP2014	08:09	47.5		22.7		
508-0002/64/M/A1	Screening	13FEB2014	08:28	62.6		40.5		
	Week 2	27FEB2014	09:25	35.7		36.8		
	Week 4	10MAR2014	10:43	57.8		24.4		
	Week 8	11APR2014	10:35	19.8		34.3		

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Pharmacodynamic Analysis Results
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Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
508-0004/58/M/A1	Screening	25AUG2014	10:05	75.5		28.2		
	Week 2	03SEP2014	10:08	73.7		26.7		
509-0003/39/M/A1	Screening	23JUL2014	15:30	68.2		22.9		
	Week 2	31JUL2014	09:35	82.5		22.7		
	Week 4	14AUG2014	10:30	64.4		21.7		
	Week 8	11SEP2014	10:56	60.8		23.5		
	Week 12	09OCT2014	10:45	102		20.5		
510-0001/67/M/A1	Screening	25FEB2014	08:30	136		69.1		
	Week 2	05MAR2014	08:20	134		64.9		
	Week 4	19MAR2014	08:30	131		57.6		
	Week 8	16APR2014	08:00	120		64.7		
	Week 12	14MAY2014	07:55	143		62.4		
	Week 16	11JUN2014	08:20	122		51.7		
	Week 20	09JUL2014	08:30	105		59.9		

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Pharmacodynamic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
510-0001/67/M/A1	Week 24	06AUG2014	08:30	104		57.8		
	Week 28	04SEP2014	08:50	134		61.4		
	Week 32	30SEP2014	07:30	102		53.9		
	Week 36	29OCT2014	07:30	131		69.1		
	Week 40	26NOV2014	07:30	127		74.5		
510-0003/43/M/A1	Screening	04JUN2014	08:30	94.2		40.1		
	Week 2	11JUN2014	08:10	92.8		37.7		
	Week 4	25JUN2014	08:30	92.4		29.1		
	Week 8	30JUL2014	09:30	61.3		22.5		
513-0003/46/M/A1	Screening	25APR2014	10:14	114		20.9		
	Week 2	07MAY2014	08:38	49.6		16.3		
515-0005/45/M/A1	Screening	23JUN2014	10:00	62.3		26.6		
	Week 2	30JUN2014	09:30	46.9		25.3		
	Week 4	14JUL2014	09:55	46.0		17.0		

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Pharmacodynamic Analysis Results
(Safety Population)

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Subject No./ Age[1]/ Gender/ Race[2]	Visit	Sample Date	Sample Time	Arginine Level (µmol/L)	Average Arginine Levels[3] (µmol/L)	Citrulline Level (µmol/L)	Average Citrulline Levels[3] (µmol/L)	Comment
515-0005/45/M/A1	Week 8	11AUG2014	09:20	42.3		23.5		
517-0003/45/M/A1	Screening	12MAY2014	09:30	58.8		21.9		
	Week 2	20MAY2014	09:05	105		35.4		
	Week 4	04JUN2014	09:30	101		36.1		
	Week 8	02JUL2014	09:01	109		28.6		
	Week 12	30JUL2014	10:04	83.1		27.3		
517-0010/67/M/A1	Screening	04NOV2014	09:04	106		48.4		
	Week 2	19NOV2014	09:10	123		37.9		
	Week 4	03DEC2014	09:10	81.0		31.6		
	Week 8	30DEC2014	08:54	128		45.0		
	Week 12	28JAN2015	09:26	92.0		24.7		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE – ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE – WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
101-0001/59/M/A2	Screening	20JAN2009	Unknown	<800		
	Week 4	16AUG2011	14:39	4710		
	Week 8	16SEP2011	10:34	5860		
	Week 12	14OCT2011	12:44	1950		
	Week 16	11NOV2011	15:22	<800		
	Week 24	06JAN2012	15:39	<800		
101-0005/77/M/W2	Screening	02AUG2011	09:45	<800		
	Week 4	30AUG2011	12:40	4820		
	Week 8	27SEP2011	12:23	4610		
	Week 12	25OCT2011	14:11	3680		
101-0006/62/M/W2	Screening	05AUG2011	08:25	<800		
	Week 4	02SEP2011	07:48	3950		
	Week 8	30SEP2011	Unknown	3770		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
101-0007/77/M/A1	Screening	10DEC2009	Unknown	<800		
	Week 4	13SEP2011	10:31	7630		
	Week 8	11OCT2011	11:14	8040		
	Week 12	08NOV2011	15:26	7650		
101-0008/83/M/BL	Screening	22FEB2008	Unknown	<800		
	Week 4	20SEP2011	08:38	7350		
	Week 8	18OCT2011	15:22	971		
	Week 12	15NOV2011	14:51	<800		
101-0009/82/M/A1	Week 4	25OCT2011	15:53	6940		
	Week 8	15NOV2011	17:53	1550		
	Week 12	20DEC2011	14:42	<800		
101-0011/75/F/W2	Screening	27JUN2011	Unknown	<800		
101-0012/68/M/W2	Screening	01SEP2010	Unknown	<800		
	Week 4	20DEC2011	11:16	2510		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
101-0012/68/M/W2	Week 8	17JAN2012	09:34	<800		
101-0013/66/F/A5	Screening	29NOV2011	10:38	<800	800	Collected on 29Nov2011
	Screening	02JAN2012	10:38	<800		Collected on 02Jan2012
	Week 4	31JAN2012	09:57	4340		
	Week 8	28FEB2012	11:09	<800		
	Week 12	27MAR2012	10:18	<800		
	Week 16	24APR2012	14:55	<800		
	Week 20	Unknown	Unknown	<800		
101-0016/61/M/A4	Screening	05JUN2007	Unknown	<800		
	Week 4	07FEB2012	10:23	7560		
	Week 8	06MAR2012	15:24	7780		
	Week 12	06APR2012	15:45	4890		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
	Week 16	04MAY2012	07:37	4940		
	Week 20	29MAY2012	12:57	4430		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
101-0016/61/M/A4	Week 24	26JUN2012	09:43	4140		
	Week 28	24JUL2012	12:01	1320		
	Week 32	21AUG2012	07:54	<800		
	Week 36	18SEP2012	11:45	<800		
	Week 40	19OCT2012	09:35	<800		Uns Continuation
	Week 44	16NOV2012	12:59	<800		Uns Continuation
	Week 48	11DEC2012	13:01	<800		Uns Continuation
	Week 52	08JAN2013	13:09	<800		Uns Continuation
	Week 56	08FEB2013	07:49	<800		Uns Continuation
	Week 60	08MAR2013	12:37	<800		Uns Continuation
101-0018/51/M/A1	Screening	21FEB2012	16:28	<800		Back up sample, no primary sample was received
101-0019/68/M/W2	Screening	28FEB2012	09:11	<800		Week 4 in sample list from CLS

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
	Week 8	17APR2012	11:39	<800		
	Week 12	15MAY2012	15:26	<800		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
101-0021/74/M/W2	Screening	20MAR2012	11:57	<800		
	Week 4	10APR2012	14:24	4250		
	Week 8	08MAY2012	10:43	<800		
	Week 12	05JUN2012	08:58	<800		
101-0022/55/M/BL	Screening	26NOV2008	Unknown	<800		
	Week 4	10APR2012	18:21	1860		
101-0023/70/M/W2	Screening	30MAR2012	16:40	<800		
	Week 4	20APR2012	07:52	3190		
	Week 8	18MAY2012	08:20	4250		
	Week 12	15JUN2012	08:13	2150		
	Week 12	15JUN2012	08:13	1450		
101-0024/35/F/A4	Screening	19MAR2012	Unknown	<800		
	Week 4	22MAY2012	11:59	7300		
	Week 8	19JUN2012	15:19	1290		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
101-0024/35/F/A4	Week 12	17JUL2012	14:58	804		
101-0025/57/F/W2	Screening	01MAR2012	Unknown	<800		
	Week 4	11MAY2012	08:36	3310		
	Week 8	08JUN2012	12:48	<800		
101-0026/82/M/W2	Screening	17NOV2003	Unknown	<800		
	Week 4	05JUN2012	15:39	2460		
	Week 8	05JUL2012	11:09	3800		
	Week 12	03AUG2012	14:54	5250		
	Week 16	31AUG2012	14:19	978		
	Week 20	28SEP2012	15:54	<800		
	Week 24	23OCT2012	11:22	<800		
	Week 28	23NOV2012	13:02	<800		
	Week 32	18DEC2012	09:39	<800		
	Week 36	Unknown	Unknown	<800		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
101-0028/60/M/W2	Screening	14DEC2011	Unknown	<800		
	Week 4	03JUL2012	07:58	4550		
	Week 8	31JUL2012	07:37	<800		
	Week 12	28AUG2012	07:41	<800		
101-0029/70/M/A1	Screening	15JUN2012	10:31	<800		
	Week 4	10JUL2012	10:23	4980		
	Week 8	07AUG2012	10:35	<800		
	Week 12	Unknown	Unknown	<800		
101-0030/51/M/W2	Screening	04APR2011	Unknown	<800		
	Week 4	24JUL2012	08:03	4420		
	Week 8	21AUG2012	07:38	903		
101-0032/84/M/W2	Screening	04DEC2006	Unknown	<800		
	Week 4	21AUG2012	11:52	1260		
	Week 8	21SEP2012	09:30	<800		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
101-0033/66/F/W2	Screening	03AUG2012	11:57	<800		
	Week 4	24AUG2012	10:20	6640		
	Week 8	21SEP2012	10:22	<800		
	Week 12	16OCT2012	11:29	<800		
	Week 16	16NOV2012	10:55	<800		
	Week 20	14DEC2012	07:04	<800		
	Week 24	11JAN2013	Unknown	<800		
101-0036/67/M/A4	Screening	23OCT2012	15:02	<800		
	Week 4	27NOV2012	14:30	3800		
101-0037/57/M/A1	Screening	11JUN2008	Unknown	<800		
	Week 4	28DEC2012	09:26	5060		
101-0038/56/M/W2	Screening	27JUN2012	Unknown	<800		
	Week 2	12FEB2013	14:28	3060		
	Week 4	01MAR2013	11:10	3580		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
101-0039/77/F/W2	Screening	05APR2013	12:07	<800		
	Week 2	12APR2013	08:57	1750		
	Week 4	26APR2013	08:38	<800		
	Week 8	24MAY2013	11:21	<800		
	Week 12	21JUN2013	08:44	<800		
	Week 16	16JUL2013	08:41	<800		
	Week 20	13AUG2013	10:51	<800		
	Week 24	10SEP2013	07:36	<800		
	Week 28	08OCT2013	07:15	<800		
	Week 32	04NOV2013	07:43	<800		
	Week 36	02DEC2013	07:33	826		
101-0040/60/M/W2	Screening	18OCT2013	Unknown	<800		
	Week 2	08JUL2013	08:04	3400		
	Week 4	22JUL2013	08:40	1770		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
101-0041/54/M/W2	Screening	21DEC2012	Unknown	<800		
	Week 2	06AUG2013	12:33	2160		
101-0042/64/M/W2	Screening	22MAY2012	Unknown	<800		
	Week 2	13AUG2013	09:42	4480		
	Week 4	27AUG2013	16:02	6110		
	Week 8	23SEP2013	14:50	878		
101-0044/78/M/W2	Screening	18OCT2013	07:26	<800		
	Week 4	08NOV2013	07:16	6560		
	Week 8	06DEC2013	07:30	2130		
	Week 12	03JAN2014	08:58	<800		
101-0045/74/F/W2	Screening	22OCT2013	08:26	<800		
	Week 2	12NOV2013	07:21	3230		
	Week 4	26NOV2013	07:40	<800		
	Week 8	23DEC2013	07:51	<800		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
101-0045/74/F/W2	Week 12	21JAN2014	10:49	<800		
101-0046/70/M/OTH	Screening	17DEC2012	Unknown	<800		
	Week 2	29OCT2013	10:39	1830		
	Week 4	12NOV2013	08:03	2270		
	Week 8	10DEC2013	07:30	1710		
	Week 12	07JAN2014	07:28	1730		
101-0047/52/M/W2	Screening	10JAN2012	Unknown	<800		
	Week 2	28OCT2013	10:50	3310		
	Week 4	11NOV2013	08:29	4020		
	Week 8	09DEC2013	07:43	3870		
101-0048/66/F/W2	Screening	22OCT2013	09:35	<800		
	Week 2	29OCT2013	09:30	3270		
	Week 4	19NOV2013	09:19	3070		
	Week 8	10DEC2013	10:05	<800		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
101-0048/66/F/W2	Week 12	06JAN2014	10:15	<800		
101-0049/71/M/A8	Screening	28OCT2013	11:03	<800		
	Week 2	04NOV2013	10:02	3660		
	Week 4	18NOV2013	10:01	3860		
	Week 8	16DEC2013	12:06	858		
	Week 12	13JAN2014	08:36	<800		
101-0050/59/M/W2	Screening	29OCT2013	17:51	<800		
	Week 2	04NOV2013	12:37	4290		
	Week 4	18NOV2013	08:46	6040		
102-0001/53/M/BL	Screening	19APR2012	09:09	<800		
	Week 4	15MAY2012	08:45	<800		
	Week 8	12JUN2012	08:57	<800		
102-0003/63/M/BL	Screening	29AUG2012	09:28	<800		
	Week 4	02OCT2012	08:18	<800		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
102-0003/63/M/BL	Week 8	31OCT2012	07:22	<800		
	Week 12	28NOV2012	08:36	<800		
102-0008/64/M/BL	Screening	02JAN2013	13:23	<800	800	
	Screening	02JAN2013	13:23	<800		
	Week 2	15JAN2014	09:20	2500		
	Week 4	28JAN2014	08:16	4460		
102-0009/58/M/W2	Screening	23OCT2014	09:35	<800		
	Week 2	05NOV2014	10:25	1330		
	Week 4	19NOV2014	11:25	<800		
103-0001/56/M/W2	Screening	07MAY2012	11:15	<800		
	Week 4	01JUN2012	10:10	4590		
	Week 8	29JUN2012	10:30	<800		
103-0003/66/M/W2	Screening	04FEB2013	12:30	<800		
	Week 4	06MAR2013	11:00	4860		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
103-0003/66/M/W2	Week 8	03APR2013	11:45	1740		
	Week 12	01MAY2013	14:45	<800		
	Week 16	29MAY2013	14:45	<800		
	Week 20	24JUN2013	10:40	<800		
103-0004/40/F/A1	Screening	19NOV2012	Unknown	<800		
	Week 2	28APR2014	10:00	3820		
	Week 4	13MAY2014	13:00	7350		
	End of Treatment	09JUN2014	10:00	1640		Week 8
104-0003/56/F/W2	Screening	11JUL2012	09:55	<800		
	Week 4	08AUG2012	09:50	<800		
	Week 8	Unknown	Unknown	<800		
104-0004/74/M/W2	Screening	15JUN2012	Unknown	<800		
	Week 4	13NOV2012	10:35	5740		
104-0008/55/M/PI	Screening	29AUG2013	13:32	<800		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
104-0008/55/M/PI	Week 2	13SEP2013	12:55	4170		
	Week 4	26SEP2013	07:41	5400		
	Week 8	24OCT2013	07:52	1700		
	Week 12	21NOV2013	08:00	<800		
104-0010/71/F/A8	Screening	02JAN2014	10:20	894		
	Week 2	15JAN2014	09:20	4500		
	Week 4	29JAN2014	10:15	6800		
	Week 8	26FEB2014	10:21	<800		
	Week 12	27MAR2014	09:20	<800		
	Week 16	23APR2014	09:25	<800		
	Week 20	21MAY2014	09:24	<800		
	Week 24	18JUN2014	09:00	<800		Back up sample
	Week 28	16JUL2014	09:05	<800		
	Week 32	13AUG2014	09:06	<800		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
104-0010/71/F/A8	Week 36	10SEP2014	08:56	<800		Uns Continuation
104-0012/78/F/A2	Screening	23SEP2014	11:15	<800		
	Week 2	07OCT2014	11:14	2030		
	Week 4	22OCT2014	11:04	<800		
	Week 8	18NOV2014	11:00	<800		
106-0001/42/F/W2	Screening	20FEB2012	Unknown	<800	850	Collected on 20Feb2012
	Screening	20FEB2012	Unknown	900		Collected on 20Feb2012
	Week 4	26MAR2012	09:30	3090		
	Week 8	23APR2012	10:20	<800		
	Week 12	21MAY2012	10:35	<800		
	Week 16	18JUN2012	11:40	<800		
107-0002/71/M/W2	Screening	21JUL2010	Unknown	<800		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
	Week 4	21SEP2012	13:10	1670		
	Week 8	15OCT2012	12:15	5130		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
107-0002/71/M/W2	Week 12	12NOV2012	10:00	2080		
107-0003/73/M/BL	Screening	18FEB2013	12:05	<800		
	Week 4	18MAR2013	09:49	1140		
	Week 8	16APR2013	13:45	<800		
107-0004/63/M/W2	Screening	26FEB2013	13:16	<800		
	Week 2	12MAR2013	10:14	2030		
	Week 4	26MAR2013	10:20	1660		
	Week 8	23APR2013	07:45	938		
	Week 12	21MAY2013	10:30	1000		
107-0006/60/M/W2	Screening	06MAY2013	09:15	<800		
	Week 2	20MAY2013	09:26	4410		
	Week 4	04JUN2013	13:05	4140		
	Week 8	01JUL2013	10:00	3850		
	Week 12	29JUL2013	09:00	<800		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
108-0001/60/F/W2	Screening	07MAR2012	15:00	<800		
	Week 4	11APR2012	10:45	5310		
108-0002/78/M/BL	Screening	25MAY2012	09:55	<800		
	Week 4	21JUN2012	10:00	7130		
108-0004/61/M/W2	Screening	04APR2013	10:31	<800		
	Week 3	02MAY2013	09:07	3070		
	Week 4	09MAY2013	07:35	5810		
108-0005/68/M/W2	Screening	26APR2013	08:40	<800		
	Week 2	15MAY2013	14:40	2580		
	Week 4	29MAY2013	13:30	3070		
	Week 8	26JUN2013	09:30	2630		
	Week 12	24JUL2013	09:20	1740		
108-0008/77/M/W2	Screening	01OCT2014	08:05	<800		
	Week 2	16OCT2014	09:10	3910		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
108-0008/77/M/W2	Week 4	30OCT2014	09:20	4400		
	Week 8	26NOV2014	12:06	<800		
	Week 12	23DEC2014	08:54	<800		
	Week 16	22JAN2015	09:15	<800		
	Week 20	19FEB2015	08:15	<800		
	End of Treatment	16APR2015	Unknown	<800		Week 24 in sample list from CLS
109-0003/68/M/W2	Screening	30APR2013	11:33	<800		
	Week 2	13MAY2013	13:38	1960		
	Week 4	28MAY2013	16:00	3110		
109-0004/57/M/W2	Screening	13FEB2012	Unknown	<800		
	Week 2	26JUL2013	09:20	3400		
	Week 4	12AUG2013	13:45	2500		
	Week 8	11SEP2013	13:55	3920		
	Week 12	09OCT2013	09:10	2850		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
109-0006/62/M/PI	Screening	14AUG2013	12:25	<800		
	Week 2	30AUG2013	11:40	4590		
	Week 4	12SEP2013	11:40	5860		
	Week 8	09OCT2013	13:15	<800		
	Week 12	06NOV2013	11:45	<800		
109-0007/55/M/W2	Screening	02DEC2013	15:40	818		
	Unscheduled	10DEC2013	Unknown	806		Week 1 (backup sample)
	Unscheduled	10DEC2013	Unknown	868		Week 1
	Week 2	18DEC2013	11:20	1460		
	Week 4	03JAN2014	12:40	1550		
	Week 8	30JAN2014	13:20	846		
	Week 12	26FEB2014	12:40	<800		
	Week 16	25MAR2014	13:52	<800		
	Week 20	23APR2014	11:25	<800		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
109-0008/70/F/W2	Screening	21MAY2014	11:35	<800		
	Week 2	12JUN2014	13:30	2190		
	Week 4	25JUN2014	12:20	<800		
	Week 8	23JUL2014	12:40	<800		
	Week 12	20AUG2014	13:10	<800		
	Week 16	17SEP2014	12:45	<800		
	Week 20	14OCT2014	08:39	<800		
	Week 24	13NOV2014	09:20	<800		
109-0009/57/M/W2	Screening	25JUN2014	11:45	<800		
	Week 2	15JUL2014	14:55	1960		
	Week 4	30JUL2014	12:15	<800		
	Week 8	26AUG2014	11:19	<800		
	Week 12	23SEP2014	13:30	<800		
109-0010/65/M/W2	Screening	25JUN2014	14:45	<800		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
109-0010/65/M/W2	Week 2	16JUL2014	15:19	2620		
	Week 4	30JUL2014	14:10	2480		
	Week 8	27AUG2014	12:25	<800		
	Week 12	24SEP2014	11:30	<800		
109-0011/64/M/A4	Screening	23JAN2013	Unknown	<800		
	Week 2	01OCT2014	15:25	4560		
	Week 4	15OCT2014	15:05	7140		
	Week 8	11NOV2014	15:20	<800		
	Week 12	10DEC2014	14:50	<800		
109-0013/64/F/W2	Screening	30OCT2014	14:30	<800		
	Week 2	11NOV2014	12:31	1490		
	Week 4	Unknown	Unknown	3480		
	Week 8	22DEC2014	14:55	3500		
	Week 12	20JAN2015	11:45	1740		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
109-0013/64/F/W2	Unscheduled	24FEB2015	Unknown	897		Week 17
	Week 24	13APR2015	12:30	<800		
110-0003/63/M/OTH	Screening	25JUN2012	16:00	<800		
	Week 4	30JUL2012	12:15	4830		
	Week 8	27AUG2012	11:30	2850		
	Week 12	25SEP2012	12:30	<800		
	Week 16	22OCT2012	11:55	<800		
	Week 20	19NOV2012	11:35	<800		
110-0004/53/M/A4	Screening	11OCT2012	13:05	<800		
	Week 8	13DEC2012	11:15	1840		
110-0005/77/M/W2	Screening	22SEP2010	Unknown	<800		
	Week 4	02APR2013	14:30	3050		
	Week 8	30APR2013	13:58	2280		
	Week 12	28MAY2013	12:30	<800		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
110-0007/62/M/A4	Screening	03MAY2013	11:58	<800		
	Week 4	07JUN2013	13:05	<800		
	Week 12	02AUG2013	12:00	<800		
	Week 16	30AUG2013	11:15	<800		
	Week 24	25OCT2013	12:05	<800		
	Week 28	22NOV2013	11:35	<800		
110-0008/63/F/BL	Screening	26JUN2013	12:18	<800		
	Week 4	29JUL2013	12:05	<800		
110-0011/77/M/A1	Screening	26JUL2013	Unknown	<800		
	Week 2	29JAN2015	11:33	3820		
	Week 4	12FEB2015	11:55	3940		
	Week 8	12MAR2015	11:31	<800		
	Week 12	10APR2015	15:35	<800		
111-0001/37/M/A4	Screening	02JUL2012	11:05	<800		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
111-0001/37/M/A4	Week 4	02AUG2012	13:00	4680		
111-0004/64/M/W2	Screening	10MAY2013	11:25	<800		
	Week 2	30MAY2013	09:54	2150		
	Week 4	13JUN2013	09:52	2950		
	Week 8	11JUL2013	09:25	3520		
111-0006/59/M/W2	Screening	03OCT2013	08:25	<800		
	Week 2	17OCT2013	08:28	<800		
	Week 4	30OCT2013	07:15	2370		
	Week 8	27NOV2013	08:24	<800		
	Week 8	27NOV2013	08:24	<800		
	Week 12	02JAN2014	09:15	<800		
	Week 16	29JAN2014	11:20	<800		
	Week 20	26FEB2014	10:40	<800		
	Week 24	26MAR2014	07:25	<800		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
111-0006/59/M/W2	Week 28	23APR2014	07:55	<800		
111-0007/55/M/W2	Screening	23JAN2014	15:46	810		
	Week 2	13FEB2014	15:10	2270		
	Week 4	27FEB2014	11:12	3390		
	Week 8	27MAR2014	11:35	4760		
	Week 12	25APR2014	07:50	947		
112-0006/58/M/W2	Screening	15MAR2013	10:23	<800		
	Week 2	01APR2013	07:09	2910		
	Week 4	15APR2013	11:53	<800		
	Week 8	13MAY2013	12:09	<800		
112-0009/50/M/A8	Screening	05JUN2013	Unknown	<800		
	Week 2	26JUN2013	07:12	2150		
	Week 8	07AUG2013	09:27	1510		
	Week 12	04SEP2013	07:53	<800		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
112-0011/56/M/A4	Screening	03JAN2014	10:10	916		
	Week 2	17JAN2014	11:38	2730		
	Week 4	31JAN2014	08:44	3190		
	Week 8	28FEB2014	09:02	<800		
112-0012/71/M/W2	Screening	16MAY2014	08:05	<800		
	Week 2	30MAY2014	08:00	2330		
	Week 4	13JUN2014	07:42	<800		
	Week 8	11JUL2014	08:00	<800		
	Week 12	08AUG2014	07:24	<800		
112-0013/28/F/W2	Screening	16MAY2014	11:25	<800		
	Week 2	30MAY2014	09:00	5490		
	Week 4	13JUN2014	08:00	8040		
	Week 8	11JUL2014	08:21	2100		
112-0014/79/M/A8	Screening	30MAY2014	13:10	<800		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
112-0014/79/M/A8	Week 2	13JUN2014	13:20	1850		
	Week 4	27JUN2014	11:38	4240		
	Week 8	25JUL2014	09:20	3390		
	Week 12	22AUG2014	07:56	2820		
112-0015/66/M/A8	Screening	17OCT2014	09:31	<800		
	Week 2	31OCT2014	08:20	3700		
	Week 4	14NOV2014	08:41	2810		
	Week 8	12DEC2014	10:20	<800		
113-0001/60/M/W2	Screening	09AUG2012	15:45	<800		
	Week 4	17SEP2012	14:10	3580		
	Week 8	15OCT2012	12:30	<800		
	Week 12	15NOV2012	14:35	<800		
	Week 16	10DEC2012	11:49	<800		
	Week 20	07JAN2013	13:10	<800		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
113-0001/60/M/W2	Week 24	06FEB2013	13:00	<800		
113-0002/64/F/W2	Screening	08OCT2012	15:27	<800	2950	
	Unscheduled	08OCT2012	15:27	5100		Screening (collection date not found on visit report, date is between screening and week 1)
	Week 4	05NOV2012	11:00	<800		
	Week 8	26NOV2012	11:45	6740		
	Week 20	20FEB2013	09:05	2720		
	Week 24	25MAR2013	09:50	2120		
	Week 28	22APR2013	08:45	2960		
	Week 32	20MAY2013	08:04	3190		
113-0005/58/M/W2	Screening	08JAN2014	09:50	<800		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
	Week 2	30JAN2014	09:13	3550		
	Week 4	13FEB2014	09:27	1110		
	Week 8	12MAR2014	14:26	<800		
113-0008/78/M/A8	Screening	07FEB2014	13:25	<800		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
113-0010/59/M/W2	Screening	30APR2014	14:17	<800		
	Week 2	07MAY2014	08:59	2400		
	Week 4	23MAY2014	08:40	2370		
113-0013/56/M/W2	Screening	03MAR2011	Unknown	<800		
	Week 2	14NOV2014	08:08	3250		
	Week 4	24NOV2014	08:24	6990		
	Week 8	22DEC2014	08:35	5310		
113-0016/72/M/A8	Screening	22JAN2015	14:27	<800		
	Week 2	10FEB2015	14:25	2830		
	Week 4	25FEB2015	13:34	3820		
	Week 8	23MAR2015	08:37	2700		
114-0003/59/M/W2	Screening	19NOV2012	11:15	<800		
	Week 4	19DEC2012	11:40	4720		
	Week 8	16JAN2013	11:45	3060		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
114-0003/59/M/W2	Week 12	13FEB2013	11:34	<800		
	Week 16	13MAR2013	11:32	<800		
	Week 20	10APR2013	12:12	<800		
114-0005/73/M/W2	Screening	11SEP2012	Unknown	895		
	Week 2	18DEC2013	08:37	2280		
	Week 4	31DEC2013	08:39	2050		
	Week 8	29JAN2014	08:08	1960		
114-0007/60/F/W2	Screening	14NOV2014	11:46	<800		
	Week 2	26NOV2014	11:17	4640		
	Week 4	09DEC2014	11:49	7230		
	Week 8	06JAN2014	10:11	1430		
	Week 12	04FEB2015	10:20	BQL		
	Week 20	31MAR2015	10:27	BQL		
	Week 24	28APR2015	10:29	BQL		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
114-0007/60/F/W2	Week 28	26MAY2015	10:41	BQL		
115-0001/59/F/A4	Screening	15JUN2011	Unknown	<800		
	Week 4	18DEC2012	09:30	826		
	Week 8	15JAN2013	08:45	<800		
	Week 12	14FEB2013	07:25	<800		
115-0002/45/F/W2	Screening	26NOV2012	12:44	<800		
	Week 4	18DEC2012	13:26	<800		
115-0003/63/M/W2	Screening	17DEC2008	Unknown	<800		
	Week 4	07FEB2013	08:12	8420		
	Week 8	07MAR2013	08:14	3400		
	Week 12	04APR2013	07:16	6510		
	Week 16	02MAY2013	07:50	5250		
	Week 20	30MAY2013	07:25	3050		
115-0008/51/M/A8	Screening	13JUN2013	13:50	<800		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
115-0008/51/M/A8	Week 2	25JUN2013	09:54	2600		
115-0009/85/M/W2	Screening	03DEC2013	15:25	<800		
	Week 2	19DEC2013	13:54	1180		
	Week 4	02JAN2014	08:25	1530		
	Week 8	28JAN2014	09:55	1310		
	Week 16	27MAR2014	09:17	<800		
	Week 20	22APR2014	13:07	<800		
	Week 24	21MAY2014	08:54	<800		
115-0011/56/M/W2	Screening	30MAY2014	07:08	<800		
	Week 2	13JUN2014	08:00	2860		
	Week 4	26JUN2014	08:45	<800		
	Week 12	22AUG2014	07:34	<800		
115-0014/72/M/W2	Week 2	18FEB2015	11:40	852		
	Week 4	03MAR2015	08:45	2040		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
115-0014/72/M/W2	Week 8	01APR2015	12:30	BQL		
116-0002/67/F/W2	Screening	11MAR2013	16:44	<800		
	Week 2	25MAR2013	16:02	<800		
	Week 4	08APR2013	14:02	<800		
	Week 8	06MAY2013	13:54	<800		
	Week 12	03JUN2013	14:00	<800		
	Week 16	01JUL2013	13:35	<800		
	Week 20	29JUL2013	13:52	<800		
	Week 24	26AUG2013	14:09	<800		
	Week 28	23SEP2013	13:52	<800		
	Week 32	21OCT2013	13:41	<800		
	Week 36	18NOV2013	14:00	<800		
116-0003/66/M/BL	Screening	18MAR2013	16:20	<800		
	Week 2	04APR2013	09:12	1540		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
116-0003/66/M/BL	Week 4	18APR2013	10:34	<800		
117-0001/69/M/W2	Screening	19MAR2013	13:35	<800		
	Week 2	09APR2013	13:00	1460		
	Week 4	23APR2013	13:45	3520		
	Week 8	21MAY2013	13:00	4080		
118-0001/67/F/A8	Screening	06AUG2013	13:20	<800	800	
	Unscheduled	06AUG2013	13:20	<800		Screening
	Unscheduled	06AUG2013	13:20	<800		Screening
	Unscheduled	06AUG2013	13:20	<800		Screening
	Week 2	20AUG2013	14:15	4250		
	Week 4	03SEP2013	13:00	6650		
	Week 8	03OCT2013	13:15	<800		
	Week 12	29OCT2013	09:35	<800		
119-0001/80/M/A8	Screening	07JAN2014	15:58	<800		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
119-0001/80/M/A8	Week 2	28JAN2014	13:32	3590		
121-0001/62/M/W2	Screening	12MAR2012	Unknown	<800		
	Week 2	25FEB2014	07:50	2060		
	Week 4	11MAR2014	09:00	1980		
	Week 8	08APR2014	09:40	865		
	Week 12	06MAY2014	09:05	<800		
121-0004/64/F/W2	Screening	18DEC2014	14:33	<800		
	Unscheduled	05JAN2015	Unknown	<800		Week 1 (3 days after week 1 visit)
201-0001/68/F/W2	Screening	20JAN2012	08:00	<800		
	Week 4	16FEB2012	08:00	5930		
	Week 8	15MAR2012	09:20	8960		
	Week 12	11APR2012	08:10	8390		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
201-0005/73/M/W2	Screening	05JUL2012	08:00	<800		
	Week 4	09AUG2012	07:50	4270		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
201-0005/73/M/W2	Week 8	06SEP2012	08:00	1550		
	Week 12	04OCT2012	08:00	<800		
201-0008/79/M/W2	Screening	10MAY2013	08:30	<800		
	Week 2	23MAY2013	08:00	2990		
	Week 4	06JUN2013	08:00	2380		
	Week 8	04JUL2013	08:15	3320		
201-0011/73/M/W2	Screening	16MAR2011	Unknown	<800		
	Week 2	11JUL2013	08:15	2700		
	Week 4	24JUL2013	08:40	3600		
	Week 8	22AUG2013	08:10	1370		
	Week 12	18SEP2013	07:50	5010		
201-0012/79/M/W2	Screening	11JUL2013	08:40	<800	800	

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
	Unscheduled	11JUL2013	08:40	<800		Screening (collection date not found on visit report, date is between screening and week 1)
	Week 2	01AUG2013	08:25	1960		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
201-0012/79/M/W2	Week 8	12SEP2013	08:05	3900		
	Week 12	10OCT2013	08:00	3840		
	Week 16	07NOV2013	08:40	4210		
	Week 20	06DEC2013	07:50	3390		
	Week 24	03JAN2014	07:50	3400		
	Week 28	30JAN2014	08:30	3740		
	Week 32	27FEB2014	08:20	4530		
	Week 36	27MAR2014	08:30	3040		
	Week 38	09APR2014	08:10	3490		Uns Continuation
	Week 40	24APR2014	08:00	2330		Uns Continuation
	Week 42	08MAY2014	08:00	1330		Uns Continuation
	Week 44	21MAY2014	08:25	1120		Uns Continuation
	Week 46	05JUN2014	08:20	2290		Uns Continuation
	Week 48	19JUN2014	08:15	1870		Uns Continuation

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
201-0012/79/M/W2	Week 50	03JUL2014	08:00	1670		Uns Continuation
	Week 52	16JUL2014	08:00	3250		Uns Continuation
	Week 54	31JUL2014	08:00	1650		Uns Continuation
	Week 58	28AUG2014	08:10	2310		Uns Continuation
	Week 60	11SEP2014	08:30	2450		Uns Continuation
201-0013/67/F/W2	Screening	11JUL2013	09:05	<800	800	
	Unscheduled	11JUL2013	09:05	<800		Screening (collection date not found on visit report, date is between screening and week 1)
	Week 2	01AUG2013	08:40	1970		
	Week 8	12SEP2013	08:20	3700		
	Week 12	10OCT2013	08:30	2480		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
	Week 12	10OCT2013	08:30	2640		
201-0016/72/M/W2	Screening	31OCT2013	08:30	<800	800	
	Unscheduled	31OCT2013	08:30	<800		Screening (collection date not found on visit report, date is between screening and week 1)
	Week 2	21NOV2013	08:30	3120		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
201-0016/72/M/W2	Week 4	06DEC2013	08:20	2960		
	Week 8	03JAN2014	08:10	1290		
	Week 12	30JAN2014	08:10	4060		
	Week 16	27FEB2014	08:00	3110		
	Week 20	27MAR2014	08:15	3840		
201-0017/82/M/W2	Screening	18NOV2013	08:00	<800		
	Week 2	06DEC2013	08:40	3950		
201-0018/78/F/W2	Screening	28NOV2013	08:20	<800		
	Week 2	12DEC2013	08:25	1840		
201-0019/68/M/W2	Screening	12DEC2013	09:00	<800		
	Week 2	27DEC2013	08:25	4460		
	Week 4	09JAN2014	08:15	5350		
	Week 8	06FEB2014	08:20	<800		
	Week 12	06MAR2014	08:10	<800		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
201-0020/67/M/W2	Screening	17JAN2014	09:30	<800		
	Week 2	30JAN2014	09:00	3610		
201-0021/54/M/W2	Screening	04FEB2014	08:00	<800		
	Week 2	20FEB2014	08:00	4510		
	Week 4	06MAR2014	07:50	4520		
	Week 8	03APR2014	08:00	4160		
	Week 12	30APR2014	08:00	<800		
201-0024/74/M/W2	Screening	16JAN2015	09:30	<800		
	Week 2	05FEB2015	08:00	2070		
	Week 4	19FEB2015	07:50	BQL		
201-0025/75/M/W2	Screening	21JAN2015	08:00	<800		
	Week 2	05FEB2015	07:45	3450		
203-0001/61/F/W2	Screening	29FEB2012	08:00	<800		
	Week 4	29MAR2012	08:00	<800		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
203-0002/72/M/W2	Screening	02MAR2012	08:00	<800		
	Week 4	27MAR2012	08:00	3960		
203-0005/53/M/W2	Screening	29MAR2012	08:00	<800		
	Week 4	27APR2012	08:00	1610		
	Week 8	31MAY2012	09:00	<800		
203-0013/68/M/W2	Screening	23DEC2013	09:00	<800		
	Week 2	08JAN2014	08:00	4870		
	Week 4	22JAN2014	08:00	7970		
	End of Treatment	31JAN2014	09:00	5960		Week 6 (9 days after week 4 visit)
203-0015/85/M/W2	Screening	17JAN2014	09:00	<800		
	Week 2	07FEB2014	08:00	3960		
	Week 4	24FEB2014	09:00	<800		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
	Week 8	28MAR2014	09:00	<800		
203-0017/58/M/W2	Screening	18FEB2014	09:00	<800		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
203-0017/58/M/W2	Week 2	12MAR2014	09:00	2120		
203-0018/58/F/W2	Screening	26MAR2014	08:00	<800		
	Week 2	14APR2014	09:00	2200		
	Week 8	04JUN2014	09:00	<800		
205-0001/77/M/W2	Screening	14FEB2012	09:00	<800		
	Week 4	14MAR2012	09:00	<800		
	Week 8	13APR2012	09:00	<800		
	Week 12	08MAY2012	09:00	<800		
	Week 16	08JUN2012	09:00	<800		
	Week 20	06JUL2012	09:00	<800		
	Week 24	06AUG2012	09:00	<800		
	Week 28	31AUG2012	09:00	<800		
	Week 32	28SEP2012	09:00	<800		
	Week 36	23OCT2012	09:00	<800		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
205-0001/77/M/W2	Week 40	20NOV2012	09:00	<800		Uns Continuation
	Week 44	20DEC2012	09:00	<800		Uns Continuation
	Week 52	13FEB2013	09:00	<800		Uns Continuation
	Week 56	13MAR2013	09:00	<800		Uns Continuation
	Week 68	13JUN2013	09:00	<800		Uns Continuation
	Week 70	25JUN2013	09:30	<800		Uns Continuation
	Week 72	09JUL2013	08:30	<800		Uns Continuation
	Week 74	19JUL2013	09:30	<800		Uns Continuation
	Week 78	26AUG2013	09:40	<800		Uns Continuation
	Week 80	10SEP2013	09:00	<800		Uns Continuation
	Week 82	24SEP2013	09:30	<800		Uns Continuation
205-0004/77/F/W2	Screening	12MAR2012	09:00	<800		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
	Week 4	12APR2012	09:00	<800		Back up sample, no primary sample was received
	Week 8	10MAY2012	09:00	<800		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
205-0004/77/F/W2	Week 12	05JUN2012	09:00	<800		
205-0008/76/M/W2	Screening	20APR2012	09:00	<800		
	Unscheduled	27APR2012	Unknown	<800		Week 1
	Week 4	17MAY2012	09:00	5370		
205-0012/73/F/W2	Screening	27NOV2012	09:00	<800		
	Week 4	27DEC2012	09:00	<800		
205-0015/71/M/W2	Screening	07JUN2013	07:30	<800		
	Week 2	27JUN2013	09:30	2140		
	Week 4	12JUL2013	08:30	3040		
	Week 7	02AUG2013	08:00	3450		
	Week 8	09AUG2013	10:30	4310		
205-0016/70/M/W2	Screening	11JUN2013	08:30	<800		
	Week 2	02JUL2013	09:30	4860		
	Week 4	19JUL2013	09:30	2390		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
205-0016/70/M/W2	Week 12	20SEP2013	10:00	2220		
	Week 16	17OCT2013	11:00	2420		
	Week 20	14NOV2013	14:00	2400		
	Week 24	10DEC2013	10:45	2620		
	Week 28	10JAN2014	11:00	1060		
	Week 32	07FEB2014	11:15	1310		
	Week 36	07MAR2014	10:30	2000		
	Week 38	21MAR2014	10:30	2070		Uns Continuation
	Week 40	03APR2014	10:00	4600		Uns Continuation
	Week 44	29APR2014	09:30	5860		Uns Continuation
	Week 48	27MAY2014	10:15	5850		Uns Continuation
	Week 50	10JUN2014	10:30	3940		Uns Continuation
	Week 52	24JUN2014	10:00	6050		Uns Continuation
	Week 56	22JUL2014	11:30	2320		Uns Continuation

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
205-0016/70/M/W2	Week 60	11AUG2014	10:15	6510		Uns Continuation
	Week 64	11SEP2014	10:00	4090		Uns Continuation
	Week 68	09OCT2014	10:30	5670		Uns Continuation
	Week 72	06NOV2014	11:00	4690		Uns Continuation
	Week 76	04DEC2014	11:00	3360		Uns Continuation
	Week 78	18DEC2014	10:00	3320		Uns Continuation
	Week 80	30DEC2014	10:00	6580		Uns Continuation
	Week 84	29JAN2015	10:20	3780		Uns Continuation
	Week 88	26FEB2015	10:50	3510		Uns Continuation
	Week 92	26MAR2015	11:00	3950		Uns Continuation
	Week 96	21APR2015	11:00	4790		Uns Continuation
	Week 100	21MAY2015	11:00	4440		Uns Continuation
205-0017/71/M/W2	Screening	02AUG2013	10:00	<800		
	Unscheduled	08AUG2013	Unknown	<800		Week 1

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
205-0017/71/M/W2	Week 4	26AUG2013	10:00	2250		
	Week 8	24SEP2013	09:00	<800		
	Week 12	25OCT2013	12:30	<800		
	Week 16	22NOV2013	09:30	<800		
	Week 20	20DEC2013	09:15	<800		
	Week 24	14JAN2014	08:45	<800		
205-0020/82/M/W2	Screening	01OCT2013	09:30	<800		
	Week 2	17OCT2013	12:30	3030		
	Week 4	31OCT2013	11:30	2670		
	Week 8	29NOV2013	09:30	958		
	Week 12	23DEC2013	09:00	<800		
205-0022/67/M/W2	Screening	25OCT2013	10:00	<800	800	
	Screening	25OCT2013	10:00	<800		
	Week 2	12NOV2013	11:00	2400		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
205-0024/80/M/W2	Screening	19NOV2013	09:45	<800		
	Week 2	13DEC2013	09:40	1630		
	Week 4	23DEC2013	11:00	6600		
	Week 8	23JAN2014	12:30	3450		
	Week 12	25FEB2014	12:00	<800		
205-0025/63/F/W2	Screening	21NOV2013	12:30	<800		
	Week 2	03DEC2013	10:30	3440		
	Week 4	19DEC2013	10:00	1000		
	Week 8	14JAN2014	11:15	<800		
	Week 12	14FEB2014	10:30	811		
207-0001/81/F/W2	Screening	08MAR2012	11:30	<800		
207-0005/74/M/W2	Screening	21MAY2012	13:30	<800	800	

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
	Screening	21MAY2012	13:30	<800		Screening (collection date not found on visit report, date is between screening and week 1)
207-0006/73/M/W2	Screening	08JUN2012	11:30	<800		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
207-0006/73/M/W2	Week 4	09JUL2012	09:30	2290		
	Week 8	06AUG2012	09:40	2030		
207-0008/66/M/W2	Screening	25JUN2012	12:00	<800		
	Week 4	13AUG2012	09:25	2130		
207-0011/78/M/W2	Screening	09JAN2013	12:45	<800		
207-0015/77/M/W2	Screening	08AUG2013	11:20	<800		
	Week 2	20AUG2013	09:00	3670		
	Week 4	03SEP2013	11:45	4230		
	Week 8	01OCT2013	09:50	5860		
207-0020/77/M/W2	Screening	11JUN2014	10:20	<800		
	Week 2	25JUN2014	09:45	4120		
	Week 4	09JUL2014	09:50	<800		
	Week 8	06AUG2014	09:45	<800		
207-0021/74/M/W2	Screening	11JUN2014	11:15	<800		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
207-0021/74/M/W2	Week 2	26JUN2014	10:35	3190		
	Week 4	10JUL2014	11:30	4650		
	Week 8	07AUG2014	11:15	2660		
	Week 12	04SEP2014	11:00	<800		
	Week 16	02OCT2014	11:30	<800		
	Week 20	30OCT2014	09:40	<800		
	Week 24	28NOV2014	13:00	<800		
	Week 28	29DEC2014	10:30	1180		
	Week 32	23JAN2015	09:30	<800		
207-0022/74/M/W2	Screening	30JUN2014	10:45	<800		
	Week 2	17JUL2014	11:05	2640		
	Week 8	28AUG2014	10:30	<800		
208-0001/59/M/W2	Screening	14SEP2012	09:15	<800		
	Week 4	11OCT2012	08:30	922		

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[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
208-0001/59/M/W2	Week 8	07NOV2012	08:30	<800		
	Week 12	05DEC2012	08:50	<800		
	Week 16	02JAN2013	08:20	<800		
	Week 20	30JAN2013	08:40	<800		
	Week 24	01MAR2013	09:00	<800		
	Week 28	27MAR2013	08:45	<800		
	Week 32	24APR2013	09:00	<800		
	Week 36	22MAY2013	08:30	<800		
	Week 40	19JUN2013	08:30	<800		Uns Continuation
	Week 44	17JUL2013	08:30	<800		Uns Continuation
	Week 48	19AUG2013	08:15	<800		Uns Continuation
	Week 52	11SEP2013	08:30	<800		Uns Continuation
	Week 56	09OCT2013	08:15	<800		Uns Continuation
	Week 60	06NOV2013	08:30	<800		Uns Continuation

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
208-0001/59/M/W2	Week 64	04DEC2013	09:00	<800		Uns Continuation
	Week 68	02JAN2014	08:50	<800		Uns Continuation
	Week 72	29JAN2014	08:30	<800		Uns Continuation
	Week 76	26FEB2014	08:30	863		Uns Continuation
	Week 80	26MAR2014	08:40	1030		Uns Continuation
	Week 84	23APR2014	09:00	<800		Uns Continuation
	Week 86	07MAY2014	08:10	<800		Uns Continuation
	Week 88	21MAY2014	08:30	<800		Uns Continuation
	Unscheduled	18JUN2014	08:15	<800		Week 92
	Unscheduled	16JUL2014	08:20	<800		Week 96
	Week 100	13AUG2014	09:15	<800		Uns Continuation
	Week 104	10SEP2014	09:00	<800		Uns Continuation
	Week 108	08OCT2014	08:20	<800		Uns Continuation
	Week 110	22OCT2014	08:15	<800		Uns Continuation

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
208-0001/59/M/W2	Week 112	05NOV2014	08:30	<800		Retest in sample list from CLS
	Week 116	03DEC2014	09:40	<800		Uns Continuation
	Week 120	02JAN2015	08:30	<800		Uns Continuation
	Week 124	28JAN2015	08:15	<800		Uns Continuation
	Week 128	25FEB2015	08:30	BQL		Uns Continuation
	Week 132	25MAR2015	08:15	BQL		Uns Continuation
	Week 136	Unknown	Unknown	BQL		Uns Continuation
	Week 140	Unknown	Unknown	BQL		Uns Continuation
208-0002/82/F/W2	Screening	14SEP2012	10:00	<800		
	Week 4	11OCT2012	09:00	<800		
	Week 8	07NOV2012	08:45	<800		
208-0006/69/F/W2	Screening	19AUG2013	09:45	<800		
	Week 2	05SEP2013	09:00	1150		
	Week 4	18SEP2013	09:00	1310		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
208-0006/69/F/W2	Week 8	16OCT2013	09:15	<800		
	Week 12	13NOV2013	08:45	<800		
208-0007/53/M/W2	Screening	23JUN2014	10:00	<800		
	Week 2	16JUL2014	08:30	3460		
	Week 4	30JUL2014	08:30	<800		
	Week 8	27AUG2014	08:20	<800		
	Week 12	25SEP2014	08:30	<800		
209-0001/66/M/W2	Screening	08NOV2012	10:30	<800		
	Week 4	06DEC2012	10:10	5870		
	Week 8	03JAN2013	09:50	<800		
	Week 12	31JAN2013	10:15	<800		
209-0004/74/M/W2	Screening	28MAR2013	10:15	<800		
	Week 4	30APR2013	09:15	4750		
	Week 8	30MAY2013	09:30	4220		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
209-0004/74/M/W2	Week 12	25JUN2013	10:45	3870		
209-0008/66/M/W2	Screening	26JUN2013	07:45	<800		
	Week 4	31JUL2013	09:30	1120		
	Week 12	24SEP2013	09:00	<800		
209-0012/63/M/W2	Screening	26NOV2013	10:10	<800		
	Week 2	10DEC2013	10:20	2960		
	Week 4	23DEC2013	09:00	1910		
	Week 8	22JAN2014	09:30	<800		
	Week 12	19FEB2014	09:00	<800		
	Week 16	19MAR2014	10:00	<800		
	Week 20	16APR2014	09:00	<800		
	Week 24	15MAY2014	10:00	<800		
209-0013/52/M/W2	Screening	10DEC2013	09:00	<800		
	Week 4	14JAN2014	09:30	977		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
209-0013/52/M/W2	Week 8	12FEB2014	09:35	827		
	Week 12	11MAR2014	11:05	<800		
	Week 16	08APR2014	10:40	800		
	Week 20	07MAY2014	09:30	<800		
	Week 24	04JUN2014	10:15	<800		
	Week 28	02JUL2014	09:15	<800		
	Week 32	29JUL2014	10:15	<800		
	Week 36	26AUG2014	09:40	<800		
210-0001/67/M/W2	Screening	28AUG2013	09:30	<800		
	Week 2	05SEP2013	11:00	2780		
	Week 4	19SEP2013	09:30	3870		
	Week 8	17OCT2013	10:00	<800		
	Week 12	14NOV2013	10:15	<800		
	Week 16	12DEC2013	09:45	Not analyz		Empty tube

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
210-0001/67/M/W2	Week 20	09JAN2014	09:30	<800		
	Week 24	06FEB2014	09:30	<800		
210-0002/80/M/W2	Screening	02OCT2013	10:15	<800		
	Week 2	16OCT2013	11:00	3010		
	Week 4	31OCT2013	10:10	1650		
	Week 8	29NOV2013	10:10	<800		
	Week 12	23DEC2013	09:30	<800		
	Week 16	22JAN2014	09:15	<800		
	Week 20	19FEB2014	09:30	828		
	Week 24	19MAR2014	09:15	<800		
	Week 32	14MAY2014	09:30	<800		
	Week 36	12JUN2014	09:30	<800		
	Week 40	09JUL2014	09:30	<800		Uns Continuation
	Week 44	06AUG2014	09:20	<800		Uns Continuation

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
210-0007/72/M/W2	Screening	03JUL2014	09:30	964		
	Week 2	16JUL2014	10:15	2710		
	Week 4	31JUL2014	09:15	2830		
	Week 8	28AUG2014	09:10	<800		
	Week 12	24SEP2014	09:30	<800		
	Week 20	27NOV2014	09:45	853		
	Week 24	22DEC2014	10:10	<800		
	Week 28	22JAN2015	09:45	<800		
	Week 32	19FEB2015	10:40	BQL		
	Week 36	19MAR2015	09:45	BQL		
210-0009/49/F/W2	Screening	05NOV2014	09:30	<800		
	Week 2	19NOV2014	10:00	1970		
	Week 4	03DEC2014	10:00	1620		
	Week 8	29DEC2014	09:40	<800		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
210-0009/49/F/W2	Week 12	28JAN2015	10:00	<800		
210-0011/73/M/W2	Screening	12NOV2014	09:30	<800		
	Week 2	26NOV2014	10:05	2180		
	Week 4	10DEC2014	10:00	3120		
	Week 8	08JAN2015	10:15	2270		
210-0012/47/F/W2	Screening	11DEC2014	09:30	<800		
	Week 2	22DEC2014	10:00	2490		
	Week 4	08JAN2015	09:35	1720		
	Week 8	05FEB2015	09:55	BQL		
	Week 12	05MAR2015	09:40	BQL		
210-0014/71/F/W2	Screening	15JAN2015	10:15	<800		
	Week 2	05FEB2015	10:00	1920		
	Week 4	19FEB2015	10:35	4530		
	Week 8	19MAR2015	09:40	819		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
210-0014/71/F/W2	Week 12	16APR2015	10:10	BQL		
251-0001/55/F/W2	Screening	23JUL2012	14:50	<800		
	Week 4	21AUG2012	12:00	1760		Retest in sample list from CLS
	Week 8	18SEP2012	11:30	2440		
	Week 12	16OCT2012	12:00	<800		
252-0002/76/M/W2	Screening	21AUG2012	11:45	<800	800	
	Unscheduled	21AUG2012	11:45	<800		Screening
	Week 4	Unknown	Unknown	<800		
252-0003/68/M/W2	Screening	11DEC2012	14:00	<800		
	Week 4	22JAN2013	10:10	3840		
	Week 8	19FEB2013	10:15	<800		
	Week 12	19MAR2013	09:30	<800		
252-0007/77/M/W2	Screening	11FEB2014	08:25	<800		
252-0011/81/M/BL	Screening	18NOV2014	11:20	<800		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
252-0011/81/M/BL	Week 2	02DEC2014	08:45	1190		
	Week 8	13JAN2015	08:15	846		
	Week 12	10FEB2015	08:25	902		
	Week 16	10MAR2015	12:00	1200		
	Week 20	07APR2015	09:00	BQL		
	Week 24	05MAY2015	08:50	BQL		
253-0002/63/M/W2	Screening	02MAR2012	13:45	<800		
	Week 4	30MAR2012	10:10	1180		
	Week 8	27APR2012	11:15	<800		
253-0010/76/M/W2	Screening	31MAY2013	10:30	<800		
	Week 4	28JUN2013	11:00	5280		
	Week 8	26JUL2013	11:30	2790		
	Week 12	23AUG2013	11:00	<800		
	Week 16	20SEP2013	10:40	<800		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
253-0010/76/M/W2	Week 20	18OCT2013	10:30	<800		
	Week 24	18NOV2013	10:30	<800		
254-0001/69/M/W2	Screening	04MAY2012	12:15	<800		
	Week 4	13JUN2012	12:30	2190		
	Week 8	10JUL2012	13:05	<800		
	Week 12	06AUG2012	13:00	<800		
257-0001/47/M/A4	Screening	29MAR2012	12:45	<800		
	Week 4	26APR2012	14:25	1300		
	Week 8	24MAY2012	10:55	<800		
257-0002/56/M/W2	Screening	12APR2012	10:35	<800		
257-0007/80/M/W2	Screening	13FEB2013	09:13	<800	800	

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
	Unscheduled	13FEB2013	09:13	<800		Screening (collection date not found on visit report, date is between screening and week 1)
	Unscheduled	21FEB2013	Unknown	<800		Week 1
	Week 2	28FEB2013	12:00	2970		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
257-0007/80/M/W2	Week 4	14MAR2013	11:05	3320		
	Week 8	11APR2013	10:50	4130		
	Week 12	09MAY2013	11:20	<800		
257-0008/80/F/W2	Screening	21MAR2013	13:15	<800	800	
	Unscheduled	21MAR2013	13:15	<800		Screening (collection date not found on visit report, date is between screening and week 1)
	Week 2	04APR2013	10:28	2470		
	Week 4	18APR2013	10:05	2030		
	Week 8	16MAY2013	12:05	2880		
	Week 12	13JUN2013	12:50	4220		
257-0010/42/M/BL	Screening	16MAY2013	14:35	<800	800	

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
	Unscheduled	16MAY2013	14:35	<800		Screening (collection date not found on visit report, date is between screening and week 1)
	Week 2	30MAY2013	10:19	3510		
	Week 4	13JUN2013	12:40	4660		
	Week 8	08JUN2013	14:13	1850		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
257-0010/42/M/BL	Week 12	05AUG2013	14:12	1540		
257-0012/75/M/W2	Screening	09MAY2013	11:08	<800		
	Week 2	23MAY2013	11:10	1120		
	Week 4	07JUN2013	11:24	<800		
257-0015/69/F/BL	Screening	31MAR2014	13:57	<800		
257-0017/74/M/A8	Screening	28APR2014	14:20	1140		
	Week 2	12MAY2014	14:10	4340		
	Week 4	27MAY2014	15:30	6040		
	Week 8	23JUN2014	15:05	1330		
257-0018/53/M/A6	Screening	17APR2014	11:00	813		
	Week 2	02MAY2014	14:20	3210		
	Week 4	19MAY2014	14:20	<800		
257-0022/60/M/W2	Screening	26NOV2014	11:35	<800		
	Week 2	08DEC2014	14:10	3090		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
257-0022/60/M/W2	Week 4	22DEC2014	14:00	3400		
	Week 8	19JAN2015	15:20	1400		
	Unscheduled	26JAN2015	Unknown	<800		Week 9
257-0024/75/M/W2	Screening	15DEC2014	13:20	<800		
	Week 2	29DEC2014	13:20	4950		
	Week 4	12JAN2015	13:30	2830		
	Week 8	09FEB2015	15:34	2700		
257-0025/69/M/BL	Screening	15DEC2014	14:15	891		
	Week 2	29DEC2014	13:44	4290		
	Week 4	12JAN2015	13:20	3430		
	Week 8	09FEB2015	15:05	3160		
	Unscheduled	16FEB2015	Unknown	2440		Week 9
	Week 12	09MAR2015	14:00	3390		
257-0026/65/M/W2	Screening	12JAN2015	15:10	<800		

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[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
257-0026/65/M/W2	Week 2	26JAN2015	13:45	4420		
	Week 4	09FEB2015	14:45	BQL		
	Week 8	09MAR2015	14:00	BQL		
	Week 12	Unknown	Unknown	BQL		
257-0027/52/M/A6	Screening	12JAN2015	15:45	<800		
	Week 2	26JAN2015	16:10	3450		
	Week 4	09FEB2015	15:00	5580		
258-0005/64/M/OTH	Screening	31JUL2013	10:50	<800		
	Week 2	21AUG2013	11:20	2620		
	Week 4	04SEP2013	11:15	3800		
	Week 8	02OCT2013	11:25	1350		
258-0007/74/M/W2	Screening	02OCT2013	12:28	<800		
	Week 2	18OCT2013	11:58	2680		
	Week 4	01NOV2013	11:32	1430		

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[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
258-0008/70/M/W2	Screening	06NOV2013	10:14	<800		
258-0009/64/M/W2	Screening	16MAY2014	12:09	840		
	Week 2	30MAY2014	10:05	5380		
	Week 4	11JUN2014	10:05	3880		
	Week 8	09JUL2014	10:38	3400		
	Week 12	06AUG2014	10:40	<800		
	Week 16	03SEP2014	10:45	<800		
	Week 20	01OCT2014	10:25	<800		
	Week 24	29OCT2014	11:43	<800		
258-0010/53/M/W2	Screening	30MAY2014	11:12	<800		
	Week 2	11JUN2014	11:20	5500		
	Week 4	25JUN2014	10:10	<800		
	Week 8	21JUL2014	10:20	909		
	Week 12	20AUG2014	09:12	<800		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
258-0010/53/M/W2	Week 16	17SEP2014	10:20	<800		
	Week 20	16OCT2014	09:30	<800		
	Week 24	12NOV2014	10:05	<800		
258-0012/66/F/W2	Screening	09JUL2014	10:30	<800		
	Week 2	23JUL2014	12:20	5800		
	Week 4	06AUG2014	12:15	<800		
	Week 8	03SEP2014	12:05	<800		
	Week 12	01OCT2014	11:20	<800		
258-0015/65/M/W2	Screening	28NOV2014	09:33	<800		
	Week 2	10DEC2014	09:43	5380		
259-0001/68/F/W2	Screening	24MAY2013	09:15	<800		
	Week 2	13JUN2013	13:20	2100		
	Week 4	26JUN2013	14:00	<800		
	Week 8	24JUL2013	13:20	<800		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
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[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
259-0001/68/F/W2	Week 12	21AUG2013	13:50	<800		
	Week 20	16OCT2013	13:20	<800		
	Week 36	05FEB2014	10:15	<800		
	Week 40	05MAR2014	13:00	<800		Uns Continuation
	Week 48	30APR2014	10:45	<800		Uns Continuation
	Week 52	28MAY2014	10:50	<800		Uns Continuation
259-0002/54/F/W2	Screening	04SEP2013	12:45	<800		
	Week 2	18SEP2013	11:15	1000		
	Week 4	02OCT2013	11:56	<800		
	Week 8	30OCT2013	12:05	<800		
	Week 12	27NOV2013	11:30	<800		
260-0003/81/M/A7	Screening	22OCT2014	14:00	<800		
	Week 2	12NOV2014	11:40	4340		
	Week 4	26NOV2014	10:50	8110		

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Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
260-0003/81/M/A7	Week 8	22DEC2014	11:30	5330		
	Week 12	21JAN2015	11:30	<800		
	Week 16	18FEB2015	11:00	BQL		
	Week 20	18MAR2015	11:00	BQL		
	Week 24	15APR2015	10:30	BQL		
	Week 28	13MAY2015	10:30	BQL		
301-0005/61/M/A2	Screening	17MAY2012	10:00	<800		
	Week 4	14JUN2012	10:05	5410		
	Week 8	12JUL2012	10:00	<800		
	Week 12	09AUG2012	09:20	<800		
301-0007/55/F/A2	Screening	26DEC2012	09:35	<800		
	Week 4	25JAN2013	10:10	6010		
	Week 8	22FEB2013	09:56	4110		
301-0009/55/M/A2	Screening	08JAN2013	09:45	<800		

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Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
301-0009/55/M/A2	Week 4	31JAN2013	09:55	<800		
	Week 8	01MAR2013	09:45	<800		
	Week 12	28MAR2013	10:00	<800		
302-0002/32/F/A2	Screening	03NOV2011	11:00	<800		
	Week 4	29NOV2011	10:50	<800		
302-0004/57/M/A2	Screening	04JAN2012	09:15	<800		
	Week 4	01FEB2012	09:15	4420		
	Week 8	28FEB2012	09:15	1670		
302-0007/76/M/A2	Screening	08FEB2012	08:44	<800		
	Week 4	06MAR2012	09:00	4750		
	Week 8	03APR2012	09:10	2980		
	Week 12	01MAY2012	08:35	<800		
302-0008/37/M/A2	Screening	23FEB2012	09:12	<800		
	Week 4	20MAR2012	09:30	<800		

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[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
302-0008/37/M/A2	Week 8	17APR2012	09:20	<800		
302-0010/45/M/A2	Screening	12APR2012	10:35	<800		
	Week 4	08MAY2012	09:15	7370		
	Week 8	05JUN2012	09:20	7020		
	Week 12	03JUL2012	08:55	1940		
302-0011/52/M/A2	Screening	17APR2012	11:02	<800		
	Week 4	15MAY2012	09:25	7110		
302-0015/60/M/A2	Screening	11APR2013	08:40	<800		
	Week 2	23APR2013	08:50	2880		
	Week 4	07MAY2013	08:55	4220		
	Week 8	04JUN2013	09:10	3620		
	Week 12	02JUL2013	08:40	3840		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
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[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
302-0016/60/M/A2	Screening	11APR2013	09:05	<800		Additional sample with visit screening-1 is listed in sample list
	Week 2	23APR2013	09:20	2320		

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[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
302-0016/60/M/A2	Week 4	07MAY2013	08:50	2390		
	Week 8	04JUN2013	09:05	<800		
	Week 12	02JUL2013	08:40	<800		
302-0019/52/M/A2	Screening	09MAY2013	09:15	<800		
	Week 2	21MAY2013	09:20	4820		
	Week 4	04JUN2013	09:15	4960		
	Week 8	02JUL2013	09:10	<800		
	Week 12	30JUL2013	09:15	<800		
302-0022/65/M/A2	Screening	04JUL2013	09:05	886		
	Week 2	16JUL2013	09:30	4470		
	Week 4	30JUL2013	09:30	2760		
	Week 8	27AUG2013	09:00	869		
302-0023/68/M/A2	Screening	15SEP2009	Unknown	<800		
	Week 2	17SEP2013	08:20	2920		

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[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
302-0023/68/M/A2	Week 4	01OCT2013	09:13	1290		
302-0024/66/F/A2	Screening	04JAN2013	Unknown	<800		
	Week 2	01OCT2013	09:08	4270		
	Week 4	15OCT2013	08:28	2840		
	Week 8	12NOV2013	08:20	<800		
	Week 12	10DEC2013	08:10	<800		
302-0025/40/M/A2	Screening	07SEP2011	Unknown	<800		
	Week 2	29OCT2013	08:15	7350		
302-0026/49/M/A2	Screening	05NOV2013	10:45	<800		
	Week 2	19NOV2013	08:25	6750		
	Week 4	03DEC2013	08:50	8130		
	Week 8	31DEC2013	08:40	<800		
	Week 12	28JAN2014	09:35	<800		
	Week 16	25FEB2014	08:55	<800		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
302-0026/49/M/A2	Week 20	25MAR2014	09:00	<800		
	Week 24	22APR2014	09:00	<800		
	Week 28	22MAY2014	09:10	<800		
	Week 32	17JUN2014	09:30	<800		
	Week 36	15JUL2014	08:40	<800		
303-0001/50/M/A2	Screening	20JAN2012	09:20	<800		
	Week 4	22FEB2012	13:25	<800		
	Week 8	21MAR2012	14:30	<800		
	Week 12	18APR2012	13:00	<800		
303-0003/47/M/A2	Screening	14NOV2012	10:15	<800		
	Week 4	19DEC2012	10:30	<800		
	Week 8	16JAN2013	10:00	<800		
	Week 12	15FEB2013	14:00	<800		
303-0004/18/M/A2	Screening	26NOV2012	14:50	<800		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
303-0004/18/M/A2	Week 4	02JAN2013	14:00	6640		
	Week 8	30JAN2013	13:30	<800		
	Week 12	27FEB2013	13:50	<800		
303-0006/64/M/A2	Screening	27MAR2013	15:10	<800		
	Week 4	01MAY2013	13:30	<800		
	Week 8	29MAY2013	13:25	<800		
303-0007/50/M/A2	Screening	03JUL2013	Unknown	854		
	Week 2	31JUL2013	13:30	4180		
	Week 4	14AUG2013	13:30	2410		
	Week 8	11SEP2013	13:25	<800		
304-0001/54/M/A2	Screening	30OCT2012	10:30	<800		
	Week 4	27NOV2012	11:00	<800		
304-0005/58/M/A2	Screening	30MAY2013	11:16	959		
	Week 2	13JUN2013	08:15	1730		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
304-0005/58/M/A2	Week 4	26JUN2013	08:30	3670		
305-0002/57/M/A2	Screening	13FEB2012	09:15	<800		
305-0003/50/M/A2	Screening	26AUG2008	Unknown	<800		
	Week 4	09MAR2012	09:00	1510		
	Week 8	06APR2012	09:00	<800		
	Week 12	04MAY2012	09:00	<800		
	Week 16	01JUN2012	08:45	<800		
	Week 20	29JUN2012	08:52	<800		
	Week 24	27JUL2012	08:32	<800		
305-0005/48/M/A2	Screening	15FEB2012	11:35	<800		
	Week 4	15MAR2012	09:09	<800		
305-0006/65/M/A2	Screening	07MAR2012	09:20	<800		
	Week 4	28MAR2012	12:15	2990		
	Week 8	25APR2012	12:30	<800		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
305-0006/65/M/A2	Week 12	23MAY2012	12:09	<800		
	Week 16	19JUN2012	12:25	<800		
	Week 20	18JUL2012	12:40	<800		
	Week 24	15AUG2012	12:40	<800		
305-0009/45/F/A2	Screening	11APR2012	09:30	<800		
	Week 4	01MAY2012	11:50	8590		
	Week 8	30MAY2012	11:53	8390		
	Week 12	27JUN2012	12:20	7050		
	Week 16	25JUL2012	12:50	9470		
	Week 20	22AUG2012	13:00	7980		
	Week 24	19SEP2012	13:05	6250		
305-0010/64/F/A2	Screening	16APR2012	11:20	<800		
	Week 4	08MAY2012	12:40	1730		
	Week 8	05JUN2012	13:35	<800		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
305-0010/64/F/A2	Week 12	04JUL2012	13:00	<800		
305-0011/68/M/A2	Screening	20APR2012	12:00	<800		
	Week 4	18MAY2012	08:20	3400		
	Week 8	15JUN2012	07:50	<800		
	Week 12	13JUL2012	07:20	1080		
	Week 16	10AUG2012	07:50	<800		
305-0012/62/F/A2	Screening	03MAY2012	15:10	<800		
	Week 4	25MAY2012	08:20	8510		
	Week 8	22JUN2012	08:20	7950		
	Week 12	20JUL2012	09:02	2590		
	Week 16	17AUG2012	07:42	2090		
	Week 20	14SEP2012	08:11	1820		
	Week 24	12OCT2012	07:56	1020		
	Week 28	09NOV2012	07:55	946		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
305-0012/62/F/A2	Week 32	07DEC2012	07:40	<800		
	Week 36	04JAN2013	07:55	<800		
305-0014/61/F/A2	Screening	04JUL2012	08:00	<800		
	Week 4	31JUL2012	11:30	6890		
	Week 8	28AUG2012	12:22	7100		
	Week 12	25SEP2012	12:09	6000		
305-0019/35/M/A2	Screening	05SEP2012	10:33	<800		
	Week 4	02OCT2012	11:55	6400		
	Week 8	30OCT2012	12:33	<800		
305-0023/54/M/A2	Screening	02JAN2013	09:45	<800		
	Week 4	29JAN2013	12:10	3830		
	Week 8	26FEB2013	12:09	<800		
	Week 12	29MAR2013	07:40	<800		
	Week 16	25APR2013	08:10	<800		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
305-0025/77/F/A2	Screening	15JAN2013	14:40	<800		
	Week 4	15FEB2013	12:15	<800		
	Week 8	12MAR2013	11:45	<800		
	Week 12	09APR2013	10:50	<800		
305-0026/45/M/A2	Screening	11MAR2002	Unknown	<800		
	Week 4	19MAR2013	12:40	6000		
	Week 8	16APR2013	13:00	<800		
	Week 12	14MAY2013	13:05	<800		
	Week 20	09JUL2013	13:05	<800		
	Week 24	06AUG2013	13:00	<800		
305-0028/73/F/A2	Screening	13MAR2013	14:00	<800		
	Week 4	03APR2013	13:00	2780		
	Week 8	30APR2013	13:22	1410		
	Week 12	29MAY2013	12:50	<800		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
305-0030/61/M/A2	Screening	28MAR2013	10:00	<800		
	Week 4	23APR2013	12:00	7620		
305-0031/29/M/A2	Screening	26MAR2013	17:58	<800		
	Week 4	26APR2013	09:33	3780		
305-0034/53/M/A2	Screening	26JUN2013	15:15	<800		
	Week 2	10JUL2013	13:05	2900		
	Week 4	22JUL2013	11:20	1940		
305-0036/38/M/A2	Screening	27AUG2013	15:03	<800		
	Week 2	12SEP2013	08:01	873		
	Week 4	26SEP2013	08:30	<800		
	Week 8	24OCT2013	08:15	<800		
	Week 12	19NOV2013	09:32	<800		
305-0037/50/M/A2	Screening	17OCT2013	15:07	<800		
	Week 4	14NOV2013	09:00	1050		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
305-0037/50/M/A2	Week 8	12DEC2013	09:07	<800		
	Week 12	09JAN2014	09:20	<800		
305-0039/35/M/A2	Screening	22NOV2013	15:25	<800		
	Week 2	05DEC2013	10:46	2640		
	Week 4	19DEC2013	10:50	2410		
305-0040/61/M/A2	Screening	11NOV2013	08:57	<800		
	Week 2	19NOV2013	12:50	4080		
305-0043/70/M/A2	Screening	27JUN2014	09:00	<800		
	Week 2	08JUL2014	12:40	3610		
	Week 4	22JUL2014	13:00	5490		
	Week 8	19AUG2014	13:00	4690		
	Week 12	16SEP2014	10:51	3350		
305-0044/67/M/A2	Screening	01JUL2014	16:30	<800		
	Week 2	15JUL2014	12:30	4170		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
305-0044/67/M/A2	Week 4	29JUL2014	12:35	5970		
	Week 8	26AUG2014	12:50	4460		
	Week 12	26SEP2014	13:00	2290		
305-0045/65/M/A2	Screening	06OCT2014	08:06	<800		
	Week 2	24OCT2014	08:00	2380		
	Week 4	07NOV2014	07:43	1850		
305-0047/58/M/A2	Screening	24DEC2014	09:30	<800		
	Week 2	31DEC2014	14:00	1450		
	Week 4	14JAN2015	12:55	4300		
305-0048/55/M/A2	Screening	10FEB2015	15:20	<800		
	Week 2	06MAR2015	09:30	2960		
	Week 4	20MAR2015	12:50	4920		
	Week 8	14APR2015	12:30	3240		
	Week 12	12MAY2015	13:07	1020		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
306-0001/56/M/A2	Screening	13FEB2012	08:30	<800		
	Week 4	09MAR2012	13:30	<800		
	Week 8	06APR2012	13:30	<800		
	Week 12	04MAY2012	09:00	<800		
306-0002/73/M/A2	Screening	09FEB2012	09:30	<800		
	Week 4	06MAR2012	09:30	4290		
	Week 8	03APR2012	08:30	<800		
	Week 12	30APR2012	15:00	<800		
306-0005/69/F/A2	Screening	22FEB2012	10:30	<800		
	Week 4	16MAR2012	09:00	5650		
	Week 8	13APR2012	09:00	<800		
306-0006/43/M/A2	Screening	13MAR2012	10:00	<800	800	
	Screening	13MAR2012	10:00	<800		
	Week 4	10APR2012	13:00	7160		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
306-0007/56/M/A2	Screening	01MAR2012	10:30	<800		
	Week 4	26MAR2012	13:30	3740		
306-0008/40/M/A2	Screening	07MAR2012	10:30	<800		
	Week 4	02APR2012	09:00	7200		
	Week 8	30APR2012	09:00	6190		
306-0011/47/M/A2	Screening	13MAR2012	13:30	<800		
	Week 4	05APR2012	10:00	4060		
	Week 8	03MAY2012	10:00	<800		
	Week 12	30MAY2012	10:00	<800		
306-0012/61/M/A2	Screening	29MAR2012	10:06	<800		
	Week 4	25APR2012	10:30	5090		
	Week 8	21MAY2012	09:00	2370		
	Week 12	19JUN2012	09:00	<800		
	Week 16	17JUL2012	09:40	<800		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
306-0012/61/M/A2	Week 20	13AUG2012	09:35	<800		
	Week 24	11SEP2012	09:15	<800		
306-0014/47/M/A2	Screening	13APR2012	11:00	<800		
	Week 4	11MAY2012	08:30	1810		
306-0017/49/M/A2	Screening	09JUL2012	09:00	<800		
	Week 4	02AUG2012	09:00	4430		
306-0019/78/M/A2	Screening	20AUG2012	09:10	<800		
	Week 4	13SEP2012	10:00	6810		
	Week 8	08OCT2012	08:20	<800		
	Week 12	05NOV2012	08:20	<800		
306-0020/63/M/A2	Screening	27SEP2012	08:20	<800		
	Week 4	25OCT2012	09:00	3580		
	Week 8	22NOV2012	09:00	<800		
	Week 12	20DEC2012	09:30	<800		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
306-0023/68/M/A2	Screening	20NOV2012	09:00	<800		
	Week 4	18DEC2012	11:00	<800		
306-0026/58/M/A2	Screening	24JAN2013	10:00	<800		
	Week 4	25FEB2013	13:50	<800		
	Week 8	28MAR2013	09:00	<800		
	Week 12	25APR2013	08:30	<800		
	Week 16	23MAY2013	09:00	<800		
	Week 20	20JUN2013	09:30	<800		
	Week 24	18JUL2013	09:00	<800		
	Week 28	15AUG2013	09:00	<800		
	Week 32	12SEP2013	09:00	<800		
	Week 36	08OCT2013	08:30	<800		
306-0027/67/M/A2	Screening	06FEB2013	13:00	<800		
	Week 4	13MAR2013	10:00	5560		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
306-0027/67/M/A2	Week 8	10APR2013	09:30	4900		
	Week 12	08MAY2013	09:30	1240		
	Week 16	05JUN2013	09:30	<800		
	Week 20	03JUL2013	09:30	<800		
	Week 24	31JUL2013	10:00	<800		
	Week 28	28AUG2013	10:00	<800		
	Week 32	25SEP2013	09:00	<800		
	Week 36	23OCT2013	09:00	<800		
	Week 40	20NOV2013	09:30	<800		
	Week 44	18DEC2013	09:30	<800		
	Week 48	15JAN2014	09:30	<800		
	Week 52	12FEB2014	09:00	<800		
	Week 56	12MAR2014	09:30	<800		
	Week 60	09APR2014	09:30	<800		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
306-0027/67/M/A2	Week 64	07MAY2014	09:40	<800		
	Week 68	06JUN2014	09:40	<800		
	Week 72	02JUL2014	09:30	<800		
306-0030/63/M/A2	Screening	12APR2013	11:30	<800		
	Week 4	14MAY2013	09:00	2350		
306-0031/40/M/A2	Screening	07MAY2013	11:00	<800		
	Week 4	05JUN2013	09:30	1770		
	Week 8	03JUL2013	09:30	<800		
306-0034/65/M/A2	Screening	20JUN2013	10:30	<800		
	Week 2	08JUL2013	13:30	1550		
	Week 4	25JUL2013	13:30	<800		
306-0035/48/M/A2	Screening	27JUN2013	10:00	<800		
	Week 2	15JUL2013	08:30	1970		
	Week 4	29JUL2013	08:40	<800		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
306-0035/48/M/A2	Week 8	26AUG2013	09:00	<800		
306-0036/73/M/A2	Screening	02JUL2013	10:00	<800		
	Week 2	16JUL2013	10:00	2670		
	Week 4	30JUL2013	08:40	2000		
	Week 8	27AUG2013	08:30	<800		
306-0038/66/M/A2	Screening	09AUG2013	13:30	<800		
	Week 2	28AUG2013	09:00	2680		
	Week 4	11SEP2013	08:30	2240		
	Week 8	09OCT2013	08:30	<800		
	Week 12	06NOV2013	08:30	<800		
306-0039/62/M/A2	Screening	09AUG2013	13:30	<800		
	Week 2	27AUG2013	09:00	2440		
	Week 4	10SEP2013	09:00	5070		
	Week 8	08OCT2013	08:30	2300		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
306-0039/62/M/A2	Week 12	05NOV2013	08:30	1810		
306-0040/44/F/A2	Screening	17SEP2013	10:00	<800		
	Week 2	01OCT2013	08:30	2630		
	Week 4	15OCT2013	10:00	2200		
	Week 8	12NOV2013	09:30	<800		
	Week 12	12DEC2013	10:00	<800		
	Week 16	07JAN2014	09:30	<800		
	Week 20	07FEB2014	12:00	<800		
	Week 24	04MAR2014	10:30	<800		
306-0041/62/M/A2	Screening	18OCT2013	10:30	<800		
	Week 2	08NOV2013	09:30	2840		
	Week 4	22NOV2013	09:30	6080		
	Week 8	20DEC2013	08:30	6110		
	Week 12	17JAN2014	09:00	4530		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
306-0041/62/M/A2	Week 16	11FEB2014	09:30	3270		
306-0043/56/M/A2	Screening	08MAY2014	10:30	<800		
	Week 2	29MAY2014	09:30	1920		
	Week 4	09JUN2014	09:20	<800		
	Week 8	10JUL2014	09:00	<800		
	Week 12	04AUG2014	09:00	<800		
307-0002/61/M/A2	Screening	31OCT2011	10:30	<800		
	Week 4	25NOV2011	11:05	<800		
	Week 8	22DEC2011	10:25	<800		
	Week 12	19JAN2012	13:26	<800		
307-0003/68/M/A2	Screening	04NOV2011	08:00	<800	800	Collected on 04Nov2011, screening in sample list
	Screening	08NOV2011	08:00	<800		Collected on 08Nov2011

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
	Week 4	29NOV2011	09:10	6610		
	Week 8	27DEC2011	10:45	5390		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
307-0003/68/M/A2	Week 12	27JAN2012	08:45	<800		
	Week 16	21FEB2012	08:46	<800		
	Week 20	20MAR2012	08:14	<800		
	Week 24	16APR2012	09:50	<800		
	Week 28	15MAY2012	10:25	<800		
	Week 32	14JUN2012	10:25	<800		
	Week 36	10JUL2012	10:25	<800		
307-0004/60/M/A2	Screening	08NOV2011	09:09	<800		
	Week 4	29NOV2011	09:20	5370		
	Week 8	27DEC2011	08:35	4640		
307-0008/58/M/A2	Screening	13DEC2011	08:30	<800		
	Week 4	10JAN2012	08:54	<800		
	Week 8	07FEB2012	08:40	<800		
	Week 12	08MAR2012	08:40	<800		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
307-0011/75/M/A2	Screening	31JAN2012	11:55	<800	800	
	Screening	31JAN2012	11:55	<800		
	Week 4	29FEB2012	08:54	<800		
307-0014/61/M/A2	Screening	14FEB2012	09:13	<800		
	Week 4	08MAR2012	08:30	3170		
	Week 8	05APR2012	13:30	<800		
	Week 12	03MAY2012	13:40	<800		
	Week 16	31MAY2012	13:23	<800		
	Week 20	28JUN2012	13:28	<800		
	Week 24	26JUL2012	09:09	<800		
307-0018/70/M/A2	Screening	11JUN2012	09:40	<800		
	Week 4	05JUL2012	14:00	<800		
	Week 8	03AUG2012	10:30	<800		
	Week 12	30AUG2012	09:45	<800		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
307-0018/70/M/A2	Week 16	27SEP2012	08:52	<800		
	Week 20	25OCT2012	08:50	<800		
	Week 24	22NOV2012	09:20	<800		
	Week 28	20DEC2012	09:07	<800		
	Week 32	17JAN2013	08:42	<800		
	Week 36	14FEB2013	09:18	<800		
	Week 40	14MAR2013	18:34	<800		
	Week 44	11APR2013	08:55	<800		
	Week 48	09MAY2013	09:25	<800		
307-0020/68/F/A2	Screening	14AUG2012	10:20	<800		
	Week 4	04SEP2012	11:15	6300		
	Week 8	02OCT2012	11:10	<800		
	Week 12	30OCT2012	10:08	<800		
307-0022/59/M/A2	Screening	21NOV2012	09:25	<800		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
307-0022/59/M/A2	Week 4	17DEC2012	10:10	9190		
	Week 8	14JAN2013	08:31	<800		
	Week 12	14FEB2013	09:53	<800		
307-0025/68/M/A2	Screening	13DEC2012	10:00	<800		
	Week 4	10JAN2013	09:55	5880		
	Week 8	05FEB2013	12:00	<800		
	Week 12	07MAR2013	09:40	<800		
	Week 16	03APR2013	09:50	<800		
	Week 20	02MAY2013	09:15	<800		
	Week 24	30MAY2013	10:10	<800		
307-0026/65/M/A2	Screening	25DEC2012	10:00	<800		
	Week 4	15JAN2013	09:00	4030		
	Week 8	14FEB2013	09:10	<800		
	Week 12	12MAR2013	09:50	<800		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
307-0026/65/M/A2	Week 16	09APR2013	08:20	<800		
	Week 20	07MAY2013	08:32	<800		
	Week 24	04JUN2013	11:05	<800		
307-0030/53/M/A2	Screening	01MAR2013	09:35	<800		
	Week 4	25MAR2013	09:36	3620		
	Week 8	22APR2013	12:07	2970		
307-0031/60/M/A2	Screening	12MAR2013	11:55	<800		
	Week 4	03APR2013	09:15	5260		
	Week 8	02MAY2013	09:25	<800		
	Week 12	30MAY2013	10:26	<800		
	Week 16	27JUN2013	09:15	<800		
	Week 20	25JUL2013	10:30	<800		
	Week 24	22AUG2013	10:25	<800		
	Week 28	17SEP2013	11:57	<800		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
307-0031/60/M/A2	Week 32	17OCT2013	09:18	<800		
	Week 36	14NOV2013	09:40	<800		
307-0032/74/F/A2	Screening	09APR2013	13:40	<800		
	Week 2	18APR2013	13:30	2400		
	Week 4	02MAY2013	13:20	2260		
307-0037/61/M/A2	Screening	30SEP2013	09:53	<800		
	Week 2	11OCT2013	08:54	3560		
	Week 4	24OCT2013	13:13	3370		
307-0039/51/M/A2	Screening	31OCT2013	11:14	<800		
	Week 2	13NOV2013	09:25	4700		
	Week 4	27NOV2013	09:15	5720		
	Week 8	23DEC2013	09:05	<800		
	Week 12	21JAN2014	10:13	<800		
307-0040/65/M/A2	Screening	22MAY2014	09:35	<800		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
307-0040/65/M/A2	Week 2	03JUN2014	13:45	3600		
	Week 4	17JUN2014	13:40	808		
307-0043/54/M/A2	Screening	20JUN2014	11:10	<800		
	Week 2	02JUL2014	08:55	5690		
	Week 4	15JUL2014	08:59	5010		
	Week 8	12AUG2014	09:04	<800		
	Week 12	09SEP2014	09:30	<800		
	Week 16	08OCT2014	09:04	<800		
307-0044/53/M/A2	Screening	26SEP2013	Unknown	<800		
	Week 2	04JUL2014	09:36	3480		
307-0045/48/M/A2	Screening	06JAN2012	Unknown	<800		
	Week 2	14JUL2014	10:22	3850		
	Week 4	28JUL2014	11:15	4530		
	Week 8	25AUG2014	09:55	1160		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
307-0045/48/M/A2	Week 12	22SEP2014	10:43	<800		
307-0046/46/M/A2	Screening	08JUL2014	13:12	<800		
	Week 2	24JUL2014	10:40	1610		
308-0003/54/M/A2	Screening	13NOV2010	Unknown	<800		
	Week 4	19FEB2013	09:05	929		
	Week 8	19MAR2013	09:10	<800		
	Week 12	16APR2013	09:30	<800		
	Week 16	14MAY2013	09:25	<800		
	Week 20	11JUN2013	09:30	<800		
	Week 24	09JUL2013	09:05	<800		
	Week 28	06AUG2013	09:00	<800		
	Week 32	03SEP2013	09:00	<800		
	Week 36	01OCT2013	12:20	<800		
308-0005/68/F/A2	Screening	24APR2013	11:00	<800		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
308-0005/68/F/A2	Week 4	21MAY2013	09:05	4230		
	Week 8	18JUN2013	08:55	2150		
	Week 12	16JUL2013	09:00	<800		
309-0001/46/M/A2	Screening	29MAY2012	13:00	<800		
	Week 4	02JUL2012	16:00	<800		
	Week 8	30JUL2012	15:35	<800		
	Week 12	27AUG2012	16:10	<800		
309-0002/56/M/A2	Screening	04JUN2012	10:35	<800		
309-0003/52/F/A2	Screening	11JUN2012	10:50	<800		
	Week 4	11JUL2012	10:30	3720		
	Week 8	08AUG2012	10:10	3650		
	Week 12	05SEP2012	10:30	995		
309-0004/55/M/A2	Screening	14JUN2012	11:50	<800		
309-0008/38/M/A2	Screening	08FEB2013	11:50	<800		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
309-0008/38/M/A2	Week 4	14MAR2013	09:45	<800		
	Week 8	11APR2013	09:30	<800		
	Week 12	09MAY2013	09:30	<800		
309-0010/47/M/A2	Screening	07MAR2013	Unknown	<800		
	Week 4	15APR2013	12:35	1720		
	Week 8	13MAY2013	13:10	<800		
	Week 12	10JUN2013	11:10	<800		
	Week 16	08JUL2013	09:20	<800		
	Week 20	05AUG2013	10:20	<800		
	Week 24	02SEP2013	09:15	<800		
	Week 28	30SEP2013	10:25	<800		
	Week 32	28OCT2013	10:05	<800		
	Week 36	25NOV2013	09:30	<800		
	Week 40	23DEC2013	09:58	<800		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
309-0010/47/M/A2	Week 44	20JAN2014	11:20	<800		
	Week 48	17FEB2014	09:40	<800		
	Week 52	17MAR2014	09:45	<800		
	Week 56	14APR2014	09:30	<800		
	Week 60	12MAY2014	09:50	<800		
	Week 64	09JUN2014	10:50	<800		
	Week 68	07JUL2014	09:44	<800		
	Week 72	04AUG2014	09:50	<800		
	Week 76	01SEP2014	10:15	<800		
	Week 80	29SEP2014	10:12	<800		
	Week 84	27OCT2014	09:55	<800		
309-0011/59/M/A2	Screening	28MAR2013	15:10	<800		
	Week 2	15APR2013	14:30	2130		
	Week 4	29APR2013	14:50	2440		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
309-0011/59/M/A2	Week 8	27MAY2013	14:15	2540		
	Week 12	24JUN2013	15:40	<800		
309-0012/82/M/A2	Screening	13MAY2013	12:00	<800		
	Week 2	30MAY2013	09:20	2510		
	Week 4	13JUN2013	10:05	4150		
	Week 8	11JUL2013	09:50	<800		
	Week 12	08AUG2013	10:05	<800		
309-0015/62/M/A2	Screening	18JUN2013	13:35	<800		
	Week 2	01JUL2013	09:40	3100		
	Week 4	15JUL2013	09:30	<800		
	Week 8	12AUG2013	10:50	<800		
	Week 12	09SEP2013	10:49	<800		
309-0016/72/F/A2	Screening	26AUG2013	11:20	<800		
	Week 2	12SEP2013	09:50	1840		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
309-0016/72/F/A2	Week 4	26SEP2013	10:00	1860		
	Week 8	24OCT2013	09:05	<800		
	Week 12	21NOV2013	09:28	<800		
309-0017/73/F/A2	Screening	20NOV2013	12:50	<800		
	Week 2	09DEC2013	11:20	3330		
	Week 4	23DEC2013	11:15	5150		
	Week 8	20JAN2014	11:00	5930		
	Week 12	17FEB2014	11:30	4190		
309-0018/82/M/A2	Screening	03JUN2014	12:30	<800		
	Week 2	23JUN2014	09:40	4220		
	Week 4	07JUL2014	12:10	3760		
	Week 8	04AUG2014	10:44	<800		
	Week 12	01SEP2014	09:40	<800		
309-0021/54/F/A2	Screening	04JUL2014	12:15	<800		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
309-0021/54/F/A2	Week 2	24JUL2014	10:35	6320		
	Week 4	07AUG2014	11:50	3800		
	Week 8	04SEP2014	09:55	<800		
309-0025/49/M/A2	Screening	12AUG2014	13:35	<800		
	Week 2	01SEP2014	11:00	2850		
309-0026/41/M/A2	Screening	09SEP2014	14:00	<800		
	Week 2	29SEP2014	10:25	1780		
	Week 4	13OCT2014	09:45	2970		
	Week 8	10NOV2014	11:10	<800		
	Week 12	08DEC2014	11:15	806		
	Week 16	05JAN2015	12:20	<800		
309-0028/62/M/A2	Screening	22OCT2014	12:00	<800		
	Week 2	10NOV2014	09:45	3340		
	Week 4	24NOV2014	11:10	5850		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
309-0028/62/M/A2	Week 8	22DEC2014	08:40	3570		
	Week 12	19JAN2015	09:00	2320		
	Week 16	16FEB2015	09:10	1830		
	Week 20	16MAR2015	08:50	1100		
	Week 24	13APR2015	09:32	BQL		
309-0030/33/M/A2	Screening	04DEC2014	13:30	<800		
	Week 2	22DEC2014	10:45	3440		
	Week 4	05JAN2015	11:25	<800		
	Week 8	02FEB2015	10:10	<800		
309-0031/34/M/A2	Screening	18DEC2014	13:25	<800		
	Week 2	31DEC2014	10:55	3540		
	Week 4	15JAN2015	10:50	4770		
	Week 8	12FEB2015	10:40	2200		
309-0032/63/M/A2	Screening	26DEC2014	12:20	845		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
309-0032/63/M/A2	Week 2	15JAN2015	12:00	2610		
	Week 4	29JAN2015	10:20	2150		
	Week 8	26FEB2015	09:55	<800		
	Week 12	26MAR2015	09:40	BQL		
309-0033/78/F/A2	Screening	16JAN2015	12:30	<800		
	Week 2	05FEB2015	10:55	3850		
	Week 4	17FEB2015	13:10	6170		
	Week 8	17MAR2015	16:10	3320		
	Week 12	16APR2015	11:20	1990		
	Week 16	14MAY2015	10:55	912		
310-0001/61/M/A2	Screening	12JUN2012	14:25	<800		
	Week 4	10JUL2012	13:10	5840		
	Week 8	07AUG2012	13:35	4070		
310-0002/55/M/A2	Screening	28JUN2012	10:25	<800		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
310-0002/55/M/A2	Week 4	31JUL2012	13:10	3450		
310-0003/61/M/A2	Screening	23JAN2013	10:00	<800		
	Week 4	27FEB2013	08:50	7190		
	Week 8	27MAR2013	09:30	5000		
	Week 12	24APR2013	09:15	<800		
310-0008/49/M/A2	Screening	11JUN2013	09:30	<800		
	Week 2	26JUN2013	09:00	5200		
310-0012/73/M/A2	Screening	01NOV2013	08:40	<800		
	Week 2	14NOV2013	09:00	5000		
	Week 4	26NOV2013	14:29	6320		
	Week 8	26DEC2013	09:08	5680		
	Week 12	23JAN2014	09:05	3670		
	Week 16	18FEB2014	13:30	<800		
	Week 20	18MAR2014	13:30	<800		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
310-0013/54/M/A2	Screening	22AUG2014	07:59	<800		
	Week 2	10SEP2014	08:13	2630		
	Week 4	24SEP2014	08:10	1580		
	Week 8	22OCT2014	07:49	<800		
311-0002/60/M/A2	Screening	08AUG2013	09:10	<800		
	Week 2	21AUG2013	09:30	4530		
	Week 4	04SEP2013	11:40	<800		
	Week 8	02OCT2013	10:10	<800		
311-0007/55/M/A2	Screening	11NOV2013	14:00	<800		
	Week 2	25NOV2013	09:30	5160		
	Week 4	09DEC2013	10:30	7500		
	Week 8	08JAN2014	14:15	1150		
311-0008/71/M/A2	Screening	14MAY2014	15:00	<800		
	Week 2	28MAY2014	14:07	1780		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
311-0008/71/M/A2	Week 4	11JUN2014	11:27	1530		
	Week 8	08JUL2014	08:45	<800		
401-0003/36/M/A7	Screening	24JUN2013	10:20	<800		
	Week 2	02JUL2013	13:07	4140		
	Week 4	17JUL2013	09:46	1590		
	Week 8	13AUG2013	10:21	1630		
401-0005/58/M/A7	Screening	10OCT2013	08:14	<800		
	Week 2	22OCT2013	09:04	2590		
	Week 4	05NOV2013	08:05	3250		
	Week 8	06DEC2013	12:24	<800		
402-0003/75/M/A7	Screening	30APR2013	14:00	4340		
	Week 2	07MAY2013	12:00	7590		
	Week 4	21MAY2013	12:30	<800		
	Week 8	19JUN2013	11:52	5800		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
402-0003/75/M/A7	Week 12	16JUL2013	12:00	5190		
	Week 16	13AUG2013	15:00	4670		
	Week 20	10SEP2013	12:00	6280		
	Week 24	08OCT2013	12:30	4850		
402-0006/71/M/A7	Screening	25APR2013	10:20	<800		
	Week 2	09MAY2013	10:54	3660		
	Week 4	28MAY2013	11:30	5640		
	Week 8	25JUN2013	11:06	4070		
	Week 12	22JUL2013	11:26	<800		
402-0008/43/M/A7	Screening	08MAY2013	14:30	<800		
	Week 2	28MAY2013	12:00	3670		
402-0009/70/M/A7	Screening	09MAY2013	13:20	<800		
	Week 2	23MAY2013	08:30	4260		
	Week 4	07JUN2013	08:42	3990		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
402-0009/70/M/A7	Week 8	04JUL2013	08:00	3860		
402-0011/64/M/A7	Screening	14MAY2013	10:40	<800		
	Week 2	31MAY2013	10:00	4270		
	Week 4	13JUN2013	09:20	5700		
	Week 8	Unknown	Unknown	2760		
402-0017/50/M/A7	Screening	11JUN2013	11:20	<800		
	Week 2	24JUN2013	12:00	5040		
	Week 4	08JUL2013	12:30	7580		
402-0018/48/M/A7	Screening	12JUN2013	11:20	<800		
	Week 2	01JUL2013	14:00	4170		
	Week 4	15JUL2013	12:00	8480		
	Week 8	12AUG2013	12:00	<800		
	Week 12	09SEP2013	12:30	<800		
402-0019/54/M/A7	Screening	01JUL2013	14:00	<800		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
402-0019/54/M/A7	Week 2	08JUL2013	12:00	6380		
	Week 4	22JUL2013	12:00	801		
	Week 8	19AUG2013	14:00	<800		
	Week 12	16SEP2013	13:00	830		
402-0021/64/M/A7	Screening	13AUG2013	13:30	<800		
	Week 2	20AUG2013	12:00	7150		
	Week 4	03SEP2013	12:30	4650		
	Week 8	01OCT2013	12:30	<800		
	Week 12	29OCT2013	11:50	<800		
	Week 16	26NOV2013	12:20	<800		
	Week 20	24DEC2013	11:50	<800		
	Week 24	21JAN2014	11:50	<800		
	Week 28	18FEB2014	12:00	<800		
	Week 32	18MAR2014	11:49	<800		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
402-0021/64/M/A7	Week 36	15APR2014	12:00	<800		
	Week 40	13MAY2014	11:30	<800		
	Week 44	10JUN2014	12:00	<800		
	Week 48	08JUL2014	12:30	<800		
	Week 52	05AUG2014	11:30	<800		
	Week 56	02SEP2014	11:30	<800		
402-0024/57/M/A7	Screening	23AUG2013	10:10	<800		
	Week 2	03SEP2013	12:00	5080		
	Week 4	17SEP2013	12:30	7550		
	Week 8	15OCT2013	11:40	<800		
	Week 12	12NOV2013	11:50	<800		
402-0025/58/M/A7	Screening	25SEP2013	13:30	<800		
	Week 2	04OCT2013	09:40	5820		
	Week 4	17OCT2013	09:00	6760		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
402-0025/58/M/A7	Week 8	14NOV2013	09:10	899		
	Week 12	12DEC2013	09:38	837		
402-0027/52/M/A7	Screening	25SEP2013	15:10	911		
	Week 2	10OCT2013	08:40	4690		
	Week 4	23OCT2013	12:30	4850		
	Week 8	Unknown	Unknown	909		
402-0028/60/M/A7	Screening	26SEP2013	15:10	859		
	Week 2	10OCT2013	11:00	3080		
	Week 4	22OCT2013	12:30	5520		
	Week 8	26NOV2013	11:30	827		
402-0031/65/M/A7	Screening	05NOV2013	14:30	<800		
	Week 2	21NOV2013	08:00	4160		
	Week 4	06DEC2013	08:00	<800		
	Week 8	02JAN2014	08:00	<800		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
402-0031/65/M/A7	Week 12	29JAN2014	08:00	<800		
402-0033/63/F/A7	Screening	29NOV2013	16:00	<800		
	Week 2	16DEC2013	12:00	2860		
	Week 4	30DEC2013	12:10	2770		
	Week 8	27JAN2014	13:00	<800		
402-0035/44/M/A7	Screening	24DEC2013	12:00	<800		
	Week 2	31DEC2013	12:00	2910		
	Week 4	14JAN2014	12:00	<800		
403-0001/55/M/A7	Screening	20MAY2013	15:41	<800		
	Week 2	29MAY2013	08:45	4210		
	Week 4	12JUN2013	08:38	1510		
403-0002/52/M/A7	Screening	11JUN2013	15:23	<800		
	Week 2	19JUN2013	09:03	2930		
	Week 4	03JUL2013	09:30	<800		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
403-0002/52/M/A7	Week 8	31JUL2013	08:14	<800		
403-0005/50/F/A7	Screening	15JUL2013	15:13	<800		
	Week 2	22JUL2013	10:17	3070		
403-0006/66/M/A7	Screening	25JUL2013	09:45	<800		
	Week 2	07AUG2013	09:36	3820		
	Week 4	22AUG2013	08:53	2760		
	Week 8	16SEP2013	10:36	<800		
	Week 12	17OCT2013	08:35	<800		
403-0007/64/M/	Screening	16AUG2013	11:01	814		
	Week 2	27AUG2013	12:32	3250		
	Week 4	11SEP2013	13:56	4230		
	Week 8	08OCT2013	11:10	1590		
	Week 12	07NOV2013	11:58	2460		
404-0001/71/M/A7	Screening	08JUL2013	08:30	<800		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
404-0001/71/M/A7	Week 2	29JUL2013	09:30	4200		
	Week 4	12AUG2013	09:30	4350		
404-0002/56/F/A7	Screening	22AUG2013	14:30	<800		
	Week 2	29AUG2013	13:40	1770		
	Week 4	12SEP2013	09:20	<800		
405-0002/46/M/A7	Screening	10APR2013	17:30	<800		
	Week 2	24APR2013	14:30	2230		
405-0004/38/M/A7	Screening	19APR2013	11:03	<800		
	Week 2	29APR2013	10:07	5230		
	Week 4	15MAY2013	12:23	8800		
	Week 8	10JUN2013	09:00	5610		
	Week 12	10JUL2013	Unknown	1880		
405-0006/62/M/A7	Screening	23APR2013	10:30	<800		
	Week 2	08MAY2013	Unknown	2960		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
405-0006/62/M/A7	Week 4	22MAY2013	10:30	4750		
405-0007/53/M/A7	Screening	23APR2013	16:35	<800		
	Week 2	14MAY2013	09:40	4240		
	Week 4	28MAY2013	10:40	<800		
	Week 8	25JUN2013	10:25	<800		
	Week 12	23JUL2013	11:25	<800		
	Week 16	20AUG2013	11:05	<800		
	Week 20	Unknown	Unknown	<800		
405-0009/50/M/A7	Screening	07MAY2013	11:30	<800		
	Week 2	21MAY2013	10:06	3750		
	Week 4	05JUN2013	12:45	3290		
	Week 8	03JUL2013	13:10	<800		
405-0010/39/M/A7	Screening	23MAY2013	13:10	<800		
	Week 2	31MAY2013	10:35	3000		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
405-0010/39/M/A7	Week 4	11JUN2013	10:10	4580		
	Week 8	08JUL2013	10:10	3510		
	Week 12	06AUG2013	10:17	1080		
405-0011/63/M/A7	Screening	08MAY2013	19:12	<800		
	Week 2	20MAY2013	09:40	4680		
	Week 4	03JUN2013	10:00	6240		
	Week 8	01JUL2013	09:32	1380		
	Week 12	29JUL2013	08:52	<800		
	Week 16	26AUG2013	08:55	<800		
	Week 20	23SEP2013	08:45	<800		
	Week 24	21OCT2013	08:45	<800		
405-0013/45/M/A7	Screening	13MAY2013	12:05	<800		
	Week 2	20MAY2013	09:53	3360		
	Week 4	10JUN2013	09:50	1960		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
405-0013/45/M/A7	Week 8	08JUL2013	09:15	<800		
	Week 12	05AUG2013	09:07	<800		
	Week 16	02SEP2013	10:00	<800		
405-0014/35/M/A7	Screening	23MAY2013	16:50	<800		
	Week 2	05JUN2013	12:40	3210		
	Week 4	19JUN2013	13:00	852		
405-0016/41/M/A7	Screening	27MAY2013	09:30	<800		
	Week 2	03JUN2013	09:20	2890		
	Week 4	17JUN2013	09:15	<800		
405-0018/70/F/A7	Screening	07JUN2013	15:30	<800		
	Week 2	21JUN2013	09:40	3030		
405-0020/69/M/A7	Screening	19JUN2013	15:00	<800		
	Week 2	26JUN2013	10:40	3290		
	Week 4	10JUL2013	11:05	3860		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
405-0020/69/M/A7	Week 8	07AUG2013	10:40	5020		
	Week 12	04SEP2013	09:25	3380		
	Week 16	30SEP2013	09:45	3010		
	Week 20	30OCT2013	10:50	1290		
	Week 24	27NOV2013	11:20	2470		
	Week 28	23DEC2013	09:15	5330		
	Week 32	22JAN2014	10:25	3100		
	Week 36	19FEB2014	09:55	3970		
	Week 40	19MAR2014	11:00	4670		
	Week 44	14APR2014	10:30	3340		
	Week 48	14MAY2014	09:55	4080		
405-0021/47/M/A7	Screening	17JUN2013	13:20	<800		
	Week 2	26JUN2013	12:25	2190		
	Week 4	10JUL2013	11:50	<800		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
405-0021/47/M/A7	Week 8	07AUG2013	11:40	1490		
	Week 12	04SEP2013	11:40	1140		
	Week 16	02OCT2013	11:55	<800		
	Week 20	30OCT2013	11:05	<800		
	Week 24	27NOV2013	12:00	<800		
	Week 28	23DEC2013	09:07	<800		
	Week 32	22JAN2014	10:25	<800		
	Week 36	17FEB2014	09:40	<800		
	Week 40	17MAR2014	09:25	<800		
	Week 44	18APR2014	10:30	<800		
	Week 48	14MAY2014	11:50	<800		
	Week 52	09JUN2014	09:35	<800		
	Week 56	14JUL2014	09:00	<800		
405-0022/65/M/A7	Screening	04JUL2013	12:30	<800	855.5	

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
405-0022/65/M/A7	Screening	04JUL2013	12:30	911		
	Week 2	10JUL2013	11:10	2920		
	Week 4	22JUL2013	10:48	1510		
	Week 8	21AUG2013	10:53	<800		
	Week 12	16SEP2013	10:00	<800		
	Week 16	14OCT2013	10:00	<800		
	Week 20	13NOV2013	10:20	<800		
	Week 24	11DEC2013	10:55	<800		
405-0023/46/M/A7	Screening	17JUN2013	08:35	<800		
	Week 2	24JUN2013	09:35	2850		
	Week 4	08JUL2013	09:40	2310		
	Week 8	05AUG2013	09:25	<800		
	Week 12	02SEP2013	09:53	<800		
405-0025/47/M/A7	Screening	24JUN2013	10:30	<800		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
405-0025/47/M/A7	Week 2	03JUL2013	13:30	4640		
	Week 4	17JUL2013	11:45	<800		
405-0028/67/M/A7	Screening	17JUL2013	11:07	<800		
	Week 2	29JUL2013	08:56	2910		
	Week 4	14AUG2013	10:50	3620		
	Week 8	11SEP2013	10:49	2870		
	Week 12	07OCT2013	08:50	<800		
405-0030/35/M/A7	Screening	17JUL2013	16:38	<800		
	Week 2	05AUG2013	08:45	4410		
	Week 4	19AUG2013	08:45	5700		
	Week 8	16SEP2013	09:15	4050		
405-0032/69/M/A7	Screening	19JUL2013	14:25	<800		
	Week 2	29JUL2013	08:50	2350		
	Week 4	12AUG2013	08:35	3720		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
405-0032/69/M/A7	Week 8	09SEP2013	10:30	3140		
	Week 12	08OCT2013	08:43	<800		
	Week 16	04NOV2013	08:40	<800		
	Week 20	02DEC2013	08:40	<800		
	Week 24	30DEC2013	08:40	<800		
	Week 28	27JAN2014	08:32	<800		
	Week 32	24FEB2014	08:35	<800		
	Week 36	24MAR2014	08:30	<800		
	Week 40	21APR2014	08:50	<800		
	Week 44	19MAY2014	08:40	<800		
	Week 48	16JUN2014	08:40	<800		
	Week 52	14JUL2014	08:45	<800		
	Week 56	12AUG2014	08:40	<800		
	Week 60	05SEP2014	08:50	<800		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
405-0033/43/M/A7	Screening	29JUL2013	11:20	<800		
	Week 2	14AUG2013	11:25	4640		
	Week 4	28AUG2013	11:40	4860		
	Week 8	25SEP2013	12:00	2440		
	Week 12	23OCT2013	11:45	1860		
405-0034/61/M/A7	Screening	29JUL2013	09:58	<800		
	Week 2	14AUG2013	09:42	4140		
	Week 4	28AUG2013	10:00	1670		
	Week 8	25SEP2013	09:55	<800		
	Week 12	23OCT2013	10:00	<800		
405-0035/66/M/A7	Screening	04MAY2010	Unknown	<800		
	Week 2	26AUG2013	08:50	2740		
	Week 4	11SEP2013	11:40	5280		
	Week 8	11OCT2013	09:03	<800		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
405-0039/73/M/A7	Screening	13AUG2012	Unknown	<800		
	Week 2	23SEP2013	08:35	2020		
	Week 4	07OCT2013	08:43	1020		
	Week 8	04NOV2013	08:38	<800		
	Week 12	29NOV2013	08:30	<800		
405-0040/65/M/A7	Screening	09SEP2013	12:12	<800		
	Week 2	30SEP2013	09:40	4920		
	Week 4	14OCT2013	09:55	2720		
	Week 8	11NOV2013	09:05	<800		
	Week 12	09DEC2013	08:40	<800		
405-0042/53/M/A7	Screening	24SEP2013	Unknown	<800		
	Week 2	14OCT2013	09:45	3320		
	Week 4	30OCT2013	10:55	837		
	Week 8	27NOV2013	11:10	<800		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
405-0043/49/M/A7	Screening	16SEP2013	11:53	<800		
	Week 2	02OCT2013	14:40	5950		
	Week 4	17OCT2013	12:15	8610		
	Week 8	14NOV2013	12:05	1270		
405-0044/56/M/A7	Screening	25SEP2013	13:35	<800		
	Week 2	02OCT2013	12:48	5580		
	Week 4	18OCT2013	11:40	5190		
	Week 8	13NOV2013	11:40	<800		
501-0001/59/M/A1	Screening	13NOV2013	07:20	<800		
	Week 2	20NOV2013	06:30	4740		
	Week 4	04DEC2013	07:00	6570		
	Week 8	02JAN2014	06:00	2970		
501-0002/36/F/A1	Screening	29NOV2013	07:00	<800		
	Week 2	09DEC2013	08:50	4130		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
501-0002/36/F/A1	Week 4	23DEC2013	08:30	3720		
	Week 8	20JAN2014	08:30	<800		
	Week 12	18FEB2014	07:00	<800		
501-0005/80/M/A1	Screening	17JAN2014	07:00	<800		
	Week 2	29JAN2014	08:00	4430		
	Week 4	13FEB2014	09:10	7200		
	Week 8	14MAR2014	08:20	9340		
	Week 12	11APR2014	08:30	8770		
	Week 16	10MAY2014	09:50	7000		
	Week 20	06JUN2014	07:58	6920		
	Week 24	03JUL2014	08:30	6700		
	Week 28	01AUG2014	08:15	6330		
	Week 32	29AUG2014	07:10	3860		
	Week 36	30SEP2014	08:30	5050		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
501-0005/80/M/A1	Week 40	23OCT2014	08:30	5680		
	Week 44	20NOV2014	08:38	7270		
	Week 48	18DEC2014	08:45	8960		
	Week 52	15JAN2015	08:37	6880		
	Week 56	10FEB2015	08:46	4720		
	Week 60	12MAR2015	08:45	4920		
	Week 64	10APR2015	08:20	4660		
	Week 68	07MAY2015	10:55	3860		
	Week 72	04JUN2015	07:45	4160		
501-0006/60/M/A1	Screening	12FEB2014	09:00	<800		
	Week 2	20FEB2014	08:30	5460		
	Week 4	06MAR2014	08:30	5750		
	Week 8	03APR2014	07:30	3900		
	Week 12	28APR2014	08:00	<800		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
501-0007/43/M/A1	Screening	03MAR2014	11:30	<800		
	Week 2	10MAR2014	09:55	4030		
	Week 4	24MAR2014	10:15	6970		
	Week 8	21APR2014	07:20	7340		
	Week 12	19MAY2014	09:50	6230		
501-0008/76/F/A1	Screening	15APR2014	07:45	<800		
	Week 2	23APR2014	08:30	4730		
	Week 4	09MAY2014	09:15	5630		
	Week 8	04JUN2014	07:30	6290		
	Week 12	01JUL2014	09:05	4540		
501-0009/62/M/A1	Screening	17JUL2014	06:00	<800		
	Week 2	25JUL2014	08:00	4430		
	Week 4	08AUG2014	08:00	6490		
	Week 8	04JUN2014	07:30	7410		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
501-0009/62/M/A1	Week 12	30SEP2014	06:00	8140		
501-0010/65/M/A1	Screening	04SEP2014	07:40	<800		
	Week 2	16SEP2014	07:00	5960		
	Week 4	28SEP2014	07:30	8340		
	Week 8	29OCT2014	09:15	7760		
	Week 12	27NOV2014	08:00	1120		
502-0002/65/M/A1	Screening	09JAN2014	07:40	<800		
503-0001/32/M/A1	Screening	09DEC2013	15:30	<800		
	Week 2	16DEC2013	09:23	2650		
	Week 4	31DEC2013	12:10	3660		
503-0004/49/M/A1	Screening	11MAR2014	10:30	<800		
	Week 2	18MAR2014	09:30	4050		
503-0006/54/M/A1	Screening	06AUG2014	11:20	<800		
	Week 2	13AUG2014	08:46	2800		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
503-0006/54/M/A1	Week 4	27AUG2014	08:30	821		
	Week 8	25SEP2014	08:40	<800		
	Week 12	22OCT2014	08:54	<800		
	Week 16	19NOV2014	Unknown	<800		
	Week 20	17DEC2014	Unknown	<800		
	Week 24	15JAN2015	15:20	<800		
	Week 28	09FEB2015	Unknown	BQL		
503-0007/57/M/A1	Screening	28OCT2014	16:00	<800		
	Week 2	04NOV2014	09:55	6640		
	Week 4	18NOV2014	Unknown	9190		
	Week 8	16DEC2014	09:36	8200		
	Week 12	13JAN2015	09:30	7470		
503-0008/50/M/A1	Screening	30OCT2014	16:50	<800		
	Week 2	05NOV2014	09:25	5800		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
503-0008/50/M/A1	Week 4	19NOV2014	09:45	5970		
503-0009/57/M/A1	Screening	19NOV2014	15:42	<800		
	Week 2	26NOV2014	15:21	6670		
504-0001/47/M/A1	Screening	17FEB2014	10:36	<800		
	Week 2	25FEB2014	10:15	3900		
	Week 4	11MAR2014	10:40	4630		
	Week 8	08APR2014	09:35	<800		
	Week 12	06MAY2014	09:25	<800		
	Week 16	03JUN2014	09:15	<800		
504-0007/32/M/A1	Screening	11OCT2014	14:26	<800		
	Week 2	17OCT2014	08:50	4670		
505-0001/70/M/A1	Screening	13AUG2014	08:00	<800		
	Week 2	02SEP2014	07:50	4770		
	Week 4	16SEP2014	08:15	4940		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
506-0002/54/M/A1	Screening	12MAY2014	06:30	<800		
	Week 2	19MAY2014	08:30	4290		
	Week 4	04JUN2014	08:45	2090		
	Week 8	02JUL2014	08:55	<800		
	Week 12	30JUL2014	08:40	<800		
	Week 16	27AUG2014	08:40	<800		
	Week 20	24SEP2014	08:55	<800		
	Week 24	22OCT2014	08:45	862		
	Week 28	19NOV2014	08:25	<800		
	Week 32	17DEC2014	08:50	<800		
	Week 36	14JAN2015	09:10	<800		
	Week 40	11FEB2015	08:40	<800		
	Week 44	11MAR2015	08:20	BQL		
	Week 48	08APR2015	09:00	BQL		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
506-0003/66/M/A1	Screening	10SEP2014	08:30	<800		
	Week 2	17SEP2014	09:20	5860		
	Week 4	30SEP2014	09:20	5840		
506-0004/49/M/A1	Screening	27OCT2014	08:10	<800		
	Week 2	05NOV2014	08:50	2080		
	Week 4	19NOV2014	08:35	1910		
	Week 8	17DEC2014	08:55	<800		
508-0001/36/M/A1	Screening	31DEC2013	09:00	<800		Week 2 in sample list
	Week 2	15JAN2014	09:50	4460		Screening in sample list
	Week 4	27JAN2014	09:40	8580		
508-0003/49/F/A1	Screening	13MAR2014	09:50	<800		
	Week 2	25MAR2014	09:50	2640		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
	Week 4	08APR2014	11:08	952		
509-0001/45/M/A1	Screening	28APR2014	11:00	<800		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
509-0001/45/M/A1	Week 2	07MAY2014	10:20	3940		
	Week 4	21MAY2014	10:05	4710		
	Week 8	17JUN2014	10:10	<800		
	Week 12	15JUL2014	10:45	<800		
509-0002/51/M/A1	Screening	22MAY2014	10:10	<800		
	Week 2	04JUN2014	10:20	5150		
510-0002/50/M/A1	Screening	22MAY2014	09:10	<800		
	Week 2	28MAY2014	08:30	4810		
	Week 4	11JUN2014	08:30	<800		
	Week 8	09JUL2014	08:20	822		
510-0004/72/M/A1	Screening	30JUL2014	08:30	<800		
	Week 2	06AUG2014	08:30	2840		
	Week 4	20AUG2014	07:30	6080		
	Week 8	17SEP2014	14:10	1680		

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[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
510-0004/72/M/A1	Week 12	15OCT2014	07:30	<800		
511-0001/35/M/A1	Screening	18JAN2014	08:00	<800		
	Week 2	28JAN2014	07:35	5520		
	Week 4	11FEB2014	08:15	8760		
511-0002/49/M/A1	Screening	07MAR2014	06:30	<800		
	Week 2	18MAR2014	08:10	5680		
	Week 4	01APR2014	09:20	9870		
	Week 8	29APR2014	09:00	8240		
	Week 12	27MAY2014	09:00	>10000		
	Week 16	24JUN2014	08:55	7620		
	Week 20	22JUL2014	08:49	6500		
	Week 24	19AUG2014	08:20	4100		
512-0001/59/M/A1	Screening	25FEB2014	10:21	<800		
	Week 2	11MAR2014	09:15	4010		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
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[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
512-0001/59/M/A1	Week 4	25MAR2014	08:45	5410		
	Week 8	22APR2014	08:32	5800		
	Week 12	20MAY2014	09:18	<800		
	Week 16	18JUN2014	09:26	7130		
513-0001/28/M/A1	Screening	10APR2014	08:02	<800		
	Week 2	18APR2014	09:14	4030		
	Week 4	04MAY2014	09:44	3700		
513-0004/46/M/A1	Screening	18JUN2014	10:18	<800		
	Week 2	25JUN2014	09:02	3750		
	Week 4	08JUL2014	08:58	1540		
513-0005/61/M/A1	Screening	30OCT2014	11:11	<800		
	Week 2	06NOV2014	09:26	3260		
	Week 4	20NOV2014	09:10	<800		
	Week 8	18DEC2014	09:25	<800		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
513-0005/61/M/A1	Week 12	14JAN2015	09:40	<800		
515-0001/64/M/A1	Screening	14FEB2014	09:30	<800		
	Week 2	26FEB2014	15:15	3110		
	Week 4	12MAR2014	15:10	4300		
	Week 8	09APR2014	15:10	1100		
	Week 12	07MAY2014	15:10	1120		
515-0003/69/M/A1	Screening	13MAY2014	10:20	<800		
	Week 2	20MAY2014	09:36	4590		
	Week 4	05JUN2014	10:00	8480		
	Week 9	11JUL2014	Unknown	<800		
	Week 12	29JUL2014	09:30	<800		
515-0004/52/M/A1	Screening	27MAY2014	14:20	<800		
	Week 2	05JUN2014	09:15	2300		
	Week 4	16JUN2014	09:30	7400		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
515-0004/52/M/A1	Week 8	14JUL2014	09:50	3020		
	Week 12	11AUG2014	10:00	<800		
	Week 16	09SEP2014	10:00	<800		
515-0006/47/M/A1	Screening	05AUG2014	09:00	873		
	Week 2	11AUG2014	09:00	4320		
	Week 4	26AUG2014	09:03	5910		
	Week 8	22SEP2014	09:40	5130		
	Week 12	20OCT2014	10:10	<800		
515-0007/39/M/A1	Screening	17SEP2014	09:30	<800		
	Week 2	22SEP2014	09:48	5170		
	Week 4	08OCT2014	10:10	<800		
515-0008/60/M/A1	Screening	27NOV2014	08:53	<800		
	Week 2	03DEC2014	09:40	4930		
	Week 4	17DEC2014	10:30	7450		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
515-0008/60/M/A1	Week 8	14JAN2015	09:40	5120		
	Week 12	09FEB2015	09:05	1770		
516-0001/45/M/A1	Screening	07AUG2014	09:20	<800		
	Week 2	15AUG2014	09:10	5160		
	Week 4	29AUG2014	08:48	7070		
	Week 8	26SEP2014	08:40	5400		
	Week 12	24OCT2014	08:10	4150		
	Week 16	21NOV2014	09:15	6250		
	Week 20	19DEC2014	08:50	4940		
	Week 24	16JAN2015	09:00	6150		
517-0001/42/M/A1	Screening	18DEC2013	09:41	<800		
	Week 2	30DEC2013	08:45	2930		
	Week 4	13JAN2014	09:05	1940		
517-0002/43/M/A1	Screening	24MAR2014	08:55	<800		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
517-0002/43/M/A1	Week 2	02APR2014	09:12	3960		
	Week 4	15APR2014	09:25	3480		
	Week 8	13MAY2014	08:43	3440		
	Week 12	10JUN2014	09:10	<800		
	Week 16	08JUL2014	09:00	<800		
	Week 20	05AUG2014	09:00	<800		
	Week 24	02SEP2014	08:54	<800		
517-0005/46/M/	Screening	22MAY2014	11:33	<800		
517-0006/67/F/A1	Screening	12AUG2014	08:40	<800		
	Week 2	27AUG2014	09:15	3820		
	Week 4	10SEP2014	09:08	7520		
	Week 8	08OCT2014	09:15	<800		
	Week 12	05NOV2014	09:30	<800		
	Week 16	03DEC2014	09:15	BQL		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
517-0006/67/F/A1	Week 20	30DEC2014	09:17	BQL		
	Week 24	28JAN2015	09:30	BQL		
	Week 28	25FEB2015	09:35	BQL		
	Week 32	25MAR2015	09:05	BQL		
	Week 36	22APR2015	09:10	BQL		
517-0007/66/M/A1	Screening	12AUG2014	09:20	<800		
	Week 2	27AUG2014	08:55	3030		
	Week 4	12SEP2014	09:10	3160		
517-0008/59/M/A1	Screening	15AUG2014	08:40	<800		
	Week 2	29AUG2014	11:30	4610		
	Week 4	12SEP2014	09:20	6200		
517-0009/23/M/A1	Screening	11SEP2014	10:05	<800		
	Week 2	24SEP2014	09:31	3690		
	Week 4	08OCT2014	10:15	<800		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
517-0009/23/M/A1	Week 8	05NOV2014	09:35	<800		
	Week 12	03DEC2014	11:10	BQL		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
101-0002/70/M/OTH	Screening	08JUN2011	Unknown	<800		
	Week 4	19AUG2011	13:43	<800		
	Week 8	20SEP2011	08:08	<800		
	Week 12	18OCT2011	07:47	<800		
101-0004/78/F/A2	Screening	02AUG2011	08:40	<800		
	Week 4	26AUG2011	10:55	<800		
	Week 8	23SEP2011	11:52	<800		
	Week 12	21OCT2011	12:51	<800		
	Week 16	18NOV2011	14:51	<800		
	Week 20	15DEC2011	16:05	<800		
	Week 28	10FEB2012	11:45	<800		
	Week 32	09MAR2012	10:23	<800		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
101-0004/78/F/A2	Week 36	10APR2012	15:25	<800		
	Week 40	11MAY2012	11:52	<800		Uns Continuation
	Week 44	08JUN2012	12:31	<800		Uns Continuation
	Week 48	06JUL2012	11:14	<800		Uns Continuation
	Week 52	03AUG2012	11:01	<800		Uns Continuation
	Week 56	31AUG2012	09:55	830		
	Week 60	28SEP2012	14:30	<800		Uns Continuation
101-0010/43/M/BL	Screening	13SEP2011	07:43	<800		
101-0014/61/M/W2	Screening	03MAY2012	Unknown	<800		
	Week 4	27JAN2012	10:07	<800		
	Week 8	24FEB2012	11:16	<800		
	Week 12	23MAR2012	07:52	<800		
101-0015/65/M/A4	Screening	06JAN2012	16:14	<800		
	Week 4	31JAN2012	13:01	<800		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
101-0015/65/M/A4	Week 8	28FEB2012	14:56	<800		
	Week 12	27MAR2012	15:20	<800		
101-0017/60/M/W2	Screening	06APR2011	Unknown	<800		
	Week 4	13MAR2012	10:09	<800		
	Week 8	10APR2012	12:29	<800		
	Week 12	08MAY2012	12:50	<800		
101-0020/86/M/W2	Screening	13MAR2012	Unknown	<800	800	Collected on 13Mar2012
	Screening	13MAR2012	Unknown	<800		Collected on 13Mar2012
	Week 4	03APR2012	08:15	<800		
	Week 8	01MAY2012	07:47	<800		
	Week 12	05JUN2012	08:58	<800		
	Week 16	03JUL2012	07:15	<800		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
	Week 20	31JUL2012	07:27	<800		
	Week 24	28AUG2012	07:35	<800		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
101-0027/72/M/W2	Screening	22MAY2012	11:02	<800		
	Week 4	15JUN2012	09:08	<800		
101-0031/69/F/W2	Screening	06DEC2010	Unknown	<800		
	Week 4	07AUG2012	10:23	<800		
	Week 8	04SEP2012	12:51	<800		
	Week 12	Unknown	Unknown	<800		
101-0034/44/M/OTH	Screening	22NOV2013	Unknown	<800		
	Week 4	02OCT2012	17:34	<800		
101-0035/37/M/A6	Screening	26OCT2012	Unknown	<800		
101-0043/69/M/W1	Screening	22OCT2013	15:53	<800		
	Week 2	29OCT2013	11:18	<800		
	Week 4	19NOV2013	08:54	<800		
	Week 8	10DEC2013	08:56	<800		
	Week 12	14JAN2014	08:01	<800		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
101-0051/70/F/W2	Screening	23JAN2014	Unknown	814		
	Week 2	03FEB2014	13:45	<800		
	Week 4	17FEB2014	13:31	<800		
102-0006/66/M/BL	Screening	05DEC2013	09:45	<800		
	Week 2	17DEC2013	10:06	<800		
	Week 4	02JAN2014	09:53	<800		
	Week 8	29JAN2014	09:22	<800		
	Week 12	26FEB2014	09:25	<800		
102-0007/61/M/W2	Screening	23DEC2013	09:25	<800		
	Week 2	09JAN2014	11:45	<800		
	Week 4	23JAN2014	10:24	<800		
	Unscheduled	27FEB2014	Unknown	<800		Week 9
	Week 12	20MAR2014	10:12	<800		
103-0002/74/M/W2	Screening	29OCT2009	Unknown	<800		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
103-0002/74/M/W2	Week 4	02JAN2013	10:48	<800		
	Week 8	30JAN2013	10:00	<800		
	Week 12	27FEB2013	10:15	<800		
	Week 16	27MAR2013	10:00	1460		
	Week 20	24APR2013	10:00	<800		
103-0006/57/M/W2	Screening	06NOV2014	10:30	<800		
	Week 2	25NOV2014	10:30	<800		
	Week 4	11DEC2014	08:30	<800		
	Week 8	06JAN2015	09:25	<800		
104-0002/80/M/W2	Screening	30APR2012	09:10	<800	800	

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
	Unscheduled	30APR2012	09:10	<800		Screening (collection date not found on visit report, date is between screening and week 1)
	Week 4	29MAY2012	10:25	<800		
	Week 8	25JUN2012	09:05	<800		
	Week 12	23JUL2012	08:55	<800		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
104-0002/80/M/W2	Week 16	20AUG2012	08:55	<800		
	Week 20	17SEP2012	09:55	<800		
	Week 24	15OCT2012	11:02	<800		
	Week 28	12NOV2012	09:50	<800		
	Week 32	10DEC2012	10:10	<800		
	Week 36	07JAN2013	09:33	<800		
104-0007/89/M/A1	Screening	30JUN2015	Unknown	<800		
	Week 2	12AUG2013	09:52	<800		
	Week 4	26AUG2013	08:42	<800		
	Week 8	23SEP2013	09:50	<800		
	Week 12	21OCT2013	09:40	<800		
	Week 16	18NOV2013	09:00	<800		
	Week 20	16DEC2013	09:45	<800		
	Week 22	02JAN2014	09:05	<800		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
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[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
104-0007/89/M/A1	Week 24	13JAN2014	09:05	<800		
	Week 28	10FEB2014	09:35	3650		
	Week 32	10MAR2014	09:05	<800		
	Week 34	27MAR2014	09:21	<800		
	Week 36	09APR2014	09:25	<800		
	Week 40	05MAY2014	09:24	<800		Uns Continuation
	Week 42	19MAY2014	09:33	<800		Uns Continuation
	Week 44	02JUN2014	09:30	857		Uns Continuation
	Week 48	02JUL2014	09:50	<800		Uns Continuation
	Week 50	14JUL2014	09:39	<800		Uns Continuation
	Week 52	28JUL2014	09:44	<800		Uns Continuation
	Week 54	13AUG2014	10:00	<800		Uns Continuation
	Week 56	25AUG2014	09:35	<800		Uns Continuation
	Week 58	08SEP2014	09:30	<800		Uns Continuation

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
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Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
104-0007/89/M/A1	Week 60	22SEP2014	09:15	<800		Uns Continuation
	Week 62	08OCT2014	09:54	<800		Uns Continuation
	Week 64	20OCT2014	10:05	<800		Uns Continuation
	Week 66	03NOV2014	09:35	<800		Uns Continuation
	Week 68	17NOV2014	09:40	<800		Uns Continuation
	Week 70	01DEC2014	09:20	<800		Uns Continuation
	Week 72	15DEC2014	09:49	<800		Uns Continuation
	Week 74	29DEC2014	09:33	<800		Uns Continuation
	Week 74	29DEC2014	09:33	<800		Uns Continuation
	Week 76	12JAN2015	10:43	<800		Uns Continuation
	Week 78	26JAN2015	09:48	<800		Uns Continuation
	Week 80	09FEB2015	09:54	<800		Uns Continuation
	Week 82	26FEB2015	08:43	<800		Uns Continuation
	Week 86	25MAR2015	10:18	<800		Uns Continuation

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Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
104-0007/89/M/A1	Week 88	06APR2015	09:52	<800		Uns Continuation
	Week 90	20APR2015	09:45	<800		Uns Continuation
	Week 92	04MAY2015	09:40	<800		Uns Continuation
	Week 94	20MAY2015	09:23	<800		Uns Continuation
105-0003/57/M/W2	Screening	31OCT2013	Unknown	<800		
	Week 2	12NOV2013	10:45	<800		
	Week 4	26NOV2013	11:05	<800		
	Week 8	27DEC2013	11:35	840		
	Week 12	24JAN2014	10:15	841		
	Week 16	21FEB2014	10:30	<800		
	Week 20	18MAR2014	10:20	<800		
	Week 24	15APR2014	10:20	<800		
	Week 28	16MAY2014	11:34	<800		
	Week 32	12JUN2014	10:40	<800		

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Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
105-0003/57/M/W2	Week 36	08JUL2014	12:00	<800		
	Week 40	08AUG2014	11:00	<800		Uns Continuation
	Week 44	05SEP2014	09:50	<800		Uns Continuation
	Week 48	30SEP2014	13:10	<800		Uns Continuation
105-0006/60/F/BL	Screening	17DEC2014	Unknown	<800		
	Week 2	06JAN2015	10:15	<800		
	Week 4	20JAN2015	10:45	<800		
	Week 8	19FEB2015	11:35	<800		
	Week 12	17MAR2015	08:30	<800		
	Week 16	15APR2015	10:30	<800		
108-0003/85/M/W2	Screening	14NOV2012	15:00	<800		
	Week 4	10DEC2012	09:35	<800		
109-0002/63/M/W2	Screening	20MAR2013	13:10	<800		
	Week 2	29MAR2013	12:52	<800		

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Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
109-0002/63/M/W2	Week 4	12APR2013	08:30	<800		
	Week 8	10MAY2013	09:00	<800		
	Week 12	07JUN2013	09:10	<800		
	Week 16	05JUN2013	10:28	<800		
	Week 20	02AUG2013	08:40	<800		
	Week 24	30AUG2013	08:35	<800		
109-0005/64/F/W2	Screening	24JUL2013	12:25	<800		
	Week 2	07AUG2013	15:00	<800		
	Week 4	21AUG2013	13:15	<800		
109-0012/21/F/W2	Screening	07MAY2012	Unknown	<800		
	Week 2	01OCT2014	13:54	<800		
	Week 4	14OCT2014	11:45	<800		
	Week 8	11NOV2014	12:25	<800		
109-0014/50/F/W2	Screening	12JAN2015	16:00	<800		

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Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
109-0014/50/F/W2	Week 2	04FEB2015	14:24	<800		
	Week 4	18FEB2015	15:25	<800		
111-0003/37/M/A1	Screening	02JAN2013	10:40	<800		
	Week 4	31JAN2013	13:20	<800		
	Week 8	28FEB2013	10:35	<800		
112-0010/56/F/W2	Screening	27NOV2013	11:15	<800	800	
	Screening	27NOV2013	11:15	<800		
	Week 2	13DEC2013	07:45	933		
	Week 4	27DEC2013	07:28	<800		
	Week 8	24JAN2014	10:55	809		
	Week 12	21FEB2014	11:10	<800		
113-0007/74/M/W2	Screening	17DEC2013	Unknown	<800		
	Week 2	05FEB2014	09:20	<800		
	Week 4	20FEB2014	09:20	<800		

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Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
113-0007/74/M/W2	Week 8	19MAR2014	08:58	<800		
	Week 12	18APR2014	08:30	<800		
	Week 16	16MAY2014	08:17	<800		
	Week 20	10JUN2014	12:35	<800		
113-0015/58/F/BL	Screening	20NOV2014	14:54	<800		
	Week 2	05DEC2014	08:20	<800		
114-0001/25/F/OTH	Screening	24JUL2012	15:20	<800		
	Week 4	21AUG2012	11:50	<800		
114-0004/54/F/A1	Screening	30JAN2013	11:35	<800		
	Week 4	27FEB2013	11:10	<800		
	Week 8	27MAR2013	09:35	<800		
115-0005/60/M/W2	Screening	08MAR2013	11:31	<800		
115-0006/62/M/W2	Screening	04APR2013	13:02	<800		
	Week 2	18APR2013	14:10	<800		

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Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
115-0006/62/M/W2	Week 4	02MAY2013	10:25	<800		
	Week 8	30MAY2013	13:10	<800		
	Week 12	27JUN2013	07:38	<800		
115-0007/57/M/W2	Screening	10APR2013	13:20	<800		
	Week 2	25APR2013	09:45	<800		
	Week 4	09MAY2013	08:20	<800		
115-0010/54/M/A4	Screening	27MAR2014	Unknown	<800		
	Week 2	21APR2014	10:50	<800		
	Week 4	05MAY2014	08:47	<800		
	Week 8	02JUN2014	10:38	<800		
121-0003/65/M/BL	Screening	03JUN2013	Unknown	<800		
	Week 2	09JUL2014	07:00	<800		
	Week 4	23JUL2014	08:00	801		
	Week 8	20AUG2014	08:35	<800		

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Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
201-0002/76/M/W2	Screening	11APR2008	Unknown	<800		
	Week 4	05APR2012	08:00	<800		
	Week 12	31MAY2012	08:00	<800		
	Week 16	28JUN2012	08:30	<800		
	Week 20	26JUL2012	08:30	<800		
	Week 24	23AUG2012	08:15	<800		
	Week 28	20SEP2012	08:30	<800		
	Week 32	18OCT2012	08:30	<800		
	Week 36	15NOV2012	08:00	<800		
	Week 40	12DEC2012	08:00	<800		Uns Continuation
	Week 44	10JAN2013	08:00	<800		Uns Continuation
	Week 48	07FEB2013	08:00	<800		Uns Continuation
201-0006/71/M/W2	Screening	05JUL2012	08:10	<800		
	Week 4	02AUG2012	08:30	<800		

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Pharmacokinetic Analysis Results
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Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
201-0006/71/M/W2	Week 8	30AUG2012	08:30	<800		
	Week 12	27SEP2012	08:30	<800		
	Week 16	25OCT2012	08:30	<800		
	Week 20	22NOV2012	08:05	<800		
	Week 24	18DEC2012	08:10	<800		
201-0007/71/M/W2	Screening	16JUL2012	08:00	<800		
	Week 8	12SEP2012	08:30	<800		
	Week 12	11OCT2012	08:00	<800		
	Week 16	08NOV2012	08:00	<800		
	Week 20	06DEC2012	07:50	<800		
	Week 24	03JAN2013	08:00	<800		
	Week 32	28FEB2013	08:00	<800		
	Week 36	28MAR2013	07:50	<800		
201-0009/64/M/W2	Screening	13JUN2013	08:30	<800		

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Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
201-0009/64/M/W2	Week 2	27JUN2013	08:20	<800		
	Week 4	11JUL2013	08:30	<800		
	Week 8	08AUG2013	07:50	<800		
	Week 12	05SEP2013	09:05	<800		
	Week 16	03OCT2013	08:00	<800		
	Week 20	31OCT2013	08:10	<800		
	Week 24	28NOV2013	07:45	<800		
	Week 36	20FEB2014	08:30	<800		
	Week 38	06MAR2014	08:30	834		Uns Continuation
	Week 40	20MAR2014	08:15	<800		Uns Continuation
	Week 42	03APR2014	08:15	<800		Uns Continuation
	Week 44	17APR2014	08:40	<800		Uns Continuation
	Week 46	30APR2014	08:15	<800		Uns Continuation
	Week 48	15MAY2014	08:00	<800		Uns Continuation

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(Safety Population)

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Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
201-0009/64/M/W2	Week 50	29MAY2014	08:10	838		Uns Continuation
	Week 52	12JUN2014	08:15	<800		Uns Continuation
	Week 54	26JUN2014	08:00	<800		Uns Continuation
	Week 56	11JUL2014	08:00	<800		Uns Continuation
	Week 58	24JUL2014	08:00	<800		Uns Continuation
	Week 60	07AUG2014	08:00	<800		Uns Continuation
	Week 64	04SEP2014	08:00	<800		Uns Continuation
	Week 68	01OCT2014	08:00	<800		Uns Continuation
	Week 72	30OCT2014	08:00	<800		Uns Continuation
	Week 76	27NOV2014	08:00	<800		Uns Continuation
	Week 84	21JAN2015	08:30	<800		Uns Continuation
	Week 88	19FEB2015	08:10	BQL		Uns Continuation
	Week 92	19MAR2015	07:50	BQL		Uns Continuation
	Week 96	16APR2015	07:50	BQL		Uns Continuation

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
201-0009/64/M/W2	Week 100	14MAY2015	07:50	BQL		Uns Continuation
201-0010/81/F/W2	Screening	20JUN2013	08:00	<800		
	Week 2	04JUL2013	08:00	<800		
	Week 4	17JUL2013	08:40	<800		
	Week 12	12SEP2013	07:50	<800		
201-0014/73/M/W2	Screening	11JUL2013	08:50	<800		
	Week 2	24JUL2013	08:25	<800		
	Week 4	08AUG2013	08:25	<800		
	Week 8	05SEP2013	08:50	<800		
	Week 12	03OCT2013	08:15	<800		
201-0015/49/M/W2	Screening	01AUG2013	09:05	<800		
	Week 4	29AUG2013	09:05	<800		
	Week 8	26SEP2013	08:35	<800		
	Week 12	24OCT2013	08:00	<800		

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[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
201-0015/49/M/W2	Week 16	21NOV2013	08:15	<800		
	Week 20	19DEC2013	08:20	<800		
	Week 24	16JAN2014	08:30	<800		
	Week 28	13FEB2014	08:30	841		
	Week 32	13MAR2014	08:00	<800		
201-0022/80/F/W2	Screening	09MAY2014	09:30	<800		
	Week 2	21MAY2014	08:00	<800		
	Week 4	05JUN2014	08:00	<800		
	Week 8	03JUL2014	08:30	<800		
	Week 12	31JUL2014	08:20	<800		
	Week 16	28AUG2014	08:30	<800		
	Week 20	25SEP2014	08:00	<800		
	Week 24	23OCT2014	08:00	<800		
203-0004/81/M/W2	Screening	22MAR2012	08:00	<800		

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Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
203-0004/81/M/W2	Week 4	19APR2012	08:00	<800		
	Week 8	22MAY2012	08:00	<800		
	Week 12	28JUN2012	08:00	<800		
	Week 16	26JUL2012	08:00	<800		
	Week 24	20SEP2012	08:30	<800		
	Week 28	18OCT2012	08:00	<800		
	Week 32	15NOV2012	08:00	<800		
	Week 36	13DEC2012	08:00	<800		
203-0006/76/M/W2	Screening	30MAR2012	08:00	<800		
	Week 4	04MAY2012	08:00	<800		
	Week 8	30MAY2012	08:30	<800		
203-0007/59/M/W2	Screening	28MAY2012	08:30	<800		
	Week 4	06JUL2012	08:00	<800		
	Week 8	01AUG2012	08:00	<800		

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[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
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Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
203-0009/73/M/W2	Screening	30AUG2012	08:00	<800		
	Week 4	08OCT2012	08:00	<800		
	Week 8	15NOV2012	08:00	<800		
	Week 12	20DEC2012	08:00	<800		
	Week 16	25JAN2013	08:00	<800		
	Week 20	27FEB2013	08:00	<800		
	Week 24	04APR2013	08:00	<800		
	Week 28	13MAY2013	08:00	<800		
	Week 32	27JUN2013	08:00	<800		
	Week 36	01AUG2013	08:00	<800		
	Week 38	22AUG2013	08:00	<800		Uns Continuation
	Week 40	12SEP2013	08:00	<800		Uns Continuation
	Week 42	27SEP2013	09:00	<800		Uns Continuation
	Week 44	14OCT2013	08:00	<800		Uns Continuation

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Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
203-0009/73/M/W2	Week 46	31OCT2013	09:00	<800		Uns Continuation
203-0010/74/M/W2	Screening	17SEP2012	08:00	<800		
	Week 4	18OCT2012	08:00	<800		
	Week 8	15NOV2012	08:00	<800		
	Week 12	13DEC2012	08:00	<800		
	Week 16	17JAN2013	08:00	<800		
	Week 20	15FEB2013	08:00	<800		
	Week 24	21MAR2013	08:00	<800		
	Week 28	17APR2013	08:00	<800		
	Week 32	17MAY2013	08:00	<800		
	Week 36	20JUN2013	08:00	<800		
	Week 40	25JUL2013	08:00	<800		Uns Continuation
	Week 46	12SEP2013	08:00	<800		Uns Continuation
	Week 48	26SEP2013	09:00	<800		Uns Continuation

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Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
203-0010/74/M/W2	Week 48	26SEP2013	09:00	<800		Uns Continuation
	Week 50	17OCT2013	09:00	<800		Uns Continuation
	Week 50	17OCT2013	09:00	<800		Uns Continuation
	Week 52	30OCT2013	09:00	<800		Uns Continuation
	Week 52	30OCT2013	09:00	<800		Uns Continuation
	Week 54	15NOV2013	08:00	<800		Uns Continuation
	Week 56	02DEC2013	09:00	<800		Uns Continuation
	Week 58	20DEC2013	08:00	<800		Uns Continuation
	Week 60	09JAN2014	08:00	<800		Uns Continuation
	Week 62	24JAN2014	09:00	<800		Uns Continuation
	Week 64	10FEB2014	09:00	<800		Uns Continuation
	Week 66	24FEB2014	08:00	<800		Uns Continuation
	Week 70	28MAR2014	09:00	859		Uns Continuation
	Week 72	17APR2014	08:30	<800		Uns Continuation

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[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
203-0010/74/M/W2	Week 74	02MAY2014	09:00	<800		Uns Continuation
	Week 76	19MAY2014	08:00	<800		Uns Continuation
	Week 78	05JUN2014	09:00	<800		Uns Continuation
	Week 80	19JUN2014	09:00	<800		Uns Continuation
	Week 82	04JUL2014	08:30	<800		Uns Continuation
	Week 84	17JUL2014	09:00	<800		Uns Continuation
	Week 86	31JUL2014	09:00	<800		Uns Continuation
	Week 90	04SEP2014	09:00	<800		Uns Continuation
	Week 92	22SEP2014	09:00	<800		Uns Continuation
	Week 96	24OCT2014	09:00	<800		Uns Continuation
203-0014/73/M/W2	Screening	10JAN2014	08:00	<800		
	Week 2	30JAN2014	08:00	<800		

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[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
	Week 4	13FEB2014	09:00	<800		
	End of Treatment	06MAR2014	09:00	<800		Week 8 (7 days after week 7 visit)

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[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
203-0016/57/M/W2	Screening	28JAN2014	09:00	840		
	Week 2	11FEB2014	09:00	<800		
	Week 4	27FEB2014	09:00	<800		
	Week 8	31MAR2014	08:30	<800		
	Week 12	02MAY2014	09:00	<800		
	Week 16	03JUN2014	09:00	<800		
	Week 20	03JUL2014	09:00	<800		
	Week 24	31JUL2014	09:00	<800		
203-0019/68/M/W2	Unscheduled	Unknown	Unknown	<800		Week 1
	Screening	12MAY2014	09:00	<800		
	Week 2	30MAY2014	09:00	<800		
	Week 4	13JUN2014	09:00	<800		
204-0003/64/M/W2	Screening	27JUN2013	13:50	<800		
	Week 4	22JUL2013	09:30	<800		

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[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
204-0003/64/M/W2	Week 8	26AUG2013	09:55	<800		
	Week 12	26SEP2013	08:20	<800		
204-0004/76/F/W2	Screening	04SEP2013	10:20	<800		
	Week 2	24SEP2013	09:15	<800		
	Week 4	11OCT2013	09:58	<800		
	Week 8	14NOV2013	08:30	<800		
	Week 12	12DEC2013	09:25	<800		
205-0002/71/M/W2	Screening	14FEB2012	09:00	<800		Retest in sample list from CLS
	Week 4	16MAR2012	09:00	<800		
	Unscheduled	30MAR2012	09:00	<800		Week 6
	Week 8	13APR2012	09:00	<800		
	Week 12	08MAY2012	09:00	<800		

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[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
205-0003/79/M/W2	Unscheduled	Unknown	Unknown	<800		Week 1 (collection date not found on visit report, date is between week 1 and week2)
	Screening	16MAR2012	09:00	<800		

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Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
205-0003/79/M/W2	Week 4	17APR2012	09:00	<800		
	Week 8	15MAY2012	09:00	<800		
	Week 12	12JUN2012	09:00	<800		
	Week 16	10JUL2012	09:00	<800		
	Week 20	14AUG2012	09:00	<800		
	Week 24	11SEP2012	09:00	<800		
	Week 28	09OCT2012	09:00	<800		Back up sample, no primary sample was received
	Week 32	06NOV2012	09:00	<800		
	Week 36	04DEC2012	09:00	<800		
205-0005/71/M/W2	Screening	12MAR2012	09:00	<800		
	Week 4	12APR2012	09:00	<800		
	Week 8	10MAY2012	09:00	<800		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
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Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
	Week 12	05JUN2012	09:00	<800		
205-0014/70/M/W2	Screening	07JUN2013	07:30	<800		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
205-0014/70/M/W2	Week 2	28JUN2013	09:30	<800		
	Week 4	26JUL2013	10:30	<800		
	Week 5	02AUG2013	10:30	<800		
205-0023/72/M/W2	Screening	29OCT2013	13:30	<800	800	
	Screening	29OCT2013	13:30	<800		
	Week 2	15NOV2013	09:15	1010		
	Week 4	29NOV2013	08:30	1050		
	Week 8	23DEC2013	09:30	1580		
	Week 12	21JAN2014	08:45	1940		
205-0026/61/F/W2	Screening	02MAR2012	Unknown	<800	400	

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
	Screening	02MAR2012	Unknown	BQL		Screening (collection date not found on visit report, date is between screening and week 1)
	Week 2	17FEB2015	10:00	BQL		
	Week 4	03MAR2015	10:30	BQL		
	Week 8	31MAR2015	10:00	BQL		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
205-0026/61/F/W2	Week 12	28APR2015	11:00	BQL		
205-0028/73/F/W2	Screening	19JAN2015	12:00	<800		
	Week 2	03FEB2015	10:30	BQL		
207-0002/71/M/W2	Screening	08MAR2012	12:30	<800		
	Week 4	12APR2012	09:40	<800		
	Week 8	10MAY2012	09:40	<800		
	Week 12	07JUN2012	09:30	<800		
207-0007/71/M/W2	Screening	18JUN2012	10:30	<800		
	Week 4	23JUL2012	10:00	<800		
	Week 8	20AUG2012	10:55	<800		
207-0012/66/M/W2	Screening	12MAR2013	08:30	<800		
	Week 4	11APR2013	09:50	<800		
	Week 8	09MAY2013	08:30	<800		
	Week 12	06JUN2013	08:45	<800		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
207-0012/66/M/W2	Week 16	04JUL2013	08:45	<800		
	Week 20	01AUG2013	09:15	<800		
	Week 24	30AUG2013	08:30	<800		
	Week 28	04OCT2013	08:50	<800		
	Week 32	31OCT2013	08:50	<800		
	Week 36	29NOV2013	09:30	<800		
	Week 42	10JAN2014	11:30	1050		Uns Continuation
	Week 44	24JAN2014	09:45	994		Uns Continuation
	Week 46	06FEB2014	10:30	889		Uns Continuation
207-0016/82/F/W2	Screening	30SEP2013	10:00	<800		
	Week 4	31OCT2013	10:40	<800		
	Week 8	28NOV2013	09:40	1220		
	Week 12	27DEC2013	09:30	1180		
207-0017/81/F/W2	Screening	22NOV2013	10:00	<800		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
207-0017/81/F/W2	Week 2	05DEC2013	10:45	<800		
	Week 4	19DEC2013	10:00	<800		
	Week 8	17JAN2014	10:50	<800		
	Week 12	13FEB2014	12:30	<800		
207-0019/55/M/W2	Screening	27MAY2014	13:15	<800		
	Week 2	10JUN2014	10:20	<800		
209-0006/68/M/W2	Screening	18APR2013	09:45	<800		
	Week 2	07MAY2013	09:30	<800		
	Week 4	21MAY2013	09:30	<800		
	Week 8	18JUN2013	10:45	<800		
	Week 12	24JUL2013	08:00	<800		
	Week 16	20AUG2013	10:00	<800		
	Week 20	20SEP2013	09:30	<800		
	Week 24	15OCT2013	10:30	<800		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
209-0006/68/M/W2	Week 28	14NOV2013	11:00	<800		
	Week 32	10DEC2013	09:30	<800		
	Week 36	07JAN2014	09:15	<800		
209-0011/69/M/W2	Screening	21NOV2013	10:50	<800		
	Week 2	10DEC2013	11:30	<800		
	Week 4	23DEC2013	09:00	<800		
	Week 8	22JAN2014	09:50	<800		
	Week 12	19FEB2014	09:30	843		
209-0014/79/M/W2	Screening	04MAR2014	10:05	914		
	Week 2	26MAR2014	10:15	981		
	Week 4	08APR2014	11:00	836		
	Week 8	07MAY2014	10:20	<800		
	Week 12	04JUN2014	10:30	<800		
	Week 16	02JUL2014	09:00	<800		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
209-0014/79/M/W2	Week 20	29JUL2014	10:00	<800		
	Week 24	26AUG2014	10:10	<800		
	End of Treatment	23SEP2014	09:00	<800		Week 28 (4 weeks after week 24 visit)
210-0003/74/M/W2	Screening	30OCT2013	10:00	<800	800	
	Screening	30OCT2013	10:00	<800		
	Week 2	14NOV2013	10:30	<800		
	Week 4	28NOV2013	11:15	<800		
210-0004/71/M/W2	Screening	02JAN2014	09:45	<800		
	Week 2	15JAN2014	09:40	<800		
	Week 4	29JAN2014	09:30	<800		
	Week 8	26FEB2014	09:35	<800		
	Week 12	26MAR2014	10:00	<800		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
210-0005/53/M/W2	Screening	13FEB2014	09:20	<800		
	Week 2	27FEB2014	09:30	<800		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
210-0005/53/M/W2	Week 4	13MAR2014	11:30	<800		
	Week 8	10APR2014	09:15	<800		
	Week 12	07MAY2014	09:10	<800		
210-0006/45/M/W2	Screening	18JUN2014	10:45	<800		
	Week 2	02JUL2014	09:20	<800		
	Week 4	16JUL2014	10:15	968		
	Week 8	14AUG2014	09:30	<800		
	Week 12	10SEP2014	10:20	<800		
251-0002/69/M/W2	Screening	06AUG2013	11:00	<800		
	Week 2	20AUG2013	11:30	<800		
	Week 4	03SEP2013	11:45	<800		
	Week 8	01OCT2013	11:30	<800		
251-0003/68/M/W2	Screening	29OCT2013	09:36	<800	800	
	Screening	29OCT2013	09:36	<800		

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[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
251-0003/68/M/W2	Week 2	12NOV2013	09:00	<800		
	Week 4	26NOV2013	09:15	<800		
	Week 12	21JAN2014	10:00	<800		
	Week 16	18FEB2014	10:00	<800		
	Week 20	18MAR2014	10:30	<800		
	Week 24	15APR2014	11:00	934		
252-0001/65/M/A3	Screening	30MAY2008	Unknown	<800		
	Week 4	29MAY2012	11:25	<800		
	Week 8	26JUN2012	11:35	<800		
252-0004/50/M/A1	Screening	21MAY2013	11:20	<800		
	Week 2	04JUN2013	11:00	<800		
	Week 4	18JUN2013	11:30	<800		
	Unscheduled	16JUL2013	10:35	<800		Week 8
252-0006/64/M/W2	Screening	25JUL2013	Unknown	<800		

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[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
252-0006/64/M/W2	Week 2	08OCT2013	08:25	<800		
	Week 4	22OCT2013	08:30	<800		
	Week 8	19NOV2013	08:30	<800		
	Week 12	17DEC2013	08:30	<800		
	Week 16	14JAN2014	08:20	<800		
	Week 20	11FEB2014	08:00	<800		
	Week 24	11MAR2014	08:00	1210		
252-0008/76/M/W2	Screening	20MAY2014	11:30	1020		
	Week 2	03JUN2014	11:05	1140		
	Week 4	17JUN2014	11:25	1130		
	Week 8	15JUL2014	11:15	980		
	Week 12	12AUG2014	12:40	<800		
252-0010/56/F/W2	Screening	28OCT2014	10:40	<800		
	Week 2	11NOV2014	11:10	<800		

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[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
252-0010/56/F/W2	Week 4	25NOV2014	10:10	<800		
	Week 8	23DEC2014	10:03	<800		
	Week 12	20JAN2015	10:45	<800		
253-0003/75/M/W2	Screening	25MAY2012	11:30	<800		
	Week 4	06JUL2012	11:44	<800		
	Week 8	03AUG2012	11:35	<800		
	Week 12	31AUG2012	11:20	<800		
	Week 16	28SEP2012	11:20	<800		
	Week 20	26OCT2012	11:30	<800		
	Week 24	23NOV2012	11:30	<800		
	Week 28	21DEC2012	11:30	<800		
	Week 32	18JAN2013	12:00	<800		
	Week 36	15FEB2013	11:20	<800		
253-0004/79/M/W2	Screening	04SEP2012	14:30	<800		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
253-0004/79/M/W2	Week 4	28SEP2012	10:20	<800		
	Week 8	26OCT2012	10:30	<800		
	Week 12	23NOV2012	10:00	<800		
253-0005/74/F/W2	Screening	03MAR2011	Unknown	<800		
253-0006/63/M/A3	Screening	16NOV2012	Unknown	<800		
	Week 4	18JAN2013	12:00	<800		
	Week 8	15FEB2013	11:45	<800		
	Week 12	15MAR2013	11:30	<800		
	Week 16	12APR2013	11:05	<800		
	Week 20	10MAY2013	10:00	<800		
253-0011/67/M/W2	Screening	25SEP2014	10:00	<800		
	Week 2	13OCT2014	10:10	<800		
	Week 4	27OCT2014	10:30	<800		
	Week 8	24NOV2014	10:20	<800		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
253-0011/67/M/W2	Week 12	22DEC2014	10:00	<800		
	Week 16	19JAN2015	11:00	<800		
	Week 20	16FEB2015	09:50	BQL		
	Week 24	16MAR2015	10:50	BQL		
	Week 28	13APR2015	09:40	BQL		
	Week 32	11MAY2015	09:58	BQL		
253-0012/67/M/W2	Screening	24NOV2014	12:10	<800		
	Week 2	15DEC2014	09:40	<800		
	Week 4	29DEC2014	09:30	<800		
257-0005/66/M/W2	Screening	11DEC2012	09:50	<800	800	

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
	Unscheduled	11DEC2012	09:50	<800		Screening (collection date not found on visit report, date is between screening and week 1)
	Week 4	24JAN2013	11:56	<800		
	Unscheduled	28FEB2013	Unknown	<800		Week 9
	Week 12	21MAR2013	10:35	<800		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
257-0013/63/M/W2	Screening	23MAY2013	12:10	<800		
	Week 2	07JUN2013	11:53	<800		
	Week 4	20JUN2013	11:45	<800		
257-0020/72/M/A1	Screening	21OCT2014	14:10	<800		
	Week 2	03NOV2014	15:30	<800		
	Week 4	17NOV2014	13:43	<800		
258-0002/69/F/W2	Screening	08APR2013	10:00	<800	800	
	Unscheduled	08APR2013	10:00	<800		Screening (collection date not found on visit report, date is between screening and week 1)
	Week 2	17APR2013	11:50	<800		
	Week 4	01MAY2013	11:00	<800		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
	Week 8	29MAY2013	11:08	<800		
	Week 12	26JUN2013	11:30	<800		
	Week 16	24JUL2013	09:45	<800		
	Week 20	21AUG2013	10:26	<800		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
258-0002/69/F/W2	Week 24	18SEP2013	10:34	<800		
	Week 28	16OCT2013	10:46	<800		
	Week 36	11DEC2013	12:13	<800		
258-0003/67/F/W2	Screening	09MAY2013	11:30	<800		
	Week 4	05JUN2013	11:25	<800		
	Week 8	03JUL2013	11:05	<800		
	Week 12	31JUL2013	11:24	<800		
	Week 16	30AUG2013	10:07	<800		
	Week 24	23OCT2013	10:25	<800		
258-0004/65/M/W2	Screening	13MAY2013	11:20	<800		
	Week 2	29MAY2013	Unknown	<800		
258-0006/69/M/W2	Screening	02OCT2013	10:50	<800		
	Week 2	25OCT2013	10:41	<800		
	Week 4	08NOV2013	10:45	<800		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
258-0013/59/M/W2	Screening	05NOV2014	10:05	<800		
	Week 2	19NOV2014	10:21	<800		
	Week 4	03DEC2014	10:40	<800		
	Week 8	29DEC2014	11:25	<800		
	Week 12	28JAN2015	12:00	<800		
259-0003/73/M/W2	Unscheduled	09JUN2014	13:50	859		Screening
	Week 2	18JUN2014	11:55	<800		
	Week 4	02JUL2014	11:15	855		
	Week 8	30JUL2014	12:05	<800		
	Week 12	27AUG2014	11:40	<800		
	Week 16	24SEP2014	11:55	<800		
	Week 20	22OCT2014	11:10	<800		
	Week 24	19NOV2014	11:00	<800		
	Week 28	17DEC2014	11:30	<800		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
259-0003/73/M/W2	Week 32	14JAN2015	11:10	<800		
	Week 40	11MAR2015	11:14	BQL		Uns Continuation
	Week 44	08APR2015	11:40	BQL		Uns Continuation
	Week 48	06MAY2015	10:50	BQL		Uns Continuation
259-0004/52/M/W2	Screening	16JUL2014	10:45	<800		
	Unscheduled	23JUL2014	Unknown	<800		Week 1 (2 days after week 1 visit)
	Week 2	30JUL2014	12:40	<800		
	Week 4	13AUG2014	11:25	<800		
260-0002/66/M/W2	Screening	18SEP2013	15:15	<800		
	Week 2	09OCT2013	14:15	<800		
	Week 4	23OCT2013	14:15	<800		
301-0001/47/F/A2	Screening	27OCT2011	10:05	<800		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
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Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
	Week 4	22NOV2011	09:25	<800		
	Week 8	20DEC2011	09:25	<800		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
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[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
301-0001/47/F/A2	Week 12	17JAN2012	11:50	<800		
301-0003/61/F/A2	Screening	23FEB2012	11:40	<800		
	Week 4	22MAR2012	10:40	<800		
	Week 8	19APR2012	11:10	<800		
	Week 12	17MAY2012	11:10	<800		
301-0008/53/M/A2	Screening	26DEC2012	09:50	<800		
	Week 4	25JAN2013	09:50	<800		
	Week 8	22FEB2013	09:50	<800		
	Week 12	22MAR2013	10:35	<800		
302-0006/49/M/A2	Screening	04JAN2012	09:30	<800		
	Week 4	31JAN2012	09:45	907		
	Week 8	28FEB2012	09:40	<800		
302-0009/73/M/A2	Screening	11APR2012	09:02	<800		
	Week 4	08MAY2012	09:03	<800		

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[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
302-0009/73/M/A2	Week 8	05JUN2012	09:12	<800		
302-0012/62/M/A2	Screening	18APR2012	08:30	<800		
	Week 4	15MAY2012	08:15	<800		
	Week 8	12JUN2012	10:22	<800		
	Week 12	10JUL2012	08:23	<800		
302-0013/62/M/A2	Screening	21MAR2013	09:55	<800		
	Week 2	02APR2013	08:35	<800		
	Week 4	16APR2013	08:05	<800		
	Week 8	14MAY2013	08:10	<800		
302-0020/52/M/A2	Screening	16MAY2013	09:00	<800		
	Week 2	28MAY2013	09:25	<800		
	Week 4	11JUN2013	09:00	<800		
302-0021/75/F/A2	Screening	06JUN2013	10:25	<800		
	Week 2	18JUN2013	09:50	863		

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Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
302-0021/75/F/A2	Week 4	02JUL2013	09:30	<800		
	Week 8	30JUL2013	09:45	870		
	Week 12	27AUG2013	09:10	913		
	Week 16	24SEP2013	09:45	<800		
	Week 20	22OCT2013	10:15	<800		
	Week 24	19NOV2013	09:20	<800		
304-0003/56/F/A2	Screening	11MAR2013	11:50	<800		
	Week 4	03APR2013	10:00	<800		
	Week 8	02MAY2013	10:00	<800		
	Week 12	30MAY2013	09:02	<800		
304-0004/69/M/A2	Screening	30MAY2013	13:00	950		
	Week 2	11JUN2013	11:40	938		
	Week 4	25JUN2013	08:02	940		
304-0007/72/M/A2	Screening	07NOV2013	11:20	<800		

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Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
304-0007/72/M/A2	Week 2	20NOV2013	09:30	<800		
	Week 4	04DEC2013	10:00	<800		
	Week 8	02JAN2014	10:00	<800		
	Week 12	28JAN2014	09:48	<800		
305-0004/79/M/A2	Screening	14FEB2012	16:50	<800		
	Week 4	15MAR2012	08:07	<800		
	Week 8	12APR2012	09:00	<800		
	Week 12	10MAY2012	08:16	<800		
305-0007/67/M/A2	Screening	10SEP2009	Unknown	<800		
	Week 4	30MAR2012	08:00	<800		
	Week 8	27APR2012	08:00	<800		
	Week 12	25MAY2012	07:40	<800		
	Week 16	22JUN2012	07:32	<800		
	Week 20	20JUL2012	07:55	<800		

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[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
305-0007/67/M/A2	Week 24	17AUG2012	07:38	<800		
305-0015/84/M/A2	Screening	04JUL2012	11:50	<800		
	Week 4	26JUL2012	07:13	<800		
	Week 8	21AUG2012	12:47	<800		
	Week 12	20SEP2012	08:14	<800		
305-0016/78/M/A2	Screening	04JUL2012	16:10	<800		
	Week 4	01AUG2012	12:40	<800		
	Week 8	28AUG2012	09:05	<800		
	Week 12	25SEP2012	12:40	<800		
305-0021/83/F/A2	Screening	16NOV2012	16:34	<800		
	Week 4	11DEC2012	12:58	<800		
	Week 8	08JAN2013	12:10	<800		
	Week 12	05FEB2013	13:00	<800		
305-0024/68/M/A2	Screening	14JAN2013	10:30	<800		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
305-0024/68/M/A2	Week 4	08FEB2013	08:00	<800		
	Week 8	05MAR2013	13:15	<800		
	Week 12	03APR2013	13:10	<800		
305-0033/37/F/A2	Screening	25JUN2013	15:20	<800		
	Week 2	09JUL2013	15:05	<800		
	Week 4	23JUL2013	15:00	<800		
	Week 8	20AUG2013	15:25	<800		
	Week 12	17SEP2013	16:00	<800		
305-0035/60/M/A2	Screening	27AUG2013	15:30	<800		
	Week 2	04SEP2013	12:55	<800		
	Week 4	18SEP2013	11:40	<800		
	Week 8	16OCT2013	12:00	<800		
	Week 12	13NOV2013	12:25	<800		
	Week 16	11DEC2013	12:50	<800		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
305-0035/60/M/A2	Week 20	08JAN2014	12:53	<800		
	Week 24	05FEB2014	12:20	<800		
305-0046/60/M/A2	Screening	03NOV2014	12:20	<800		
	Week 2	14NOV2014	13:00	<800		
	Week 4	28NOV2014	13:21	<800		
	Week 8	26DEC2014	13:15	<800		
	Week 12	23JAN2015	12:50	<800		
	Week 16	17FEB2015	13:05	<800		
	Week 20	20MAR2015	12:40	BQL		
	Week 24	14APR2015	12:50	BQL		
306-0004/46/M/A2	Screening	09FEB2012	Unknown	<800		
	Week 4	13MAR2012	09:00	<800		
306-0010/69/M/A2	Screening	18APR2006	Unknown	<800		
	Week 4	11APR2012	11:00	<800		

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[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
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Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
306-0010/69/M/A2	Week 8	09MAY2012	10:30	<800		
	Week 12	06JUN2012	10:00	<800		
306-0013/42/M/A2	Screening	09APR2012	09:30	<800		
	Week 4	07MAY2012	10:00	<800		
	Week 8	04JUN2012	09:00	<800		
306-0015/73/M/A2	Screening	15MAY2012	10:30	<800		
	Week 4	07JUN2012	09:00	<800		
306-0016/58/M/A2	Screening	21JUN2012	09:00	<800		
	Week 4	16JUL2012	09:20	<800		
	Week 8	13AUG2012	09:05	<800		
	Week 12	11SEP2012	08:20	<800		
306-0022/56/M/A2	Screening	22MAR2012	Unknown	<800		
	Week 4	04DEC2012	09:00	<800		
	Week 8	02JAN2013	08:50	<800		

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Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
306-0022/56/M/A2	Week 12	29JAN2013	08:50	<800		
	Week 16	26FEB2013	08:20	<800		
	Week 20	26MAR2013	08:30	<800		
	Week 24	23APR2013	08:20	<800		
306-0028/53/M/A2	Screening	18MAR2013	13:30	<800		
	Week 4	18APR2013	09:00	<800		
	Week 8	16MAY2013	09:30	<800		
	Week 12	13JUN2013	09:30	<800		
306-0045/60/F/A1	Screening	11JUN2014	12:30	<800		
	Week 2	25JUN2014	13:00	<800		
	Week 4	08JUL2014	13:00	<800		
	Week 8	05AUG2014	13:00	<800		
	Week 12	02SEP2014	13:00	<800		
307-0006/72/M/A2	Screening	25NOV2011	09:09	<800		

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Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
307-0009/53/M/A2	Screening	28DEC2011	09:45	<800		
	Week 4	27JAN2012	09:15	<800		
307-0012/42/M/A2	Screening	31JAN2012	09:00	<800		
307-0015/75/M/A2	Screening	18APR2012	08:43	<800		
	Week 4	16MAY2012	08:45	<800		
	Week 8	13JUN2012	09:25	<800		
	Week 12	11JUL2012	10:50	<800		
	Week 16	08AUG2012	09:57	<800		
	Week 20	05SEP2012	09:30	<800		
	Week 24	04OCT2012	10:50	<800		
307-0021/68/M/A2	Screening	14AUG2012	09:30	<800		
	Week 4	13SEP2012	08:57	<800		
	Week 8	09OCT2012	08:35	<800		
	Week 12	08NOV2012	09:18	<800		

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Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
307-0021/68/M/A2	Week 16	06DEC2012	09:20	<800		
307-0028/69/F/A2	Screening	09JAN2013	09:49	<800		
	Week 4	04FEB2013	09:35	<800		
	Week 8	04MAR2013	09:34	<800		
	Week 12	01APR2013	09:32	<800		
307-0034/48/M/A2	Screening	08AUG2013	11:48	<800		
	Week 2	20AUG2013	10:25	<800		
	Week 4	03SEP2013	10:24	<800		
	Week 8	01OCT2013	09:10	<800		
	Week 12	29OCT2013	09:35	<800		
307-0036/76/M/A2	Screening	27SEP2013	08:06	<800		
	Week 2	08OCT2013	10:50	<800		
	Week 4	24OCT2013	08:33	<800		
	Week 8	21NOV2013	09:20	<800		

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Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
307-0036/76/M/A2	Week 12	18DEC2013	09:09	<800		
307-0042/55/M/A2	Screening	10JUN2014	10:35	<800		
	Week 2	26JUN2014	10:55	<800		
	Week 4	10JUL2014	09:22	<800		
	Week 8	07AUG2014	09:40	<800		
	Week 12	04SEP2014	10:50	<800		
	Week 16	02OCT2014	09:37	<800		
	Week 20	30OCT2014	09:28	<800		
	Week 24	27NOV2014	10:37	<800		
308-0002/36/F/A2	Screening	27DEC2012	09:15	<800		
	Week 4	22JAN2013	11:30	<800		
	Week 8	19FEB2013	12:30	<800		
	Week 12	19MAR2013	12:30	<800		
308-0004/52/M/A2	Screening	31JAN2013	11:10	<800		

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Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
308-0004/52/M/A2	Week 4	26FEB2013	12:30	<800		
	Week 8	26MAR2013	12:30	<800		
	Week 12	23APR2013	12:10	<800		
308-0006/64/M/A2	Screening	12OCT2007	Unknown	<800		
	Week 2	21MAY2013	09:20	<800		
	Week 4	04JUN2013	13:20	<800		
	Week 8	02JUL2013	13:05	<800		
308-0008/47/M/A2	Screening	11JUL2013	14:10	<800		
	Week 2	30JUL2013	12:40	<800		
	Week 4	13AUG2013	09:15	<800		
	Week 8	10SEP2013	09:10	<800		
	Week 12	08OCT2013	09:00	<800		
308-0009/61/M/A2	Screening	11JUL2013	13:40	<800		
	Week 2	25JUL2013	14:30	<800		

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Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
308-0009/61/M/A2	Week 4	08AUG2013	11:10	<800		
	Week 8	05SEP2013	13:30	<800		
309-0006/56/M/A2	Screening	19NOV2012	12:15	<800		
	Week 4	17DEC2012	10:45	<800		
	Week 8	14JAN2013	11:20	<800		
	Week 12	08FEB2013	10:00	<800		
	Week 16	11MAR2013	09:40	<800		
	Week 20	08APR2013	10:50	<800		
	Week 24	06MAY2013	09:20	<800		
	Week 28	03JUN2013	10:20	<800		
	Week 32	01JUL2013	09:10	<800		
	Week 36	29JUL2013	09:50	<800		
309-0007/58/M/A2	Screening	19MAY2011	Unknown	<800		
	Week 4	07JAN2013	11:30	<800		

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Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
309-0007/58/M/A2	Week 8	04FEB2013	09:40	<800		
	Week 12	04MAR2013	09:20	<800		
309-0013/45/M/A2	Screening	11DEC2012	Unknown	<800		
	Week 2	27JUN2013	10:10	<800		
	Week 4	11JUL2013	09:35	<800		
	Week 8	08AUG2013	09:30	<800		
	Week 12	05SEP2013	09:15	<800		
309-0014/39/M/A2	Screening	14JUN2013	12:30	<800		
	Week 2	27JUN2013	09:50	<800		
	Week 4	11JUL2013	09:51	<800		
	Week 8	08AUG2013	09:35	<800		
	Week 12	05SEP2013	10:05	<800		
309-0019/68/M/A2	Screening	17JUN2014	12:30	<800		
	Week 2	01JUL2014	11:00	<800		

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Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
309-0019/68/M/A2	Week 4	15JUL2014	10:50	<800		
	Week 8	12AUG2014	13:10	<800		
	Week 12	09SEP2014	11:20	<800		
	Week 16	07OCT2014	11:15	<800		
	Week 20	04NOV2014	11:20	<800		
	Week 24	01DEC2014	11:20	<800		
	Week 28	29DEC2014	10:40	<800		
	Week 32	28JAN2015	09:10	<800		
	Week 36	24FEB2015	11:00	<800		
	Week 40	24MAR2015	11:25	BQL		
	Week 44	22APR2015	09:30	BQL		
	Week 48	19MAY2015	11:20	BQL		
309-0027/49/M/A2	Screening	22OCT2014	12:20	<800		
	Week 2	10NOV2014	10:45	<800		

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[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
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Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
309-0027/49/M/A2	Week 4	24NOV2014	10:55	<800		
	Week 8	22DEC2014	10:16	<800		
	Week 12	19JAN2015	10:14	<800		
309-0029/50/M/A2	Screening	18NOV2014	13:00	<800		
	Week 2	08DEC2014	10:30	<800		
	Week 4	22DEC2014	10:25	<800		
	Week 8	19JAN2015	09:35	<800		
310-0004/50/F/A2	Screening	25JAN2013	09:40	<800		
	Week 4	27FEB2013	09:00	<800		
	Week 8	27MAR2013	08:50	<800		
	Week 12	24APR2013	11:10	<800		
310-0005/58/M/A2	Screening	13MAR2013	14:00	<800		
	Week 2	03APR2013	10:45	<800		
	Week 4	17APR2013	11:00	<800		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
310-0005/58/M/A2	Week 8	15MAY2013	09:40	<800		
	Week 12	10JUN2013	09:30	<800		
310-0006/50/F/A2	Screening	24APR2013	08:50	<800		
	Week 2	08MAY2013	08:40	<800		
	Week 4	22MAY2013	09:20	<800		
	Week 8	19JUN2013	08:30	<800		
	Week 12	17JUL2013	11:25	<800		
	Week 16	14AUG2013	09:00	<800		
	Week 20	11SEP2013	10:00	<800		
	Week 24	09OCT2013	09:50	<800		
	Week 28	06NOV2013	10:50	<800		
	Week 32	02DEC2013	11:00	<800		
310-0007/74/M/A2	Screening	03JUN2013	14:30	<800		
	Week 2	20JUN2013	10:30	<800		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
310-0007/74/M/A2	Week 4	04JUL2013	11:00	<800		
	Week 8	01AUG2013	10:45	<800		
	Week 12	30AUG2013	11:00	<800		
	Week 16	26SEP2013	10:45	<800		
	Week 20	24OCT2013	11:00	<800		
	Week 24	21NOV2013	10:50	<800		
	Week 28	19DEC2013	10:55	<800		
	Week 32	16JAN2014	09:40	<800		
	Week 36	13FEB2014	11:00	<800		
	Week 40	11MAR2014	11:00	<800		
	Week 44	08APR2014	11:10	<800		
310-0009/46/M/A2	Screening	31JUL2013	09:30	<800		
	Week 2	14AUG2013	10:45	<800		
	Week 4	28AUG2013	10:45	818		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
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[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
310-0009/46/M/A2	Week 8	25SEP2013	10:30	<800		
310-0010/34/F/A2	Screening	15AUG2013	14:20	<800		
	Week 2	02SEP2013	10:00	<800		
	Week 4	16SEP2013	08:20	<800		
310-0011/52/M/A2	Screening	17OCT2013	12:40	<800		
	Week 2	31OCT2013	12:20	<800		
	Week 4	14NOV2013	12:15	<800		
	Week 8	09DEC2013	08:40	<800		
310-0014/64/M/A2	Screening	17SEP2014	08:37	<800		
	Week 2	01OCT2014	08:03	<800		
	Week 4	15OCT2014	07:05	<800		
	Week 8	10NOV2014	07:01	<800		
311-0003/44/M/A2	Screening	18SEP2013	10:10	<800		
	Week 2	02OCT2013	14:20	<800		

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[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
311-0003/44/M/A2	Week 4	16OCT2013	09:00	<800		
	Week 8	13NOV2013	10:10	<800		
	Week 12	10DEC2013	08:00	<800		
311-0004/68/M/A2	Screening	26SEP2013	09:00	<800		
	Week 2	07OCT2013	08:55	<800		
311-0005/58/M/A2	Screening	07OCT2013	14:00	<800		
	Week 2	28OCT2013	14:00	<800		
	Week 4	11NOV2013	14:00	<800		
	Week 8	09DEC2013	13:30	<800		
311-0006/73/F/A2	Screening	04NOV2013	15:00	<800		
	Week 2	12NOV2013	10:00	<800		
	Week 4	26NOV2013	09:45	<800		
	Week 8	24DEC2013	08:30	<800		
311-0009/51/F/A2	Screening	01JUL2014	16:10	<800		

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[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
311-0009/51/F/A2	Week 2	22JUL2014	09:25	<800		
	Week 4	05AUG2014	14:40	<800		
	Week 8	02SEP2014	12:00	<800		
	Week 12	30SEP2014	09:47	<800		
311-0010/47/M/A2	Screening	26AUG2014	08:55	<800		
	Week 2	09SEP2014	14:00	<800		
	Week 4	23SEP2014	14:30	<800		
	Week 8	21OCT2014	13:25	<800		
	Week 12	18NOV2014	09:45	<800		
	Week 16	17DEC2014	11:00	<800		
	Week 20	14JAN2015	10:50	<800		
	Week 24	12FEB2015	13:10	<800		
	Week 28	11MAR2015	13:32	BQL		
	Week 32	09APR2015	13:30	BQL		

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Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
311-0010/47/M/A2	Week 36	07MAY2015	13:20	BQL		
311-0011/46/M/A2	Screening	28OCT2014	09:20	<800		
	Week 2	05NOV2014	14:30	<800		
	Week 4	19NOV2014	09:15	<800		
	Week 8	17DEC2014	12:10	<800		
311-0012/55/M/A2	Screening	20JAN2015	09:56	<800		
	Week 2	05FEB2015	13:46	<800		
	Week 4	17FEB2015	14:49	<800		
	Week 8	19MAR2015	13:57	BQL		
	Week 12	16APR2015	11:27	BQL		
	Week 16	14MAY2015	14:00	BQL		
401-0001/70/M/A7	Screening	03JUN2013	09:30	<800		
	Week 2	Unknown	Unknown	<800		
401-0002/55/M/A7	Screening	12JUN2013	11:30	<800		

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Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
401-0002/55/M/A7	Week 2	27JUN2013	10:15	<800		
402-0001/35/M/A7	Screening	15APR2013	14:30	<800		
	Week 2	29APR2013	13:00	<800		
	Week 4	13MAY2013	12:40	<800		
	Week 8	10JUN2013	12:00	<800		
402-0002/58/M/A7	Screening	23APR2013	15:00	<800		
	Week 2	30APR2013	14:12	835		
	Week 4	14MAY2013	13:00	<800		
	Week 8	11JUN2013	12:30	<800		
	Week 12	09JUL2013	12:00	947		
402-0005/70/M/A7	Screening	09MAY2013	09:30	<800		
	Week 2	16MAY2013	09:40	<800		
	Week 4	28MAY2013	09:30	<800		
	Week 8	27JUN2013	09:10	821		

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Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
402-0005/70/M/A7	Week 12	23JUL2013	08:20	<800		
402-0010/50/M/A7	Screening	10MAY2013	11:30	<800		
	Week 2	27MAY2013	13:20	<800		
	Week 4	10JUN2013	12:00	<800		
	Week 8	Unknown	Unknown	<800		
402-0022/60/F/A7	Screening	09AUG2013	09:30	<800		
	Week 2	30AUG2013	09:00	<800		
	Week 4	12SEP2013	08:10	<800		
	Week 8	10OCT2013	09:10	<800		
	Week 12	11NOV2013	08:11	<800		
402-0023/57/M/A7	Screening	22AUG2013	14:20	<800		
	Week 2	10SEP2013	12:10	<800		
	Week 4	24SEP2013	12:30	<800		
	Week 8	22OCT2013	12:20	<800		

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[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
402-0023/57/M/A7	Week 12	19NOV2013	12:00	<800		
402-0029/49/M/A7	Screening	06NOV2013	14:40	882		
	Week 2	18NOV2013	12:30	<800		
	Week 4	02DEC2013	11:40	<800		
	Week 8	30DEC2013	12:00	<800		
402-0032/49/F/A7	Screening	28NOV2013	14:10	<800		
	Week 2	12DEC2013	10:00	<800		
	Week 4	26DEC2013	09:50	<800		
	Week 8	23JAN2014	10:00	<800		
	Week 12	20FEB2014	10:00	<800		
402-0034/43/F/A7	Screening	11DEC2013	11:20	<800		
	Week 2	26DEC2013	10:00	<800		
	Week 4	09JAN2014	10:00	<800		
	Week 8	07FEB2014	10:30	<800		

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Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
402-0034/43/F/A7	Week 12	06MAR2014	10:00	<800		
	Week 16	03APR2014	10:00	<800		
	Week 20	02MAY2014	10:00	<800		
	Week 24	29MAY2014	10:00	<800		
403-0004/37/M/A7	Screening	03JUL2013	08:34	<800		
	Week 2	17JUL2013	10:11	<800		
	Week 4	31JUL2013	09:08	<800		
	Week 8	28AUG2013	12:28	<800		
	Week 12	25SEP2013	09:32	<800		
404-0003/53/M/A7	Screening	02SEP2013	08:30	<800		
	Week 2	17SEP2013	07:30	<800		
404-0004/61/F/A7	Screening	08OCT2013	11:00	<800		
	Week 2	21OCT2013	12:05	<800		
	Week 4	04NOV2013	12:00	<800		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
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Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
404-0004/61/F/A7	Week 8	02DEC2013	11:45	<800		
405-0001/55/M/A7	Screening	22APR2013	08:55	<800		
	Week 2	29APR2013	08:45	<800		
	Week 4	15MAY2013	13:20	<800		
	Week 8	10JUN2013	08:35	<800		
	Week 12	10JUL2013	10:10	<800		
405-0005/35/M/A6	Screening	19APR2013	13:40	<800		
	Week 2	29APR2013	09:00	<800		
	Week 4	15MAY2013	11:05	<800		
	Week 8	10JUN2013	09:00	<800		
	Week 12	10JUL2013	09:05	<800		
	Week 16	07AUG2013	09:25	<800		
	Week 20	04SEP2013	09:20	<800		
	Week 24	02OCT2013	09:05	<800		

[1] Age is calculated to be the integer part of (Date of Informed Consent - Date of Birth + 1)/365.25.
[2] Race: MIX= Mixed Race, BL = BLACK OR AFRICAN AMERICAN, AI = AMERICAN INDIAN OR ALASKA NATIVE,A1 = ASIAN – MAINLAND CHINA, A2 = ASIAN – TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN -JAPANESE HERITAGE,A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN -OTHER, AMX= ASIAN - MIXED,PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2 = WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, WMX= WHITE - MIXED, OTH= OTHER RACE.
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Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
405-0005/35/M/A6	Week 28	30OCT2013	09:10	<800		
	Week 32	27NOV2013	09:20	<800		
	Week 32	27NOV2013	09:20	<800		
405-0012/72/M/A7	Screening	09MAY2013	15:51	<800		
	Week 2	22MAY2013	11:35	<800		
	Week 4	05JUN2013	10:25	<800		
	Week 8	01JUL2013	09:00	<800		
	Week 12	29JUL2013	08:40	<800		
	Week 16	26AUG2013	09:00	<800		
	Week 20	23SEP2013	08:50	<800		
	Week 24	21OCT2013	09:00	<800		
405-0019/61/M/A7	Screening	17JUN2013	10:50	<800		
	Week 2	01JUL2013	10:10	<800		
	Week 4	15JUL2013	09:15	<800		

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[3] Only applicable to patients that had multiple Arginine/Citrulline measurements at one visit.

Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
405-0024/69/M/A7	Screening	19JUN2013	17:25	<800		
	Week 2	10JUL2013	10:20	<800		
405-0026/67/M/A7	Screening	27JUN2013	15:20	<800		
	Week 2	17JUL2013	11:40	<800		
	Week 4	31JUL2013	12:35	<800		
	Week 8	28AUG2013	11:27	<800		
	Week 12	25SEP2013	11:47	<800		
405-0036/70/M/A7	Screening	17APR2012	Unknown	<800		
	Week 2	28AUG2013	08:50	<800		
	Week 4	13SEP2013	09:20	<800		
	Week 8	14OCT2013	08:45	<800		
	Week 12	11NOV2013	08:45	<800		
405-0041/57/M/A7	Screening	11SEP2013	14:40	<800		
	Week 2	16SEP2013	09:45	<800		

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Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
405-0041/57/M/A7	Week 4	02OCT2013	10:30	<800		
	Week 8	28OCT2013	08:35	<800		
	Week 12	25NOV2013	08:40	<800		
	Week 16	23DEC2013	08:30	<800		
	Week 20	22JAN2014	12:10	<800		
	Week 24	17FEB2014	08:35	<800		
	Week 28	12MAR2014	13:58	<800		
	Week 32	11APR2014	10:30	<800		
	Week 36	09MAY2014	10:35	<800		
501-0003/22/M/A1	Screening	10DEC2013	09:00	<800		
	Week 2	17DEC2013	10:00	<800		
	Week 4	31DEC2013	09:00	<800		
	Week 8	28JAN2014	08:17	<800		
	Week 12	25FEB2014	08:20	<800		

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Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
501-0004/26/M/A1	Screening	17DEC2013	06:00	<800		
	Week 2	25DEC2013	08:30	<800		
	Week 4	09JAN2014	08:00	<800		
	Week 8	07FEB2014	08:35	<800		
	Week 12	05MAR2014	08:00	<800		
501-0011/61/M/A1	Screening	25SEP2014	10:10	<800		
	Week 2	29SEP2014	08:00	<800		
	Week 4	23OCT2014	10:40	<800		
	Week 8	12NOV2014	08:30	<800		
	Week 12	10DEC2014	08:30	848		
502-0001/70/M/A1	Screening	23DEC2013	08:30	<800		
	Week 2	20DEC2013	08:20	<800		
	Week 4	03JAN2014	08:20	<800		
502-0003/48/M/A1	Screening	13JAN2014	08:00	<800		

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Listing 16.2.6.10
Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
502-0003/48/M/A1	Week 2	22JAN2014	09:20	814		
	Week 4	07FEB2014	08:30	800		
	Week 8	07MAR2014	09:30	<800		
	Week 12	04APR2014	08:40	<800		
503-0002/71/F/A1	Screening	20FEB2014	09:00	<800		
	Week 2	27FEB2014	09:00	1050		
	Week 4	13MAR2014	10:00	808		
	Week 8	10APR2014	09:30	804		
	Week 12	08MAY2014	08:50	<800		
	Week 16	03JUN2014	08:35	<800		
	Week 20	01JUL2014	08:40	<800		
	Week 24	29JUL2014	08:35	<800		
	Week 28	26AUG2014	09:01	<800		
	Week 32	23SEP2014	08:15	<800		

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Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
503-0002/71/F/A1	Week 36	21OCT2014	09:00	1300		
503-0003/47/F/A1	Screening	07MAR2014	18:15	<800		
	Week 2	13MAR2014	10:00	<800		
	Week 4	27MAR2014	12:00	857		
503-0005/72/M/A1	Screening	25MAR2014	09:50	<800		
	Week 2	01APR2014	09:00	<800		
	Week 4	15APR2014	09:00	<800		
	Week 8	13MAY2014	08:30	<800		
	Week 12	10JUN2014	08:30	<800		
	Week 16	08JUL2014	09:25	<800		
	Week 20	05AUG2014	09:10	<800		
	Week 24	02SEP2014	08:15	<800		
	Week 28	29SEP2014	08:30	<800		
	Week 32	28OCT2014	08:35	<800		

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Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
503-0005/72/M/A1	Week 36	25NOV2014	Unknown	5460		
	Week 40	23DEC2014	09:30	<800		
	Week 44	21JAN2015	09:15	<800		
	Week 48	15FEB2015	Unknown	BQL		
504-0003/53/M/A1	Screening	13MAR2014	15:15	<800		
	Week 2	20MAR2014	10:40	<800		
	Week 4	03APR2014	08:30	<800		
504-0005/41/F/A1	Screening	02SEP2014	14:15	<800		
	Week 2	10SEP2014	09:40	<800		
	Week 4	24SEP2014	09:35	<800		
504-0006/51/M/A1	Screening	04SEP2014	15:30	<800		
506-0001/43/M/A1	Screening	15APR2014	06:30	1030		
	Week 2	22APR2014	10:30	<800		
	Week 4	06MAY2014	09:10	<800		

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Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: Placebo

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506-0005/24/M/A1	Screening	21DEC2014	09:45	<800		
	Week 2	31DEC2014	09:15	<800		
507-0001/51/M/A1	Screening	23JUL2014	16:30	<800		
	Week 2	31JUL2014	09:30	<800		
	Week 4	14AUG2014	09:20	<800		
	Week 8	11SEP2014	09:10	<800		
	Week 12	09OCT2014	09:40	<800		
507-0002/44/M/A1	Screening	29JUL2014	10:55	<800		
	Week 2	05AUG2014	10:00	<800		
	Week 4	20AUG2014	08:45	<800		
	Week 8	16SEP2014	08:09	<800		
508-0002/64/M/A1	Screening	13FEB2014	08:28	<800		
	Week 2	27FEB2014	09:25	1130		
	Week 4	10MAR2014	10:43	<800		

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Pharmacokinetic Analysis Results
(Safety Population)

Treatment Group: Placebo

Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
508-0002/64/M/A1	Week 8	11APR2014	10:35	<800		
508-0004/58/M/A1	Screening	25AUG2014	10:05	<800		
	Week 2	03SEP2014	10:08	<800		
509-0003/39/M/A1	Screening	23JUL2014	15:30	<800		
	Week 2	31JUL2014	09:35	<800		
	Week 4	14AUG2014	10:30	<800		
	Week 8	11SEP2014	10:56	<800		
	Week 12	09OCT2014	10:45	<800		
510-0001/67/M/A1	Screening	25FEB2014	08:30	827		
	Week 2	05MAR2014	08:20	869		
	Week 4	19MAR2014	08:30	<800		
	Week 8	16APR2014	08:00	838		
	Week 12	14MAY2014	07:55	837		
	Week 16	11JUN2014	08:20	<800		

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Pharmacokinetic Analysis Results
(Safety Population)

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Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
510-0001/67/M/A1	Week 20	09JUL2014	08:30	851		
	Week 24	06AUG2014	08:30	<800		
	Week 28	04SEP2014	08:50	<800		
	Week 32	30SEP2014	07:30	<800		
	Week 36	29OCT2014	07:30	<800		
	Week 40	26NOV2014	07:30	<800		
510-0003/43/M/A1	Screening	04JUN2014	08:30	849		
	Week 2	11JUN2014	08:10	819		
	Week 4	25JUN2014	08:30	<800		
	Week 8	30JUL2014	09:30	<800		
513-0003/46/M/A1	Screening	25APR2014	10:14	<800		
	Week 2	07MAY2014	08:38	<800		
515-0005/45/M/A1	Screening	23JUN2014	10:00	<800		
	Week 2	30JUN2014	09:30	<800		

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Subject No./ Age [1]/ Gender/ Race [2]	Visit	Sample Date	Sample Time	ADI-PEG 20 Level (ng/ml)	Average ADI-PEG 20 Level[3] (ng/ml)	Comment
515-0005/45/M/A1	Week 4	14JUL2014	09:55	<800		
	Week 8	11AUG2014	09:20	<800		
517-0003/45/M/A1	Screening	12MAY2014	09:30	<800		
	Week 2	20MAY2014	09:05	<800		
	Week 4	04JUN2014	09:30	<800		
	Week 8	02JUL2014	09:01	<800		
	Week 12	30JUL2014	10:04	<800		
517-0010/67/M/A1	Screening	04NOV2014	09:04	<800		
	Week 2	19NOV2014	09:10	<800		
	Week 4	03DEC2014	09:10	BQL		
	Week 8	30DEC2014	08:54	BQL		
	Week 12	28JAN2015	09:26	BQL		

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