

Listing 16.2.1
Disposition
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Date of Randomization/ First/ Last Visit	Date of First/ Last Dose	Reason for Discontinuation	Reason No Longer Followed	Date of Last Contact[3]
101-0001/59/ M/A2	26JUL2011/15JUL2011 /31JAN2012	26JUL2011/30DEC2011	Disease Progression	Voluntary Withdrawal	20FEB2012
101-0005/77/ M/W2	08AUG2011/02AUG2011 /11NOV2011	09AUG2011/18OCT2011	Disease Progression	Death	17APR2013
101-0006/62/ M/W2	12AUG2011/05AUG2011 /01NOV2011	12AUG2011/07OCT2011	Disease Progression	Death	17APR2012
101-0007/77/ M/A1	16AUG2011/12AUG2011 /09DEC2011	23AUG2011/01NOV2011	Disease Progression	Death	11MAY2013
101-0008/83/ M/BL	22AUG2011/16AUG2011 /16DEC2011	26AUG2011/08NOV2011	Disease Progression	Death	11AUG2012
101-0009/82/ M/A1	14SEP2011/06SEP2011 /27JAN2012	04OCT2011/13DEC2011	Disease Progression	Death	05SEP2012
101-0011/75/ F/W2	14NOV2011/11NOV2011 /29NOV2011	15NOV2011/22NOV2011	Disease Progression	Death	03JAN2012

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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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101-0012/68/ M/W2	29NOV2011/22NOV2011 /28FEB2012	29NOV2011/10JAN2012	Disease Progression	Death	20AUG2012
101-0013/66/ F/A5	10JAN2012/03JAN2012 /08JUN2012	10JAN2012/08MAY2012	Disease Progression	Death	17JUL2014
101-0016/61/ M/A4	10JAN2012/10JAN2012 /02APR2013	13JAN2012/01MAR2013	Disease Progression	Unknown	16JUN2015*
101-0018/51/ M/A1	21FEB2012/21FEB2012 /27MAR2012	21FEB2012/06MAR2012	Disease Progression	Death	31MAR2012
101-0019/68/ M/W2	28FEB2012/21FEB2012 /05JUL2012	28FEB2012/08MAY2012	Disease Progression	Voluntary Withdrawal	14MAY2013
101-0021/74/ M/W2	20MAR2012/20MAR2012 /26JUN2012	20MAR2012/29MAY2012	Disease Progression	Death	10JUN2013
101-0022/55/ M/BL	20MAR2012/20MAR2012 /04MAY2012	20MAR2012/03APR2012	Disease Progression	Death	04JUN2012

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101-0023/70/ M/W2	30MAR2012/30MAR2012 /07SEP2012	30MAR2012/08JUN2012	Disease Progression	Death	18DEC2012
101-0024/35/ F/A4	01MAY2012/17APR2012 /14AUG2012	01MAY2012/10JUL2012	Disease Progression	Death	07NOV2013
101-0025/57/ F/W2	20APR2012/20APR2012 /03JUL2012	20APR2012/15JUN2012	Disease Progression	Death	03AUG2012
101-0026/82/ M/W2	15MAY2012/15MAY2012 /29JAN2013	15MAY2012/11JAN2013	Disease Progression	Death	17MAY2013
101-0028/60/ M/W2	15JUN2012/15JUN2012 /14SEP2012	15JUN2012/21AUG2012	Disease Progression	Death	02APR2013
101-0029/70/ M/A1	18JUN2012/15JUN2012 /04OCT2012	19JUN2012/28AUG2012	Disease Progression	Death	02AUG2013
101-0030/51/ M/W2	05JUL2012/05JUL2012 /07SEP2012	05JUL2012/28AUG2012	Disease Progression	Death	27NOV2012

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101-0032/84/ M/W2	01AUG2012/31JUL2012 /06NOV2012	01AUG2012/09OCT2012	Withdrew Consent	Death	12SEP2013
101-0033/66/ F/W2	03AUG2012/03AUG2012 /05FEB2013	03AUG2012/04JAN2013	Disease Progression	Unknown	25JUN2015*
101-0036/67/ M/A4	23OCT2012/19OCT2012 /04JAN2013	06NOV2012/27NOV2012	Disease Progression	Death	05FEB2013
101-0037/57/ M/A1	07DEC2012/04DEC2012 /05JAN2013	07DEC2012/28DEC2012	Disease Progression	Lost to Follow-up	06APR2015
101-0038/56/ M/W2	05FEB2013/18JAN2013 /14MAY2013	05FEB2013/12MAR2013	Disease Progression	Death	01FEB2014
101-0039/77/ F/W2	05APR2013/05APR2013 /30DEC2013	05APR2013/25NOV2013	Disease Progression	Unknown	26JUN2015*
101-0040/60/ M/W2	27JUN2013/18JUN2013 /09SEP2013	01JUL2013/06AUG2013	Disease Progression	Death	04NOV2013

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101-0041/54/ M/W2	30JUL2013/30JUL2013 /10SEP2013	30JUL2013/06AUG2013	Adverse Event	Death	25NOV2014
101-0042/64/ M/W2	05AUG2013/05AUG2013 /21OCT2013	05AUG2013/03SEP2013	Adverse Event	Death	12OCT2014
101-0044/78/ M/W2	17OCT2013/11OCT2013 /31JAN2014	18OCT2013/27DEC2013	Disease Progression	Death	24OCT2014
101-0045/74/ F/W2	21OCT2013/21OCT2013 /21JAN2014	04NOV2013/14JAN2014	Disease Progression	Death	03JUN2014
101-0046/70/ M/OTH	22OCT2013/21OCT2013 /04FEB2014	22OCT2013/31DEC2013	Disease Progression	Death	04JUN2014
101-0047/52/ M/W2	22OCT2013/21OCT2013 /20JAN2014	22OCT2013/09DEC2013	Disease Progression	Death	11MAR2015
101-0048/66/ F/W2	22OCT2013/21OCT2013 /04FEB2014	22OCT2013/30DEC2013	Disease Progression	Unknown	25JUN2015*

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101-0049/71/ M/A8	28OCT2013/22OCT2013 /10FEB2014	28OCT2013/06JAN2014	Disease Progression	Unknown	24JUN2015*
101-0050/59/ M/W2	29OCT2013/29OCT2013 /10DEC2013	29OCT2013/02DEC2013	Death	Death	15JAN2014
102-0001/53/ M/BL	25APR2012/25APR2012 /03JUL2012	25APR2012/05JUN2012	Disease Progression	Death	07SEP2012
102-0003/63/ M/BL	12SEP2012/29AUG2012 /28NOV2012	12SEP2012/28NOV2012	Disease Progression	Death	07JAN2013
102-0008/64/ M/BL	08JAN2014/02JAN2014 /05FEB2014	08JAN2014/05FEB2014	Adverse Event	Death	05FEB2014
102-0009/58/ M/W2	29OCT2014/08OCT2014 /13JAN2015	29OCT2014/10DEC2014	Disease Progression	Death	19FEB2015
103-0001/56/ M/W2	11MAY2012/07MAY2012 /20AUG2012	11MAY2012/20JUL2012	Disease Progression	Death	23OCT2012

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103-0003/66/ M/W2	15FEB2013/04FEB2013 /19AUG2013	15FEB2013/18JUL2013	Disease Progression	Death	26OCT2013
103-0004/40/ F/A1	17APR2014/11APR2014 /09JUN2014	21APR2014/02JUN2014	Disease Progression	Death	01SEP2014
104-0003/56/ F/W2	19JUL2012/09JUL2012 /29SEP2012	19JUL2012/29AUG2012	Disease Progression	Death	29OCT2012
104-0004/74/ M/W2	23OCT2012/18OCT2012 /11DEC2012	26OCT2012/06NOV2012	Disease Progression	Death	12JUN2013
104-0008/55/ M/PI	03SEP2013/09AUG2013 /27DEC2013	03SEP2013/22NOV2013	Disease Progression	Death	14OCT2014
104-0010/71/ F/A8	08JAN2014/23DEC2013 /01OCT2014	08JAN2014/17SEP2014	Disease Progression	Unknown	03JUN2015*
104-0012/78/ F/A2	02OCT2014/23SEP2014 /23DEC2014	02OCT2014/24NOV2014	Disease Progression	Death	25MAR2015

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106-0001/42/ F/W2	28FEB2012/20FEB2012 /02JUL2012	05MAR2012/25JUN2012	Disease Progression	Lost to Follow-up	02JUL2012
107-0002/71/ M/W2	23AUG2012/15AUG2012 /05DEC2012	27AUG2012/05NOV2012	Disease Progression	Death	23DEC2013
107-0003/73/ M/BL	22FEB2013/18FEB2013 /03MAY2013	25FEB2013/23APR2013	Withdrew Consent	Death	07MAY2013
107-0004/63/ M/W2	01MAR2013/18FEB2013 /18JUN2013	04MAR2013/14MAY2013	Withdrew Consent	Unknown	29JUN2015*
107-0006/60/ M/W2	14MAY2013/06MAY2013 /19AUG2013	14MAY2013/23JUL2013	Disease Progression	Death	07APR2014
108-0001/60/ F/W2	20MAR2012/07MAR2012 /09MAY2012	21MAR2012/02MAY2012	Disease Progression	Death	19JUN2012
108-0002/78/ M/BL	31MAY2012/25MAY2012 /10JUL2012	31MAY2012/05JUL2012	Disease Progression	Death	03APR2013

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108-0004/61/ M/W2	18APR2013/04APR2013 /30MAY2013	18APR2013/09MAY2013	Other	Death	07JUL2014
108-0005/68/ M/W2	08MAY2013/22APR2013 /30JUL2013	08MAY2013/17JUL2013	Disease Progression	Death	19OCT2013
108-0008/77/ M/W2	09OCT2014/01OCT2014 /16APR2015	09OCT2014/05MAR2015	Disease Progression	Unknown	04JUN2015*
109-0003/68/ M/W2	03MAY2013/30APR2013 /25JUL2013	06MAY2013/01JUL2013	Disease Progression	Death	08AUG2013
109-0004/57/ M/W2	19JUL2013/12JUL2013 /09OCT2013	19JUL2013/03OCT2013	Disease Progression	Death	14MAR2014
109-0006/62/ M/PI	22AUG2013/14AUG2013 /09DEC2013	23AUG2013/30OCT2013	Disease Progression	Death	16SEP2014
109-0007/55/ M/W2	05DEC2013/02DEC2013 /21MAY2014	10DEC2013/15APR2014	Disease Progression	Death	16SEP2014

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109-0010/65/ M/W2	09JUL2014/25JUN2014 /22OCT2014	09JUL2014/17SEP2014	Disease Progression	Unknown	18JUN2015*
109-0011/64/ M/A4	24SEP2014/17SEP2014 /07JAN2015	25SEP2014/03DEC2014	Disease Progression	Unknown	12JUN2015*
109-0013/64/ F/W2	05NOV2014/30OCT2014 /05MAY2015	05NOV2014/06APR2015	Disease Progression	Death	12MAY2015
110-0003/63/ M/OTH	09JUL2012/25JUN2012 /18DEC2012	09JUL2012/10DEC2012	Disease Progression	Death	07DEC2013
110-0004/53/ M/A4	25OCT2012/11OCT2012 /11JAN2013	25OCT2012/03JAN2013	Disease Progression	Death	03DEC2013

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110-0007/62/ M/A4	17MAY2013/03MAY2013 /20JAN2014	17MAY2013/13DEC2013	Disease Progression	Death	26FEB2014
110-0008/63/ F/BL	09JUL2013/26JUN2013 /03SEP2013	09JUL2013/05AUG2013	Disease Progression	Death	03MAR2014
110-0011/77/ M/A1	22JAN2015/12JAN2015 /17APR2015	22JAN2015/03APR2015	Disease Progression	Unknown	09JUN2015*
111-0001/37/ M/A4	12JUL2012/28JUN2012 /29AUG2012	12JUL2012/26JUL2012	Disease Progression	Death	08JUL2014
111-0004/64/ M/W2	23MAY2013/02MAY2013 /31JUL2013	23MAY2013/27JUN2013	Disease Progression	Death	18OCT2013
111-0006/59/ M/W2	03OCT2013/03OCT2013 /07MAY2014	10OCT2013/02APR2014	Death	Death	12MAY2014

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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] * means subject is on follow-up, the last telephone contacted date is used; + means subject is still ongoing at the time of database lock, the last dose date is used; # means subject is discontinued from treatment within 30-35 days before database lock, date of EOT visit is used.

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Listing 16.2.1
Disposition
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Date of Randomization/ First/ Last Visit	Date of First/ Last Dose	Reason for Discontinuation	Reason No Longer Followed	Date of Last Contact[3]
111-0007/55/ M/W2	06FEB2014/23JAN2014 /22MAY2014	06FEB2014/10APR2014	Disease Progression	Unknown	12JUN2015*
112-0006/58/ M/W2	26MAR2013/15MAR2013 /28JUN2013	26MAR2013/03JUN2013	Disease Progression	Death	29AUG2013
112-0009/50/ M/A8	19JUN2013/12JUN2013 /13SEP2013	19JUN2013/14AUG2013	Disease Progression	Death	06DEC2013
112-0011/56/ M/A4	10JAN2014/03JAN2014 /28MAR2014	10JAN2014/21FEB2014	Disease Progression	Death	23JUN2014
112-0012/71/ M/W2	23MAY2014/16MAY2014 /19SEP2014	23MAY2014/08AUG2014	Disease Progression	Death	07FEB2015
112-0013/28/ F/W2	23MAY2014/16MAY2014 /29AUG2014	23MAY2014/11JUL2014	Other	Death	29AUG2014
112-0014/79/ M/A8	06JUN2014/30MAY2014 /19SEP2014	06JUN2014/15AUG2014	Disease Progression	Death	24OCT2014

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

[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = 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 16.2.1
Disposition
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Date of Randomization/ First/ Last Visit	Date of First/ Last Dose	Reason for Discontinuation	Reason No Longer Followed	Date of Last Contact[3]
112-0015/66/ M/A8	24OCT2014/17OCT2014 /12DEC2014	24OCT2014/03DEC2014	Disease Progression	Death	02JAN2015
113-0001/60/ M/W2	24AUG2012/09AUG2012 /11MAR2013	24AUG2012/28JAN2013	Disease Progression	Death	18NOV2013
113-0002/64/ F/W2	12OCT2012/10AUG2012 /24JUN2013	15OCT2012/10JUN2013	Disease Progression	Death	22APR2014
113-0005/58/ M/W2	22JAN2014/08JAN2014 /12MAR2014	22JAN2014/12MAR2014	Withdrew Consent	Voluntary Withdrawal	20MAR2014
113-0008/78/ M/A8	13FEB2014/07FEB2014 /13FEB2014	13FEB2014/13FEB2014	Withdrew Consent	Unknown	16JUN2015*
113-0010/59/ M/W2	28APR2014/16APR2014 /23MAY2014	28APR2014/23MAY2014	Disease Progression	Other	04JUN2014
113-0013/56/ M/W2	04NOV2014/29OCT2014 /26JAN2015	04NOV2014/12JAN2015	Disease Progression	Unknown	10JUN2015*

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Listing 16.2.1
Disposition
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Date of Randomization/ First/ Last Visit	Date of First/ Last Dose	Reason for Discontinuation	Reason No Longer Followed	Date of Last Contact[3]
113-0016/72/ M/A8	03FEB2015/22JAN2015 /18MAY2015	03FEB2015/15APR2015	Disease Progression	Unknown	17JUN2015*
114-0003/59/ M/W2	29NOV2012/13NOV2012 /16APR2013	29NOV2012/10APR2013	Disease Progression	Death	07OCT2013
114-0005/73/ M/W2	05DEC2013/04DEC2013 /12FEB2014	11DEC2013/06FEB2014	Disease Progression	Voluntary Withdrawal	09APR2015
114-0007/60/ F/W2	18NOV2014/14NOV2014 /Unknown	19NOV2014/07JUL2015		Unknown	07JUL2015+
115-0001/59/ F/A4	27NOV2012/14NOV2012 /22MAR2013	27NOV2012/05FEB2013	Disease Progression	Unknown	02JUN2015*
115-0002/45/ F/W2	27NOV2012/14NOV2012 /07FEB2013	27NOV2012/08JAN2013	Disease Progression	Death	19FEB2013
115-0003/63/ M/W2	17JAN2013/14JAN2013 /29JUL2013	17JAN2013/01JUL2013	Disease Progression	Death	20AUG2013

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Listing 16.2.1
Disposition
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Date of Randomization/ First/ Last Visit	Date of First/ Last Dose	Reason for Discontinuation	Reason No Longer Followed	Date of Last Contact[3]
115-0008/51/ M/A8	19JUN2013/13JUN2013 /22JUL2013	19JUN2013/02JUL2013	Death	Death	22JUL2013
115-0009/85/ M/W2	12DEC2013/03DEC2013 /12JUN2014	12DEC2013/15MAY2014	Disease Progression	Death	03SEP2014
115-0011/56/ M/W2	05JUN2014/30MAY2014 /25SEP2014	06JUN2014/28AUG2014	Disease Progression	Death	01DEC2014
115-0014/72/ M/W2	10FEB2015/30JAN2015 /10APR2015	10FEB2015/17MAR2015	Disease Progression	Death	11MAY2015
116-0002/67/ F/W2	18MAR2013/11MAR2013 /02DEC2013	18MAR2013/11NOV2013	Disease Progression	Death	14DEC2013
116-0003/66/ M/BL	28MAR2013/18MAR2013 /23MAY2013	28MAR2013/30APR2013	Disease Progression	Death	29MAY2013
117-0001/69/ M/W2	02APR2013/19MAR2013 /18JUN2013	02APR2013/11JUN2013	Disease Progression	Death	12NOV2014

[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 16.2.1
Disposition
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Date of Randomization/ First/ Last Visit	Date of First/ Last Dose	Reason for Discontinuation	Reason No Longer Followed	Date of Last Contact[3]
118-0001/67/ F/A8	09AUG2013/06AUG2013 /22NOV2013	12AUG2013/22OCT2013	Disease Progression	Death	29NOV2014
119-0001/80/ M/A8	21JAN2014/07JAN2014 /14FEB2014	21JAN2014/28JAN2014	Adverse Event	Death	14FEB2014
121-0001/62/ M/W2	14FEB2014/11FEB2014 /06JUN2014	18FEB2014/06MAY2014	Withdrew Consent	Voluntary Withdrawal	02DEC2014
201-0001/68/ F/W2	25JAN2012/17JAN2012 /23MAY2012	26JAN2012/19APR2012	Disease Progression	Death	08OCT2012
201-0005/73/ M/W2	19JUL2012/29JUN2012 /21NOV2012	19JUL2012/04OCT2012	Disease Progression	Death	21JAN2013
201-0008/79/ M/W2	16MAY2013/03MAY2013 /01AUG2013	16MAY2013/17JUL2013	Other	Death	21OCT2013
201-0011/73/ M/W2	04JUL2013/21JUN2013 /21OCT2013	04JUL2013/18SEP2013	Disease Progression	Unknown	19JUN2015*

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Listing 16.2.1
Disposition
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Date of Randomization/ First/ Last Visit	Date of First/ Last Dose	Reason for Discontinuation	Reason No Longer Followed	Date of Last Contact[3]
201-0012/79/ M/W2	24JUL2013/05JUL2013 /15OCT2014	24JUL2013/11SEP2014	Disease Progression	Unknown	19JUN2015*
201-0013/67/ F/W2	24JUL2013/18JUL2013 /11NOV2013	24JUL2013/10OCT2013	Disease Progression	Death	20MAY2014
201-0016/72/ M/W2	14NOV2013/24OCT2013 /21MAY2014	14NOV2013/17APR2014	Disease Progression	Death	19MAY2015
201-0017/82/ M/W2	28NOV2013/06NOV2013 /30JAN2014	28NOV2013/06DEC2013	Adverse Event	Death	26MAR2015
201-0018/78/ F/W2	06DEC2013/26NOV2013 /19DEC2013	06DEC2013/19DEC2013	Other	Death	27JAN2014
201-0019/68/ M/W2	19DEC2013/10DEC2013 /07APR2014	19DEC2013/06MAR2014	Disease Progression	Unknown	19JUN2015*
201-0020/67/ M/W2	23JAN2014/17JAN2014 /24MAR2014	23JAN2014/30JAN2014	Adverse Event	Unknown	22JUN2015*

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Listing 16.2.1
Disposition
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Date of Randomization/ First/ Last Visit	Date of First/ Last Dose	Reason for Discontinuation	Reason No Longer Followed	Date of Last Contact[3]
201-0021/54/ M/W2	13FEB2014/30JAN2014 /04JUN2014	13FEB2014/30APR2014	Disease Progression	Death	02JUL2014
201-0024/74/ M/W2	29JAN2015/16JAN2015 /11MAR2015	29JAN2015/11MAR2015	Disease Progression	Death	13APR2015
201-0025/75/ M/W2	29JAN2015/21JAN2015 /19MAR2015	29JAN2015/13FEB2015	Other	Unknown	19JUN2015*
203-0001/61/ F/W2	06MAR2012/29FEB2012 /30APR2012	06MAR2012/13APR2012	Adverse Event	Death	30APR2012
203-0002/72/ M/W2	06MAR2012/01MAR2012 /19APR2012	06MAR2012/11APR2012	Death	Death	19APR2012
203-0005/53/ M/W2	05APR2012/29MAR2012 /21SEP2012	05APR2012/05JUL2012	Disease Progression	Death	23DEC2014
203-0013/68/ M/W2	30DEC2013/23DEC2013 /31JAN2014	30DEC2013/22JAN2014	Disease Progression	Death	30APR2014

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Listing 16.2.1
Disposition
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Date of Randomization/ First/ Last Visit	Date of First/ Last Dose	Reason for Discontinuation	Reason No Longer Followed	Date of Last Contact[3]
203-0015/85/ M/W2	30JAN2014/17JAN2014 /14APR2014	30JAN2014/04APR2014	Disease Progression	Death	19SEP2014
203-0017/58/ M/W2	03MAR2014/18FEB2014 /12MAR2014	03MAR2014/12MAR2014	Adverse Event	Death	29AUG2014
203-0018/58/ F/W2	04APR2014/26MAR2014 /16JUN2014	04APR2014/11JUN2014	Adverse Event	Death	22SEP2014
205-0001/77/ M/W2	24FEB2012/14FEB2012 /12NOV2013	24FEB2012/01OCT2013	Disease Progression	Death	26NOV2014
205-0004/77/ F/W2	20MAR2012/12MAR2012 /24JUN2012	20MAR2012/05JUN2012	Disease Progression	Death	24JUN2012
205-0008/76/ M/W2	27APR2012/20APR2012 /12JUN2012	27APR2012/10MAY2012	Disease Progression	Death	30JUL2012
205-0012/73/ F/W2	06DEC2012/27NOV2012 /08JAN2013	06DEC2012/20DEC2012	Disease Progression	Death	08JAN2013

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Listing 16.2.1
Disposition
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Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Date of Randomization/ First/ Last Visit	Date of First/ Last Dose	Reason for Discontinuation	Reason No Longer Followed	Date of Last Contact[3]
205-0015/71/ M/W2	19JUN2013/07JUN2013 /03SEP2013	19JUN2013/02AUG2013	Adverse Event	Death	11SEP2014
205-0016/70/ M/W2	25JUN2013/11JUN2013 /Unknown	25JUN2013/18JUN2015		Unknown	18JUN2015+
205-0017/71/ M/W2	08AUG2013/02AUG2013 /18FEB2014	08AUG2013/14JAN2014	Disease Progression	Death	18AUG2014
205-0020/82/ M/W2	11OCT2013/01OCT2013 /23DEC2013	11OCT2013/23DEC2013	Disease Progression	Death	24JUN2015
205-0022/67/ M/W2	05NOV2013/25OCT2013 /12NOV2013	05NOV2013/12NOV2013	Adverse Event	Death	28NOV2013
205-0024/80/ M/W2	03DEC2013/19NOV2013 /18APR2014	03DEC2013/07MAR2014	Disease Progression	Death	20AUG2014
205-0025/63/ F/W2	29NOV2013/21NOV2013 /28FEB2014	29NOV2013/14FEB2014	Disease Progression	Death	21MAR2014

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Listing 16.2.1
Disposition
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Date of Randomization/ First/ Last Visit	Date of First/ Last Dose	Reason for Discontinuation	Reason No Longer Followed	Date of Last Contact[3]
207-0001/81/ F/W2	19MAR2012/08MAR2012 /23APR2012	19MAR2012/19MAR2012	Other	Death	21DEC2012
207-0005/74/ M/W2	12JUN2012/21MAY2012 /04JUL2012	12JUN2012/12JUN2012	Withdrew Consent	Voluntary Withdrawal	04JUL2012
207-0006/73/ M/W2	18JUN2012/08JUN2012 /19SEP2012	18JUN2012/03SEP2012	Disease Progression	Death	19SEP2012
207-0008/66/ M/W2	09JUL2012/25JUN2012 /28AUG2012	09JUL2012/13AUG2012	Disease Progression	Death	13AUG2012
207-0011/78/ M/W2	21JAN2013/09JAN2013 /21JAN2013	21JAN2013/21JAN2013	Adverse Event	Other	26FEB2013
207-0015/77/ M/W2	13AUG2013/08AUG2013 /28NOV2013	13AUG2013/22OCT2013	Disease Progression	Death	16OCT2014
207-0020/77/ M/W2	18JUN2014/11JUN2014 /05SEP2014	18JUN2014/13AUG2014	Disease Progression	Death	29SEP2014

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(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Date of Randomization/ First/ Last Visit	Date of First/ Last Dose	Reason for Discontinuation	Reason No Longer Followed	Date of Last Contact[3]
207-0021/74/ M/W2	19JUN2014/11JUN2014 /20FEB2015	19JUN2014/13FEB2015	Disease Progression	Death	10APR2015
207-0022/74/ M/W2	10JUL2014/30JUN2014 /21OCT2014	10JUL2014/18SEP2014	Other	Unknown	25JUN2015*
208-0001/59/ M/W2	20SEP2012/07SEP2012 /Unknown	20SEP2012/07JUL2015		Unknown	07JUL2015+
208-0002/82/ F/W2	20SEP2012/07SEP2012 /12DEC2012	20SEP2012/16NOV2012	Disease Progression	Death	08MAR2013
208-0006/69/ F/W2	28AUG2013/19AUG2013 /27DEC2013	28AUG2013/27NOV2013	Disease Progression	Death	30AUG2014
208-0007/53/ M/W2	07JUL2014/23JUN2014 /08OCT2014	07JUL2014/01OCT2014	Disease Progression	Unknown	04JUN2015*
209-0001/66/ M/W2	15NOV2012/08NOV2012 /28FEB2013	15NOV2012/31JAN2013	Disease Progression	Death	18APR2013

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

[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.

[3] * means subject is on follow-up, the last telephone contacted date is used; + means subject is still ongoing at the time of database lock, the last dose date is used; # means subject is discontinued from treatment within 30-35 days before database lock, date of EOT visit is used.

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Listing 16.2.1
Disposition
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Date of Randomization/ First/ Last Visit	Date of First/ Last Dose	Reason for Discontinuation	Reason No Longer Followed	Date of Last Contact[3]
209-0004/74/ M/W2	09APR2013/28MAR2013 /02AUG2013	09APR2013/25JUN2013	Disease Progression	Death	15OCT2013
209-0008/66/ M/W2	11JUL2013/26JUN2013 /24SEP2013	11JUL2013/24SEP2013	Disease Progression	Death	25OCT2013
209-0012/63/ M/W2	03DEC2013/26NOV2013 /17JUN2014	03DEC2013/15MAY2014	Disease Progression	Death	06AUG2014
209-0013/52/ M/W2	23DEC2013/10DEC2013 /23SEP2014	23DEC2013/26AUG2014	Disease Progression	Unknown	17JUN2015*
210-0001/67/ M/W2	30AUG2013/19AUG2013 /13MAR2014	30AUG2013/13FEB2014	Disease Progression	Death	07MAY2014
210-0002/80/ M/W2	09OCT2013/27SEP2013 /10SEP2014	09OCT2013/27AUG2014	Disease Progression	Death	27MAY2015
210-0007/72/ M/W2	07JUL2014/19JUN2014 /Unknown	07JUL2014/07JUL2015		Unknown	07JUL2015+

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Listing 16.2.1
Disposition
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Date of Randomization/ First/ Last Visit	Date of First/ Last Dose	Reason for Discontinuation	Reason No Longer Followed	Date of Last Contact[3]
210-0009/49/ F/W2	10NOV2014/28OCT2014 /28JAN2015	10NOV2014/28JAN2015	Disease Progression	Unknown	18JUN2015*
210-0011/73/ M/W2	17NOV2014/05NOV2014 /04FEB2015	17NOV2014/04FEB2015	Disease Progression	Death	06MAR2015
210-0012/47/ F/W2	16DEC2014/02DEC2014 /14APR2015	16DEC2014/19MAR2015	Disease Progression	Unknown	18JUN2015*
210-0014/71/ F/W2	26JAN2015/13JAN2015 /22MAY2015	26JAN2015/29APR2015	Disease Progression	Unknown	18JUN2015*
251-0001/55/ F/W2	24JUL2012/23JUL2012 /06DEC2012	31JUL2012/06NOV2012	Disease Progression	Other	06DEC2012
252-0002/76/ M/W2	28AUG2012/21AUG2012 /02OCT2012	28AUG2012/04SEP2012	Adverse Event	Death	17DEC2012
252-0003/68/ M/W2	28DEC2012/11DEC2012 /23APR2013	31DEC2012/19MAR2013	Disease Progression	Death	22AUG2013

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Listing 16.2.1
Disposition
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Date of Randomization/ First/ Last Visit	Date of First/ Last Dose	Reason for Discontinuation	Reason No Longer Followed	Date of Last Contact[3]
252-0011/81/ M/BL	24NOV2014/18NOV2014 /Unknown	25NOV2014/07JUL2015		Unknown	07JUL2015+
253-0002/63/ M/W2	09MAR2012/02MAR2012 /08JUN2012	09MAR2012/04MAY2012	Other	Death	08JUN2012
253-0010/76/ M/W2	07JUN2013/31MAY2013 /06DEC2013	07JUN2013/08NOV2013	Disease Progression	Death	06MAY2014
254-0001/69/ M/W2	17MAY2012/04MAY2012 /24SEP2012	18MAY2012/14AUG2012	Disease Progression	Death	04DEC2012
257-0001/47/ M/A4	04APR2012/29MAR2012 /28JUN2012	05APR2012/24MAY2012	Adverse Event	Death	10SEP2012
257-0002/56/ M/W2	18APR2012/12APR2012 /24MAY2012	19APR2012/17MAY2012	Adverse Event	Death	22DEC2012
257-0007/80/ M/W2	21FEB2013/13FEB2013 /20JUN2013	21FEB2013/09MAY2013	Disease Progression	Death	20JAN2014

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Listing 16.2.1
Disposition
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Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Date of Randomization/ First/ Last Visit	Date of First/ Last Dose	Reason for Discontinuation	Reason No Longer Followed	Date of Last Contact[3]
257-0008/80/ F/W2	26MAR2013/21MAR2013 /22JUL2013	28MAR2013/13JUN2013	Disease Progression	Death	06JUN2014
257-0010/42/ M/BL	23MAY2013/16MAY2013 /05AUG2013	23MAY2013/05AUG2013	Disease Progression	Unknown	13MAY2015*
257-0012/75/ M/W2	13MAY2013/09MAY2013 /25JUN2013	13MAY2013/07JUN2013	Death	Death	25JUN2013
257-0015/69/ F/BL	14APR2014/31MAR2014 /01MAY2014	14APR2014/14APR2014	Adverse Event	Death	25MAY2014
257-0017/74/ M/A8	02MAY2014/28APR2014 /28JUL2014	02MAY2014/21JUL2014	Disease Progression	Death	10JUL2015
257-0018/53/ M/A6	28APR2014/24APR2014 /31MAY2014	28APR2014/02MAY2014	Adverse Event	Death	31MAY2014
257-0022/60/ M/W2	01DEC2014/26NOV2014 /09FEB2015	01DEC2014/12JAN2015	Adverse Event	Death	29MAY2015

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Disposition
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Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Date of Randomization/ First/ Last Visit	Date of First/ Last Dose	Reason for Discontinuation	Reason No Longer Followed	Date of Last Contact[3]
257-0024/75/ M/W2	22DEC2014/15DEC2014 /02MAR2015	23DEC2014/23FEB2015	Disease Progression	Death	31MAR2015
257-0025/69/ M/BL	22DEC2014/15DEC2014 /16MAR2015	22DEC2014/09MAR2015	Disease Progression	Death	30APR2015
257-0026/65/ M/MIX	19JAN2015/12JAN2015 /13APR2015	19JAN2015/30MAR2015	Disease Progression	Unknown	30JUN2015*
257-0027/52/ M/A6	19JAN2015/12JAN2015 /23FEB2015	19JAN2015/16FEB2015	Adverse Event	Death	02MAR2015
258-0005/64/ M/OTH	09AUG2013/31JUL2013 /18OCT2013	12AUG2013/18SEP2013	Adverse Event	Death	02MAY2014
258-0007/74/ M/W2	09OCT2013/02OCT2013 /01NOV2013	10OCT2013/18OCT2013	Withdrew Consent	Death	14NOV2013
258-0008/70/ M/W2	18NOV2013/06NOV2013 /02JAN2014	18NOV2013/18NOV2013	Adverse Event	Death	03MAR2014

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Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Date of Randomization/ First/ Last Visit	Date of First/ Last Dose	Reason for Discontinuation	Reason No Longer Followed	Date of Last Contact[3]
258-0009/64/ M/W2	19MAY2014/16MAY2014 /26NOV2014	21MAY2014/29OCT2014	Disease Progression	Death	16MAR2015
258-0010/53/ M/W2	02JUN2014/30MAY2014 /10DEC2014	04JUN2014/12NOV2014	Disease Progression	Unknown	03JUN2015*
258-0012/66/ F/W2	15JUL2014/09JUL2014 /12NOV2014	16JUL2014/09OCT2014	Disease Progression	Death	18MAR2015
258-0015/65/ M/W2	02DEC2014/28NOV2014 /04FEB2015	03DEC2014/02JAN2015	Adverse Event	Unknown	26JUN2015*
259-0001/68/ F/W2	03JUN2013/24MAY2013 /23JUL2014	05JUN2013/11JUN2014	Adverse Event	Unknown	18JUN2015*
259-0002/54/ F/W2	09SEP2013/04SEP2013 /02JAN2014	11SEP2013/27NOV2013	Disease Progression	Death	06JUL2014
260-0003/81/ M/A7	05NOV2014/22OCT2014 /Unknown	05NOV2014/08JUL2015		Unknown	08JUL2015+

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Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Date of Randomization/ First/ Last Visit	Date of First/ Last Dose	Reason for Discontinuation	Reason No Longer Followed	Date of Last Contact[3]
301-0005/61/ M/A2	24MAY2012/17MAY2012 /11SEP2012	24MAY2012/09AUG2012	Disease Progression	Death	14DEC2012
301-0007/55/ F/A2	04JAN2013/26DEC2012 /26MAR2013	04JAN2013/15MAR2013	Adverse Event	Death	28MAR2013
301-0009/55/ M/A2	11JAN2013/08JAN2013 /28MAR2013	11JAN2013/19MAR2013	Disease Progression	Death	11MAY2013
302-0002/32/ F/A2	07NOV2011/07NOV2011 /15DEC2011	08NOV2011/29NOV2011	Disease Progression	Death	15DEC2011
302-0004/57/ M/A2	10JAN2012/04JAN2012 /21MAR2012	10JAN2012/28FEB2012	Disease Progression	Death	21MAR2012
302-0007/76/ M/A2	14FEB2012/07FEB2012 /12JUN2012	14FEB2012/01MAY2012	Disease Progression	Death	25MAR2013
302-0008/37/ M/A2	28FEB2012/21FEB2012 /19JUN2012	28FEB2012/08MAY2012	Disease Progression	Death	07SEP2012

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Subject No./ Age[1]/ Gender/ Race[2]	Date of Randomization/ First/ Last Visit	Date of First/ Last Dose	Reason for Discontinuation	Reason No Longer Followed	Date of Last Contact[3]
302-0010/45/ M/A2	17APR2012/10APR2012 /06AUG2012	17APR2012/03JUL2012	Disease Progression	Death	08DEC2012
302-0011/52/ M/A2	24APR2012/17APR2012 /29MAY2012	24APR2012/15MAY2012	Withdrew Consent	Death	06JUN2012
302-0015/60/ M/A2	16APR2013/11APR2013 /08JUL2013	16APR2013/02JUL2013	Disease Progression	Death	10MAR2014
302-0016/60/ M/A2	16APR2013/11APR2013 /06AUG2013	16APR2013/02JUL2013	Disease Progression	Death	28JAN2014
302-0019/52/ M/A2	14MAY2013/09MAY2013 /29AUG2013	14MAY2013/30JUL2013	Disease Progression	Death	20MAY2014
302-0022/65/ M/A2	09JUL2013/04JUL2013 /05OCT2013	09JUL2013/17SEP2013	Disease Progression	Death	05OCT2013
302-0023/68/ M/A2	10SEP2013/03SEP2013 /14NOV2013	10SEP2013/15OCT2013	Withdrew Consent	Death	07SEP2014

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Subject No./ Age[1]/ Gender/ Race[2]	Date of Randomization/ First/ Last Visit	Date of First/ Last Dose	Reason for Discontinuation	Reason No Longer Followed	Date of Last Contact[3]
302-0024/66/ F/A2	24SEP2013/17SEP2013 /09JAN2014	24SEP2013/10DEC2013	Disease Progression	Death	09APR2015
302-0025/40/ M/A2	22OCT2013/17OCT2013 /10DEC2013	22OCT2013/05NOV2013	Adverse Event	Death	06JUL2014
302-0026/49/ M/A2	12NOV2013/05NOV2013 /14AUG2014	12NOV2013/15JUL2014	Disease Progression	Unknown	18JUN2015*
303-0001/50/ M/A2	03FEB2012/20JAN2012 /18MAY2012	03FEB2012/18APR2012	Disease Progression	Death	18FEB2013
303-0003/47/ M/A2	28NOV2012/14NOV2012 /19MAR2013	28NOV2012/15FEB2013	Disease Progression	Death	25APR2013
303-0004/18/ M/A2	10DEC2012/26NOV2012 /27MAR2013	10DEC2012/20FEB2013	Disease Progression	Death	14MAY2013
303-0006/64/ M/A2	10APR2013/27MAR2013 /19JUN2013	10APR2013/20MAY2013	Disease Progression	Death	25JUL2013

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Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Date of Randomization/ First/ Last Visit	Date of First/ Last Dose	Reason for Discontinuation	Reason No Longer Followed	Date of Last Contact[3]
303-0007/50/ M/A2	24JUL2013/10JUL2013 /25OCT2013	24JUL2013/25SEP2013	Disease Progression	Death	25OCT2013
304-0001/54/ M/A2	05NOV2012/30OCT2012 /07JAN2013	06NOV2012/04DEC2012	Disease Progression	Death	04MAR2013
304-0005/58/ M/A2	05JUN2013/29MAY2013 /29JUN2013	05JUN2013/26JUN2013	Disease Progression	Death	05JUL2013
305-0002/57/ M/A2	14FEB2012/13FEB2012 /15MAR2012	14FEB2012/14FEB2012	Disease Progression	Death	23DEC2013
305-0003/50/ M/A2	15FEB2012/14FEB2012 /24AUG2012	15FEB2012/27JUL2012	Disease Progression	Death	07AUG2013
305-0005/48/ M/A2	21FEB2012/14FEB2012 /22MAR2012	21FEB2012/15MAR2012	Withdrew Consent	Death	30JUN2015
305-0006/65/ M/A2	08MAR2012/06MAR2012 /22AUG2012	08MAR2012/15AUG2012	Disease Progression	Death	22OCT2012

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

[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.

[3] * means subject is on follow-up, the last telephone contacted date is used; + means subject is still ongoing at the time of database lock, the last dose date is used; # means subject is discontinued from treatment within 30-35 days before database lock, date of EOT visit is used.

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Listing 16.2.1
Disposition
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Date of Randomization/ First/ Last Visit	Date of First/ Last Dose	Reason for Discontinuation	Reason No Longer Followed	Date of Last Contact[3]
305-0009/45/ F/A2	11APR2012/11APR2012 /17OCT2012	11APR2012/19SEP2012	Disease Progression	Death	01AUG2014
305-0010/64/ F/A2	18APR2012/16APR2012 /07AUG2012	18APR2012/04JUL2012	Disease Progression	Death	16SEP2013
305-0011/68/ M/A2	27APR2012/20APR2012 /10AUG2012	27APR2012/27JUL2012	Disease Progression	Death	14DEC2012
305-0012/62/ F/A2	04MAY2012/03MAY2012 /01FEB2013	04MAY2012/04JAN2013	Disease Progression	Unknown	29JUN2015*
305-0014/61/ F/A2	10JUL2012/03JUL2012 /23OCT2012	10JUL2012/18SEP2012	Disease Progression	Death	09MAR2013
305-0019/35/ M/A2	11SEP2012/04SEP2012 /06NOV2012	11SEP2012/16OCT2012	Adverse Event	Death	16NOV2012
305-0023/54/ M/A2	02JAN2013/02JAN2013 /11JUN2013	08JAN2013/07MAY2013	Withdrew Consent	Death	24SEP2013

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

[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.

[3] * means subject is on follow-up, the last telephone contacted date is used; + means subject is still ongoing at the time of database lock, the last dose date is used; # means subject is discontinued from treatment within 30-35 days before database lock, date of EOT visit is used.

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Listing 16.2.1
Disposition
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Date of Randomization/ First/ Last Visit	Date of First/ Last Dose	Reason for Discontinuation	Reason No Longer Followed	Date of Last Contact[3]
305-0025/77/ F/A2	22JAN2013/15JAN2013 /17APR2013	22JAN2013/02APR2013	Adverse Event	Death	02AUG2013
305-0026/45/ M/A2	26FEB2013/20FEB2013 /20AUG2013	26FEB2013/13AUG2013	Withdrew Consent	Death	20DEC2013
305-0028/73/ F/A2	15MAR2013/13MAR2013 /05JUN2013	15MAR2013/29MAY2013	Disease Progression	Death	16JUN2013
305-0030/61/ M/A2	02APR2013/21MAR2013 /07JUN2013	02APR2013/14MAY2013	Withdrew Consent	Death	26JUN2014
305-0031/29/ M/A2	02APR2013/22MAR2013 /03MAY2013	02APR2013/23APR2013	Disease Progression	Death	13MAY2013
305-0034/53/ M/A2	03JUL2013/26JUN2013 /05AUG2013	03JUL2013/31JUL2013	Disease Progression	Death	24AUG2013
305-0036/38/ M/A2	05SEP2013/27AUG2013 /28NOV2013	05SEP2013/19NOV2013	Disease Progression	Lost to Follow-up	22MAY2014

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

[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.

[3] * means subject is on follow-up, the last telephone contacted date is used; + means subject is still ongoing at the time of database lock, the last dose date is used; # means subject is discontinued from treatment within 30-35 days before database lock, date of EOT visit is used.

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Listing 16.2.1
Disposition
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Date of Randomization/ First/ Last Visit	Date of First/ Last Dose	Reason for Discontinuation	Reason No Longer Followed	Date of Last Contact[3]
305-0037/50/ M/A2	24OCT2013/15OCT2013 /11FEB2014	24OCT2013/09JAN2014	Withdrew Consent	Death	30JUL2014
305-0039/35/ M/A2	28NOV2013/14NOV2013 /26DEC2013	28NOV2013/19DEC2013	Death	Death	26DEC2013
305-0040/61/ M/A2	15NOV2013/07NOV2013 /06DEC2013	15NOV2013/29NOV2013	Withdrew Consent	Death	27JUN2014
305-0043/70/ M/A2	01JUL2014/26JUN2014 /17OCT2014	01JUL2014/16SEP2014	Disease Progression	Unknown	17JUN2015*
305-0044/67/ M/A2	08JUL2014/01JUL2014 /07OCT2014	08JUL2014/30SEP2014	Disease Progression	Unknown	22JUN2015*
305-0045/65/ M/A2	17OCT2014/03OCT2014 /14NOV2014	17OCT2014/07NOV2014	Withdrew Consent	Death	05DEC2014
305-0047/58/ M/A2	25DEC2014/23DEC2014 /27JAN2015	25DEC2014/14JAN2015	Adverse Event	Death	28JAN2015

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

[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.

[3] * means subject is on follow-up, the last telephone contacted date is used; + means subject is still ongoing at the time of database lock, the last dose date is used; # means subject is discontinued from treatment within 30-35 days before database lock, date of EOT visit is used.

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Listing 16.2.1
Disposition
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Date of Randomization/ First/ Last Visit	Date of First/ Last Dose	Reason for Discontinuation	Reason No Longer Followed	Date of Last Contact[3]
305-0048/55/ M/A2	24FEB2015/10FEB2015 /18JUN2015	24FEB2015/12MAY2015	Disease Progression	Unknown	18JUN2015#
306-0001/56/ M/A2	17FEB2012/07FEB2012 /04JUN2012	17FEB2012/04MAY2012	Disease Progression	Death	18NOV2013
306-0002/73/ M/A2	14FEB2012/07FEB2012 /22MAY2012	14FEB2012/24APR2012	Disease Progression	Death	10SEP2012
306-0005/69/ F/A2	24FEB2012/16FEB2012 /25MAY2012	24FEB2012/20APR2012	Disease Progression	Death	31JUL2012
306-0006/43/ M/A2	20MAR2012/13MAR2012 /12APR2012	20MAR2012/03APR2012	Disease Progression	Death	14MAY2012
306-0007/56/ M/A2	05MAR2012/01MAR2012 /24APR2012	05MAR2012/16APR2012	Disease Progression	Death	29NOV2012
306-0008/40/ M/A2	12MAR2012/01MAR2012 /14MAY2012	12MAR2012/07MAY2012	Disease Progression	Death	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] * means subject is on follow-up, the last telephone contacted date is used; + means subject is still ongoing at the time of database lock, the last dose date is used; # means subject is discontinued from treatment within 30-35 days before database lock, date of EOT visit is used.

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Listing 16.2.1
Disposition
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Date of Randomization/ First/ Last Visit	Date of First/ Last Dose	Reason for Discontinuation	Reason No Longer Followed	Date of Last Contact[3]
306-0011/47/ M/A2	15MAR2012/13MAR2012 /02JUN2012	15MAR2012/30MAY2012	Disease Progression	Death	02JUN2012
306-0012/61/ M/A2	02APR2012/29MAR2012 /16OCT2012	02APR2012/11SEP2012	Withdrew Consent	Death	11DEC2012
306-0014/47/ M/A2	19APR2012/13APR2012 /07JUN2012	19APR2012/01JUN2012	Withdrew Consent	Death	20JUN2012
306-0017/49/ M/A2	12JUL2012/09JUL2012 /27SEP2012	12JUL2012/23AUG2012	Disease Progression	Death	22NOV2012
306-0019/78/ M/A2	22AUG2012/20AUG2012 /03DEC2012	22AUG2012/29OCT2012	Disease Progression	Death	04DEC2012
306-0020/63/ M/A2	04OCT2012/20SEP2012 /21JAN2013	04OCT2012/20DEC2012	Disease Progression	Death	10JUN2013
306-0023/68/ M/A2	27NOV2012/20NOV2012 /06FEB2013	27NOV2012/02JAN2013	Disease Progression	Death	24JUL2013

[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] * means subject is on follow-up, the last telephone contacted date is used; + means subject is still ongoing at the time of database lock, the last dose date is used; # means subject is discontinued from treatment within 30-35 days before database lock, date of EOT visit is used.

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Listing 16.2.1
Disposition
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Date of Randomization/ First/ Last Visit	Date of First/ Last Dose	Reason for Discontinuation	Reason No Longer Followed	Date of Last Contact[3]
306-0026/58/ M/A2	04FEB2013/24JAN2013 /07NOV2013	04FEB2013/08OCT2013	Disease Progression	Unknown	09JUN2015*
306-0027/67/ M/A2	19FEB2013/06FEB2013 /06AUG2014	19FEB2013/02JUL2014	Disease Progression	Unknown	09JUN2015*
306-0030/63/ M/A2	23APR2013/12APR2013 /11JUN2013	23APR2013/04JUN2013	Withdrew Consent	Death	06AUG2013
306-0031/40/ M/A2	15MAY2013/07MAY2013 /20AUG2013	15MAY2013/17JUL2013	Disease Progression	Death	27MAY2014
306-0034/65/ M/A2	01JUL2013/20JUN2013 /01AUG2013	01JUL2013/25JUL2013	Disease Progression	Death	09AUG2013
306-0035/48/ M/A2	08JUL2013/27JUN2013 /23SEP2013	08JUL2013/19AUG2013	Disease Progression	Death	16DEC2013
306-0036/73/ M/A2	09JUL2013/02JUL2013 /24SEP2013	09JUL2013/20AUG2013	Disease Progression	Death	30NOV2013

[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 16.2.1
Disposition
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Date of Randomization/ First/ Last Visit	Date of First/ Last Dose	Reason for Discontinuation	Reason No Longer Followed	Date of Last Contact[3]
306-0038/66/ M/A2	21AUG2013/09AUG2013 /03DEC2013	21AUG2013/30OCT2013	Disease Progression	Death	20MAY2014
306-0039/62/ M/A2	20AUG2013/09AUG2013 /03DEC2013	20AUG2013/29OCT2013	Disease Progression	Death	31DEC2013
306-0040/44/ F/A2	24SEP2013/17SEP2013 /08APR2014	24SEP2013/04MAR2014	Disease Progression	Death	14JUL2014
306-0041/62/ M/A2	29OCT2013/18OCT2013 /12MAR2014	29OCT2013/11FEB2014	Disease Progression	Death	13MAR2014
306-0043/56/ M/A2	19MAY2014/08MAY2014 /04SEP2014	19MAY2014/04AUG2014	Disease Progression	Death	30OCT2014
307-0002/61/ M/A2	03NOV2011/31OCT2011 /21FEB2012	03NOV2011/19JAN2012	Disease Progression	Death	16APR2012
307-0003/68/ M/A2	10NOV2011/04NOV2011 /17AUG2012	10NOV2011/17JUL2012	Withdrew Consent	Death	01MAR2013

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

[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = 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 16.2.1
Disposition
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Date of Randomization/ First/ Last Visit	Date of First/ Last Dose	Reason for Discontinuation	Reason No Longer Followed	Date of Last Contact[3]
307-0004/60/ M/A2	10NOV2011/08NOV2011 /17FEB2012	10NOV2011/17JAN2012	Disease Progression	Death	19MAR2012
307-0008/58/ M/A2	20DEC2011/13DEC2011 /27MAR2012	20DEC2011/21FEB2012	Disease Progression	Death	02OCT2012
307-0011/75/ M/A2	07FEB2012/31JAN2012 /02APR2012	07FEB2012/16MAR2012	Adverse Event	Death	02APR2012
307-0014/61/ M/A2	16FEB2012/14FEB2012 /28AUG2012	16FEB2012/26JUL2012	Disease Progression	Death	04JUN2013
307-0018/70/ M/A2	14JUN2012/11JUN2012 /10JUN2013	14JUN2012/09MAY2013	Disease Progression	Death	14JAN2015
307-0020/68/ F/A2	16AUG2012/14AUG2012 /31OCT2012	16AUG2012/30OCT2012	Disease Progression	Death	12JUN2015
307-0022/59/ M/A2	27NOV2012/21NOV2012 /18MAR2013	27NOV2012/14FEB2013	Disease Progression	Death	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.

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Listing 16.2.1
Disposition
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Date of Randomization/ First/ Last Visit	Date of First/ Last Dose	Reason for Discontinuation	Reason No Longer Followed	Date of Last Contact[3]
307-0025/68/ M/A2	18DEC2012/13DEC2012 /03JUN2013	18DEC2012/30MAY2013	Disease Progression	Death	25SEP2013
307-0026/65/ M/A2	27DEC2012/25DEC2012 /05JUN2013	27DEC2012/04JUN2013	Disease Progression	Death	18DEC2013
307-0030/53/ M/A2	06MAR2013/01MAR2013 /31MAY2013	06MAR2013/06MAY2013	Disease Progression	Death	31MAY2013
307-0031/60/ M/A2	15MAR2013/12MAR2013 /19DEC2013	15MAR2013/14NOV2013	Disease Progression	Death	19DEC2013
307-0032/74/ F/A2	11APR2013/09APR2013 /11MAY2013	11APR2013/09MAY2013	Death	Death	13MAY2013
307-0037/61/ M/A2	03OCT2013/30SEP2013 /14NOV2013	03OCT2013/11OCT2013	Adverse Event	Death	02MAY2014
307-0039/51/ M/A2	05NOV2013/31OCT2013 /25FEB2014	05NOV2013/21JAN2014	Disease Progression	Death	12JUN2015

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Listing 16.2.1
Disposition
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Date of Randomization/ First/ Last Visit	Date of First/ Last Dose	Reason for Discontinuation	Reason No Longer Followed	Date of Last Contact[3]
307-0040/65/ M/A2	27MAY2014/22MAY2014 /24JUL2014	27MAY2014/24JUN2014	Withdrew Consent	Death	05AUG2014
307-0043/54/ M/A2	25JUN2014/20JUN2014 /01NOV2014	25JUN2014/21OCT2014	Adverse Event	Death	01NOV2014
307-0044/53/ M/A2	27JUN2014/23JUN2014 /07AUG2014	27JUN2014/04JUL2014	Withdrew Consent	Death	18JUN2015
307-0045/48/ M/A2	07JUL2014/30JUN2014 /29SEP2014	07JUL2014/22SEP2014	Disease Progression	Unknown	12MAY2015*
307-0046/46/ M/A2	17JUL2014/08JUL2014 /19AUG2014	17JUL2014/17JUL2014	Adverse Event	Death	13MAR2015
308-0003/54/ M/A2	29JAN2013/24JAN2013 /15OCT2013	29JAN2013/08OCT2013	Disease Progression	Death	10DEC2013
308-0005/68/ F/A2	30APR2013/23APR2013 /15AUG2013	30APR2013/16JUL2013	Disease Progression	Death	10SEP2013

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Listing 16.2.1
Disposition
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Date of Randomization/ First/ Last Visit	Date of First/ Last Dose	Reason for Discontinuation	Reason No Longer Followed	Date of Last Contact[3]
309-0001/46/ M/A2	12JUN2012/29MAY2012 /24SEP2012	12JUN2012/21AUG2012	Disease Progression	Death	16APR2013
309-0002/56/ M/A2	13JUN2012/04JUN2012 /27JUN2012	13JUN2012/20JUN2012	Disease Progression	Death	16NOV2012
309-0003/52/ F/A2	20JUN2012/11JUN2012 /01OCT2012	20JUN2012/29AUG2012	Disease Progression	Death	26FEB2013
309-0004/55/ M/A2	25JUN2012/14JUN2012 /16JUL2012	25JUN2012/03JUL2012	Withdrew Consent	Death	19JUL2012
309-0008/38/ M/A2	21FEB2013/08FEB2013 /09MAY2013	21FEB2013/02MAY2013	Disease Progression	Death	03JAN2014
309-0010/47/ M/A2	25MAR2013/25MAR2013 /24NOV2014	25MAR2013/20OCT2014	Disease Progression	Unknown	21JUL2015*
309-0011/59/ M/A2	08APR2013/28MAR2013 /02JUL2013	08APR2013/17JUN2013	Disease Progression	Death	10JUL2013

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

[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.

[3] * means subject is on follow-up, the last telephone contacted date is used; + means subject is still ongoing at the time of database lock, the last dose date is used; # means subject is discontinued from treatment within 30-35 days before database lock, date of EOT visit is used.

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Listing 16.2.1
Disposition
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Date of Randomization/ First/ Last Visit	Date of First/ Last Dose	Reason for Discontinuation	Reason No Longer Followed	Date of Last Contact[3]
309-0012/82/ M/A2	23MAY2013/13MAY2013 /02SEP2013	23MAY2013/01AUG2013	Disease Progression	Death	29JAN2014
309-0015/62/ M/A2	24JUN2013/18JUN2013 /03OCT2013	24JUN2013/02SEP2013	Disease Progression	Death	29MAY2014
309-0016/72/ F/A2	05SEP2013/26AUG2013 /16DEC2013	05SEP2013/14NOV2013	Disease Progression	Death	13FEB2014
309-0017/73/ F/A2	02DEC2013/20NOV2013 /17MAR2014	02DEC2013/10FEB2014	Disease Progression	Death	16JUL2014
309-0018/82/ M/A2	03JUN2014/03JUN2014 /25SEP2014	16JUN2014/25AUG2014	Disease Progression	Death	31OCT2014
309-0021/54/ F/A2	17JUL2014/04JUL2014 /16OCT2014	17JUL2014/11SEP2014	Disease Progression	Death	16DEC2014
309-0025/49/ M/A2	25AUG2014/12AUG2014 /04SEP2014	25AUG2014/01SEP2014	Death	Death	05SEP2014

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Listing 16.2.1
Disposition
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Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Date of Randomization/ First/ Last Visit	Date of First/ Last Dose	Reason for Discontinuation	Reason No Longer Followed	Date of Last Contact[3]
309-0026/41/ M/A2	22SEP2014/09SEP2014 /03FEB2015	22SEP2014/27JAN2015	Disease Progression	Death	26FEB2015
309-0028/62/ M/A2	03NOV2014/22OCT2014 /11MAY2015	03NOV2014/08APR2015	Disease Progression	Unknown	06JUL2015*
309-0030/33/ M/A2	15DEC2014/04DEC2014 /09FEB2015	15DEC2014/02FEB2015	Disease Progression	Death	24FEB2015
309-0031/34/ M/A2	25DEC2014/18DEC2014 /09MAR2015	25DEC2014/26FEB2015	Disease Progression	Death	27APR2015
309-0032/63/ M/A2	08JAN2015/26DEC2014 /26MAR2015	08JAN2015/17MAR2015	Disease Progression	Death	01APR2015
309-0033/78/ F/A2	29JAN2015/16JAN2015 /Unknown	29JAN2015/02JUL2015		Unknown	02JUL2015+
310-0001/61/ M/A2	19JUN2012/12JUN2012 /14SEP2012	19JUN2012/14AUG2012	Disease Progression	Death	10JUN2013

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Listing 16.2.1
Disposition
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Date of Randomization/ First/ Last Visit	Date of First/ Last Dose	Reason for Discontinuation	Reason No Longer Followed	Date of Last Contact[3]
310-0002/55/ M/A2	12JUL2012/28JUN2012 /06SEP2012	12JUL2012/07AUG2012	Disease Progression	Death	05NOV2012
310-0003/61/ M/A2	06FEB2013/23JAN2013 /24APR2013	06FEB2013/17APR2013	Disease Progression	Death	19MAY2014
310-0008/49/ M/A2	19JUN2013/11JUN2013 /01JUL2013	19JUN2013/19JUN2013	Disease Progression	Death	30AUG2013
310-0012/73/ M/A2	07NOV2013/29OCT2013 /14APR2014	07NOV2013/10APR2014	Disease Progression	Unknown	02JUN2015*
310-0013/54/ M/A2	03SEP2014/20AUG2014 /17DEC2014	03SEP2014/12NOV2014	Disease Progression	Death	14MAY2015
311-0002/60/ M/A2	14AUG2013/08AUG2013 /16OCT2013	14AUG2013/02OCT2013	Disease Progression	Voluntary Withdrawal	01NOV2013
311-0007/55/ M/A2	18NOV2013/11NOV2013 /24FEB2014	18NOV2013/20JAN2014	Disease Progression	Death	02DEC2014

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Disposition
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Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Date of Randomization/ First/ Last Visit	Date of First/ Last Dose	Reason for Discontinuation	Reason No Longer Followed	Date of Last Contact[3]
311-0008/71/ M/A2	21MAY2014/14MAY2014 /09JUL2014	21MAY2014/02JUL2014	Disease Progression	Voluntary Withdrawal	09JUL2014
401-0003/36/ M/A7	24JUN2013/24JUN2013 /30SEP2013	25JUN2013/27AUG2013	Disease Progression	Death	30NOV2013
401-0005/58/ M/A7	16OCT2013/10OCT2013 /14JAN2014	16OCT2013/11DEC2013	Disease Progression	Death	20AUG2014
402-0003/75/ M/A7	30APR2013/25APR2013 /17OCT2013	30APR2013/08OCT2013	Disease Progression	Death	14NOV2013
402-0006/71/ M/A7	02MAY2013/25APR2013 /20AUG2013	02MAY2013/22JUL2013	Disease Progression	Death	22NOV2013
402-0008/43/ M/A7	21MAY2013/08MAY2013 /04JUN2013	21MAY2013/28MAY2013	Disease Progression	Death	02AUG2013
402-0009/70/ M/A7	16MAY2013/09MAY2013 /11JUL2013	16MAY2013/04JUL2013	Disease Progression	Death	11AUG2013

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Disposition
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Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Date of Randomization/ First/ Last Visit	Date of First/ Last Dose	Reason for Discontinuation	Reason No Longer Followed	Date of Last Contact[3]
402-0011/64/ M/A7	23MAY2013/14MAY2013 /05AUG2013	23MAY2013/04JUL2013	Disease Progression	Death	11OCT2013
402-0017/50/ M/A7	11JUN2013/11JUN2013 /01AUG2013	17JUN2013/01AUG2013	Disease Progression	Death	16AUG2013
402-0018/48/ M/A7	24JUN2013/12JUN2013 /16SEP2013	24JUN2013/09SEP2013	Disease Progression	Death	16DEC2013
402-0019/54/ M/A7	01JUL2013/25JUN2013 /10OCT2013	01JUL2013/09SEP2013	Disease Progression	Death	15NOV2013
402-0021/64/ M/A7	13AUG2013/01AUG2013 /04NOV2014	13AUG2013/29SEP2014	Disease Progression	Unknown	05JUN2015*
402-0024/57/ M/A7	27AUG2013/23AUG2013 /12NOV2013	27AUG2013/05NOV2013	Disease Progression	Death	03JAN2014
402-0025/58/ M/A7	25SEP2013/16SEP2013 /16JAN2014	25SEP2013/12DEC2013	Disease Progression	Death	21JAN2015

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Subject No./ Age[1]/ Gender/ Race[2]	Date of Randomization/ First/ Last Visit	Date of First/ Last Dose	Reason for Discontinuation	Reason No Longer Followed	Date of Last Contact[3]
402-0027/52/ M/A7	04OCT2013/25SEP2013 /21NOV2013	04OCT2013/05NOV2013	Disease Progression	Death	28NOV2013
402-0028/60/ M/A7	04OCT2013/26SEP2013 /26DEC2013	04OCT2013/12DEC2013	Disease Progression	Death	18FEB2014
402-0031/65/ M/A7	12NOV2013/05NOV2013 /04MAR2014	12NOV2013/29JAN2014	Disease Progression	Unknown	05JUN2015*
402-0033/63/ F/A7	06DEC2013/29NOV2013 /02FEB2014	06DEC2013/20JAN2014	Disease Progression	Death	25APR2014
402-0035/44/ M/A7	24DEC2013/24DEC2013 /18FEB2014	24DEC2013/14JAN2014	Other	Death	25JUN2014
403-0001/55/ M/A7	22MAY2013/20MAY2013 /29JUL2013	23MAY2013/26JUN2013	Disease Progression	Death	30SEP2013
403-0002/52/ M/A7	11JUN2013/11JUN2013 /12SEP2013	12JUN2013/13AUG2013	Disease Progression	Death	14OCT2013

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Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Date of Randomization/ First/ Last Visit	Date of First/ Last Dose	Reason for Discontinuation	Reason No Longer Followed	Date of Last Contact[3]
403-0005/50/ F/A7	16JUL2013/15JUL2013 /30AUG2013	17JUL2013/29JUL2013	Adverse Event	Death	06NOV2013
403-0006/66/ M/A7	29JUL2013/25JUL2013 /05DEC2013	31JUL2013/17OCT2013	Disease Progression	Death	03APR2014
403-0007/64/ M/MIX	21AUG2013/21AUG2013 /12DEC2013	21AUG2013/07NOV2013	Withdrew Consent	Voluntary Withdrawal	12DEC2013
404-0001/71/ M/A7	22JUL2013/08JUL2013 /11SEP2013	22JUL2013/12AUG2013	Disease Progression	Death	11SEP2013
404-0002/56/ F/A7	22AUG2013/12AUG2013 /11OCT2013	22AUG2013/05SEP2013	Adverse Event	Death	02JUL2014
405-0002/46/ M/A7	16APR2013/10APR2013 /03MAY2013	16APR2013/30APR2013	Adverse Event	Death	04JUN2013
405-0004/38/ M/A7	24APR2013/19APR2013 /07AUG2013	24APR2013/03JUL2013	Disease Progression	Death	20MAY2014

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Subject No./ Age[1]/ Gender/ Race[2]	Date of Randomization/ First/ Last Visit	Date of First/ Last Dose	Reason for Discontinuation	Reason No Longer Followed	Date of Last Contact[3]
405-0006/62/ M/A7	29APR2013/23APR2013 /29MAY2013	29APR2013/29MAY2013	Adverse Event	Death	20JUN2013
405-0007/53/ M/A7	07MAY2013/23APR2013 /01OCT2013	07MAY2013/26SEP2013	Disease Progression	Death	19AUG2014
405-0009/50/ M/A7	14MAY2013/07MAY2013 /05AUG2013	14MAY2013/16JUL2013	Disease Progression	Death	23AUG2013
405-0010/39/ M/A7	23MAY2013/23MAY2013 /09AUG2013	23MAY2013/06AUG2013	Disease Progression	Lost to Follow-up	21FEB2014
405-0011/63/ M/A7	13MAY2013/08MAY2013 /21NOV2013	13MAY2013/21OCT2013	Disease Progression	Death	01JUL2014
405-0013/45/ M/A7	20MAY2013/13MAY2013 /16SEP2013	20MAY2013/19AUG2013	Adverse Event	Lost to Follow-up	17JAN2014
405-0014/35/ M/A7	31MAY2013/31MAY2013 /03JUL2013	31MAY2013/19JUN2013	Death	Death	12AUG2013

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Subject No./ Age[1]/ Gender/ Race[2]	Date of Randomization/ First/ Last Visit	Date of First/ Last Dose	Reason for Discontinuation	Reason No Longer Followed	Date of Last Contact[3]
405-0016/41/ M/A7	27MAY2013/27MAY2013 /25JUN2013	27MAY2013/10JUN2013	Death	Death	14JUL2013
405-0018/70/ F/A7	12JUN2013/12JUN2013 /03JUL2013	12JUN2013/12JUN2013	Disease Progression	Death	12AUG2013
405-0020/69/ M/A7	19JUN2013/12JUN2013 /02JUN2014	19JUN2013/07MAY2014	Disease Progression	Death	30OCT2014
405-0021/47/ M/A7	19JUN2013/17JUN2013 /07AUG2014	19JUN2013/14JUL2014	Disease Progression	Death	07OCT2014
405-0022/65/ M/A7	04JUL2013/04JUL2013 /13JAN2014	04JUL2013/11DEC2013	Disease Progression	Death	02APR2014
405-0023/46/ M/A7	17JUN2013/17JUN2013 /03SEP2013	17JUN2013/02SEP2013	Disease Progression	Death	11DEC2013
405-0025/47/ M/A7	26JUN2013/24JUN2013 /24JUL2013	26JUN2013/03JUL2013	Disease Progression	Death	10DEC2013

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Subject No./ Age[1]/ Gender/ Race[2]	Date of Randomization/ First/ Last Visit	Date of First/ Last Dose	Reason for Discontinuation	Reason No Longer Followed	Date of Last Contact[3]
405-0028/67/ M/A7	24JUL2013/10JUL2013 /09OCT2013	24JUL2013/02OCT2013	Disease Progression	Death	04JAN2014
405-0030/35/ M/A7	31JUL2013/17JUL2013 /18OCT2013	31JUL2013/16SEP2013	Disease Progression	Death	06NOV2013
405-0032/69/ M/A7	23JUL2013/19JUL2013 /07OCT2014	23JUL2013/05SEP2014	Disease Progression	Death	10MAR2015
405-0033/43/ M/A7	08AUG2013/29JUL2013 /30OCT2013	08AUG2013/23OCT2013	Disease Progression	Death	28APR2014
405-0034/61/ M/A7	08AUG2013/29JUL2013 /25NOV2013	08AUG2013/23OCT2013	Disease Progression	Death	07OCT2014
405-0035/66/ M/A7	19AUG2013/19AUG2013 /13NOV2013	19AUG2013/11OCT2013	Disease Progression	Unknown	08JUN2015*
405-0039/73/ M/A7	13SEP2013/13SEP2013 /30DEC2013	13SEP2013/29NOV2013	Disease Progression	Death	02JUN2014

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

[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.

[3] * means subject is on follow-up, the last telephone contacted date is used; + means subject is still ongoing at the time of database lock, the last dose date is used; # means subject is discontinued from treatment within 30-35 days before database lock, date of EOT visit is used.

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Listing 16.2.1
Disposition
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Date of Randomization/ First/ Last Visit	Date of First/ Last Dose	Reason for Discontinuation	Reason No Longer Followed	Date of Last Contact[3]
405-0040/65/ M/A7	23SEP2013/09SEP2013 /11JAN2014	23SEP2013/09DEC2013	Disease Progression	Unknown	05JUN2015*
405-0042/53/ M/A7	04OCT2013/04OCT2013 /06DEC2013	04OCT2013/27NOV2013	Disease Progression	Death	31DEC2013
405-0043/49/ M/A7	26SEP2013/16SEP2013 /06DEC2013	26SEP2013/28NOV2013	Adverse Event	Death	20DEC2013
405-0044/56/ M/A7	25SEP2013/25SEP2013 /18NOV2013	25SEP2013/13NOV2013	Disease Progression	Death	08DEC2014
501-0001/59/ M/A1	13NOV2013/07NOV2013 /26JAN2014	13NOV2013/22JAN2014	Disease Progression	Death	24JUN2014
501-0002/36/ F/A1	02DEC2013/27NOV2013 /19FEB2014	02DEC2013/11FEB2014	Disease Progression	Death	19JAN2015
501-0005/80/ M/A1	23JAN2014/17JAN2014 /26JUN2015	23JAN2014/28MAY2015	Disease Progression	Unknown	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] * means subject is on follow-up, the last telephone contacted date is used; + means subject is still ongoing at the time of database lock, the last dose date is used; # means subject is discontinued from treatment within 30-35 days before database lock, date of EOT visit is used.

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Listing 16.2.1
Disposition
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Date of Randomization/ First/ Last Visit	Date of First/ Last Dose	Reason for Discontinuation	Reason No Longer Followed	Date of Last Contact[3]
501-0006/60/ M/A1	13FEB2014/07FEB2014 /28APR2014	13FEB2014/24APR2014	Disease Progression	Death	29NOV2014
501-0007/43/ M/A1	03MAR2014/28FEB2014 /11JUN2014	03MAR2014/12MAY2014	Disease Progression	Death	11JUL2014
501-0008/76/ F/A1	15APR2014/08APR2014 /25JUL2014	15APR2014/25JUN2014	Disease Progression	Death	25MAY2015
501-0009/62/ M/A1	18JUL2014/11JUL2014 /18OCT2014	18JUL2014/26SEP2014	Disease Progression	Unknown	19JUN2015*
501-0010/65/ M/A1	10SEP2014/03SEP2014 /01DEC2014	10SEP2014/12NOV2014	Disease Progression	Death	02APR2015
502-0002/65/ M/A1	08JAN2014/08JAN2014 /19JAN2014	10JAN2014/10JAN2014	Adverse Event	Death	20JAN2014
503-0001/32/ M/A1	09DEC2013/06DEC2013 /12FEB2014	09DEC2013/31DEC2013	Disease Progression	Death	20MAR2014

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

[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = 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 16.2.1
Disposition
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Date of Randomization/ First/ Last Visit	Date of First/ Last Dose	Reason for Discontinuation	Reason No Longer Followed	Date of Last Contact[3]
503-0004/49/ M/A1	11MAR2014/06MAR2014 /18APR2014	11MAR2014/25MAR2014	Death	Death	18APR2014
503-0006/54/ M/A1	06AUG2014/01AUG2014 /08APR2015	06AUG2014/27FEB2015	Withdrew Consent	Unknown	02JUL2015*
503-0007/57/ M/A1	28OCT2014/22OCT2014 /12FEB2015	28OCT2014/13JAN2015	Disease Progression	Unknown	02JUL2015*
503-0008/50/ M/A1	30OCT2014/28OCT2014 /12JAN2015	30OCT2014/10DEC2014	Disease Progression	Death	18MAY2015
503-0009/57/ M/A1	19NOV2014/17NOV2014 /29NOV2014	19NOV2014/26NOV2014	Disease Progression	Death	29NOV2014
504-0001/47/ M/A1	17FEB2014/12FEB2014 /10JUL2014	17FEB2014/10JUN2014	Disease Progression	Death	10AUG2014
504-0007/32/ M/A1	11OCT2014/11OCT2014 /11NOV2014	11OCT2014/17OCT2014	Death	Death	11NOV2014

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Listing 16.2.1
Disposition
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Date of Randomization/ First/ Last Visit	Date of First/ Last Dose	Reason for Discontinuation	Reason No Longer Followed	Date of Last Contact[3]
505-0001/70/ M/A1	12AUG2014/12AUG2014 /28OCT2014	26AUG2014/16SEP2014	Disease Progression	Death	01FEB2015
506-0002/54/ M/A1	12MAY2014/09MAY2014 /08MAY2015	12MAY2014/07APR2015	Disease Progression	Unknown	02JUL2015*
506-0003/66/ M/A1	10SEP2014/09SEP2014 /28OCT2014	10SEP2014/22OCT2014	Disease Progression	Death	29APR2015
506-0004/49/ M/A1	27OCT2014/23OCT2014 /05JAN2015	27OCT2014/17DEC2014	Disease Progression	Death	15FEB2015
508-0001/36/ M/A1	08JAN2014/31DEC2013 /07MAR2014	08JAN2014/08FEB2014	Disease Progression	Lost to Follow-up	15AUG2014
508-0003/49/ F/A1	17MAR2014/13MAR2014 /15APR2014	17MAR2014/08APR2014	Adverse Event	Death	15APR2014
509-0001/45/ M/A1	30APR2014/15APR2014 /24JUL2014	30APR2014/15JUL2014	Disease Progression	Death	29AUG2014

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Listing 16.2.1
Disposition
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Date of Randomization/ First/ Last Visit	Date of First/ Last Dose	Reason for Discontinuation	Reason No Longer Followed	Date of Last Contact[3]
509-0002/51/ M/A1	26MAY2014/20MAY2014 /14JUL2014	26MAY2014/11JUN2014	Withdrew Consent	Lost to Follow-up	27AUG2014
510-0002/50/ M/A1	23MAY2014/12MAY2014 /25AUG2014	23MAY2014/16JUL2014	Adverse Event	Death	25AUG2014
510-0004/72/ M/A1	01AUG2014/29JUL2014 /24OCT2014	01AUG2014/15OCT2014	Disease Progression	Unknown	30JUN2015*
511-0001/35/ M/A1	21JAN2014/17JAN2014 /27MAR2014	21JAN2014/25FEB2014	Disease Progression	Death	30AUG2014
511-0002/49/ M/A1	11MAR2014/06MAR2014 /23SEP2014	11MAR2014/19AUG2014	Disease Progression	Unknown	02JUL2015*
512-0001/59/ M/A1	04MAR2014/25FEB2014 /28JUL2014	04MAR2014/24JUN2014	Disease Progression	Death	04SEP2014
513-0001/28/ M/A1	09APR2014/02APR2014 /20JUN2014	11APR2014/19MAY2014	Disease Progression	Death	22JUL2014

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Listing 16.2.1
Disposition
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Date of Randomization/ First/ Last Visit	Date of First/ Last Dose	Reason for Discontinuation	Reason No Longer Followed	Date of Last Contact[3]
513-0004/46/ M/A1	18JUN2014/16JUN2014 /26JUL2014	18JUN2014/08JUL2014	Disease Progression	Death	07AUG2014
513-0005/61/ M/A1	31OCT2014/30OCT2014 /13FEB2015	31OCT2014/14JAN2015	Disease Progression	Death	20MAR2015
515-0001/64/ M/A1	20FEB2014/14FEB2014 /05JUN2014	20FEB2014/07MAY2014	Disease Progression	Death	01AUG2014
515-0003/69/ M/A1	13MAY2014/07MAY2014 /27AUG2014	13MAY2014/29JUL2014	Disease Progression	Death	08APR2015
515-0004/52/ M/A1	27MAY2014/20MAY2014 /19SEP2014	27MAY2014/15SEP2014	Death	Death	25SEP2014
515-0006/47/ M/A1	05AUG2014/22JUL2014 /24NOV2014	05AUG2014/20OCT2014	Disease Progression	Unknown	29JUN2015*
515-0007/39/ M/A1	17SEP2014/10SEP2014 /21NOV2014	17SEP2014/20OCT2014	Disease Progression	Death	09DEC2014

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Listing 16.2.1
Disposition
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Date of Randomization/ First/ Last Visit	Date of First/ Last Dose	Reason for Discontinuation	Reason No Longer Followed	Date of Last Contact[3]
515-0008/60/ M/A1	27NOV2014/21NOV2014 /02MAR2015	27NOV2014/09FEB2015	Disease Progression	Death	04JUN2015
516-0001/45/ M/A1	07AUG2014/07AUG2014 /16FEB2015	08AUG2014/16JAN2015	Disease Progression	Unknown	30JUN2015*
517-0001/42/ M/A1	23DEC2013/16DEC2013 /26FEB2014	23DEC2013/20JAN2014	Disease Progression	Death	19MAR2014
517-0002/43/ M/A1	26MAR2014/21MAR2014 /08OCT2014	26MAR2014/03SEP2014	Disease Progression	Unknown	01JUL2015*
517-0006/67/ F/A1	20AUG2014/07AUG2014 /02JUN2015	20AUG2014/22APR2015		Unknown	01JUL2015*
517-0007/66/ M/A1	20AUG2014/11AUG2014 /15OCT2014	20AUG2014/12SEP2014	Disease Progression	Death	10DEC2014

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Listing 16.2.1
Disposition
(Safety Population)

Treatment Group: ADI-PEG 20

Subject No./ Age[1]/ Gender/ Race[2]	Date of Randomization/ First/ Last Visit	Date of First/ Last Dose	Reason for Discontinuation	Reason No Longer Followed	Date of Last Contact[3]
517-0008/59/ M/A1	22AUG2014/15AUG2014 /22OCT2014	22AUG2014/19SEP2014	Disease Progression	Death	21JAN2015
517-0009/23/ M/A1	17SEP2014/11SEP2014 /07JAN2015	17SEP2014/03DEC2014	Disease Progression	Death	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.

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Listing 16.2.1
Disposition
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Date of Randomization/ First/ Last Visit	Date of First/ Last Dose	Reason for Discontinuation	Reason No Longer Followed	Date of Last Contact[3]
101-0002/70/ M/OTH	29JUL2011/19JUL2011 /07NOV2011	29JUL2011/11OCT2011	Disease Progression	Death	07NOV2011
101-0004/78/ F/A2	05AUG2011/26JUL2011 /23OCT2012	05AUG2011/21SEP2012	Disease Progression	Unknown	06JUL2015*
101-0014/61/ M/W2	06JAN2012/03JAN2012 /03JUL2012	06JAN2012/13APR2012	Disease Progression	Death	26OCT2012
101-0015/65/ M/A4	06JAN2012/06JAN2012 /24APR2012	10JAN2012/20MAR2012	Disease Progression	Death	03JAN2013
101-0017/60/ M/W2	21FEB2012/21FEB2012 /12JUN2012	21FEB2012/01MAY2012	Disease Progression	Death	19JAN2013
101-0020/86/ M/W2	12MAR2012/06MAR2012 /28SEP2012	13MAR2012/21AUG2012	Disease Progression	Death	30DEC2012
101-0027/72/ M/W2	22MAY2012/22MAY2012 /24JUL2012	22MAY2012/08JUN2012	Disease Progression	Death	11AUG2012

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Listing 16.2.1
Disposition
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Date of Randomization/ First/ Last Visit	Date of First/ Last Dose	Reason for Discontinuation	Reason No Longer Followed	Date of Last Contact[3]
101-0031/69/ F/W2	17JUL2012/17JUL2012 /02OCT2012	20JUL2012/25SEP2012	Disease Progression	Other	22OCT2012
101-0034/44/ M/OTH	11SEP2012/11SEP2012 /27NOV2012	11SEP2012/23OCT2012	Disease Progression	Death	04DEC2013
101-0035/37/ M/A6	14SEP2012/07SEP2012 /13NOV2012	14SEP2012/11OCT2012	Disease Progression	Death	27JAN2013
101-0043/69/ M/W1	22OCT2013/08OCT2013 /14JAN2014	22OCT2013/17DEC2013	Adverse Event	Death	26MAY2014
101-0051/70/ F/W2	27JAN2014/13JAN2014 /17MAR2014	27JAN2014/03MAR2014	Disease Progression	Death	23MAY2014
102-0006/66/ M/BL	11DEC2013/11DEC2013 /31MAR2014	11DEC2013/19FEB2014	Disease Progression	Death	07OCT2014
102-0007/61/ M/W2	02JAN2014/02JAN2014 /08MAY2014	02JAN2014/24APR2014	Withdrew Consent	Death	09MAY2014

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Listing 16.2.1
Disposition
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Date of Randomization/ First/ Last Visit	Date of First/ Last Dose	Reason for Discontinuation	Reason No Longer Followed	Date of Last Contact[3]
103-0002/74/ M/W2	12DEC2012/05DEC2012 /14JUN2013	12DEC2012/15MAY2013	Disease Progression	Death	09FEB2015
103-0006/57/ M/W2	19NOV2014/06NOV2014 /26FEB2015	20NOV2014/27JAN2015	Disease Progression	Unknown	16JUN2015*
104-0002/80/ M/W2	07MAY2012/05APR2012 /11FEB2013	07MAY2012/07JAN2013	Disease Progression	Death	29JUL2013
104-0007/89/ M/A1	07AUG2013/29JUL2013 /Unknown	07AUG2013/29JUN2015		Unknown	29JUN2015+
105-0003/57/ M/W2	05NOV2013/22OCT2013 /31OCT2014	06NOV2013/30SEP2014	Withdrew Consent	Other	16JUN2015
105-0006/60/ F/BL	29DEC2014/17DEC2014 /Unknown	30DEC2014/09JUN2015	Disease Progression	Unknown	09JUN2015+
108-0003/85/ M/W2	19NOV2012/14NOV2012 /31DEC2012	19NOV2012/18DEC2012	Disease Progression	Death	30NOV2013

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

[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.

[3] * means subject is on follow-up, the last telephone contacted date is used; + means subject is still ongoing at the time of database lock, the last dose date is used; # means subject is discontinued from treatment within 30-35 days before database lock, date of EOT visit is used.

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Listing 16.2.1
Disposition
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Date of Randomization/ First/ Last Visit	Date of First/ Last Dose	Reason for Discontinuation	Reason No Longer Followed	Date of Last Contact[3]
109-0002/63/ M/W2	22MAR2013/20MAR2013 /30SEP2013	22MAR2013/23AUG2013	Disease Progression	Unknown	10JUN2015*
109-0005/64/ F/W2	30JUL2013/18JUL2013 /08OCT2013	31JUL2013/04SEP2013	Adverse Event	Death	08OCT2013
109-0012/21/ F/W2	25SEP2014/16SEP2014 /09DEC2014	25SEP2014/11NOV2014	Adverse Event	Unknown	10JUN2015*
109-0014/50/ F/W2	26JAN2015/12JAN2015 /03APR2015	26JAN2015/04MAR2015	Disease Progression	Death	03APR2015
111-0003/37/ M/A1	08JAN2013/02JAN2013 /19MAR2013	08JAN2013/21FEB2013	Disease Progression	Death	20MAR2013
112-0010/56/ F/W2	06DEC2013/27NOV2013 /26MAR2014	06DEC2013/21FEB2014	Disease Progression	Death	25APR2014
113-0007/74/ M/W2	30JAN2014/21JAN2014 /20JUN2014	30JAN2014/19JUN2014	Disease Progression	Death	21JUL2014

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

[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.

[3] * means subject is on follow-up, the last telephone contacted date is used; + means subject is still ongoing at the time of database lock, the last dose date is used; # means subject is discontinued from treatment within 30-35 days before database lock, date of EOT visit is used.

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Listing 16.2.1
Disposition
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Date of Randomization/ First/ Last Visit	Date of First/ Last Dose	Reason for Discontinuation	Reason No Longer Followed	Date of Last Contact[3]
113-0015/58/ F/BL	26NOV2014/20NOV2014 /06JAN2015	26NOV2014/09DEC2014	Withdrew Consent	Unknown	25JUN2015*
114-0001/25/ F/OTH	02AUG2012/24JUL2012 /28SEP2012	02AUG2012/11SEP2012	Disease Progression	Death	12NOV2012
114-0004/54/ F/A1	06FEB2013/30JAN2013 /03APR2013	06FEB2013/27MAR2013	Other	Death	09JUN2014
115-0005/60/ M/W2	15MAR2013/01MAR2013 /07JUN2013	15MAR2013/22MAR2013	Death	Death	07JUN2013
115-0006/62/ M/W2	11APR2013/04APR2013 /23JUL2013	11APR2013/03JUL2013	Disease Progression	Death	31JUL2013
115-0007/57/ M/W2	19APR2013/10APR2013 /06JUN2013	19APR2013/09MAY2013	Disease Progression	Death	25JUN2013
115-0010/54/ M/A4	14APR2014/08APR2014 /22JUL2014	14APR2014/16JUN2014	Disease Progression	Death	21OCT2014

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

[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.

[3] * means subject is on follow-up, the last telephone contacted date is used; + means subject is still ongoing at the time of database lock, the last dose date is used; # means subject is discontinued from treatment within 30-35 days before database lock, date of EOT visit is used.

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Listing 16.2.1
Disposition
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Date of Randomization/ First/ Last Visit	Date of First/ Last Dose	Reason for Discontinuation	Reason No Longer Followed	Date of Last Contact[3]
121-0003/65/ M/BL	01JUL2014/18JUN2014 /24SEP2014	02JUL2014/20AUG2014	Disease Progression	Death	13MAY2015
201-0002/76/ M/W2	15MAR2012/02MAR2012 /12MAR2013	15MAR2012/07FEB2013	Disease Progression	Death	07OCT2013
201-0006/71/ M/W2	12JUL2012/10JUL2012 /17JAN2013	12JUL2012/18DEC2012	Disease Progression	Death	11NOV2013
201-0007/71/ M/W2	26JUL2012/16JUL2012 /29APR2013	26JUL2012/28MAR2013	Disease Progression	Death	30JUL2014
201-0009/64/ M/W2	20JUN2013/04JUN2013 /Unknown	20JUN2013/30JUN2015		Unknown	30JUN2015+
201-0010/81/ F/W2	27JUN2013/14JUN2013 /05NOV2013	27JUN2013/12SEP2013	Disease Progression	Death	27JAN2014
201-0014/73/ M/W2	17JUL2013/05JUL2013 /05NOV2013	17JUL2013/03OCT2013	Disease Progression	Death	14APR2014

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

[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.

[3] * means subject is on follow-up, the last telephone contacted date is used; + means subject is still ongoing at the time of database lock, the last dose date is used; # means subject is discontinued from treatment within 30-35 days before database lock, date of EOT visit is used.

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Listing 16.2.1
Disposition
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Date of Randomization/ First/ Last Visit	Date of First/ Last Dose	Reason for Discontinuation	Reason No Longer Followed	Date of Last Contact[3]
201-0015/49/ M/W2	08AUG2013/29JUL2013 /17APR2014	08AUG2013/13MAR2014	Disease Progression	Death	30OCT2014
201-0022/80/ F/W2	09MAY2014/09MAY2014 /25NOV2014	15MAY2014/23OCT2014	Disease Progression	Unknown	19JUN2015*
203-0004/81/ M/W2	30MAR2012/22MAR2012 /07JAN2013	30MAR2012/07JAN2013	Disease Progression	Death	09MAY2013
203-0006/76/ M/W2	11APR2012/30MAR2012 /07JUL2012	11APR2012/11JUN2012	Death	Death	07JUL2012
203-0007/59/ M/W2	04JUN2012/28MAY2012 /14SEP2012	04JUN2012/20JUL2012	Adverse Event	Death	19OCT2012
203-0009/73/ M/W2	13SEP2012/30AUG2012 /20NOV2013	13SEP2012/31OCT2013	Disease Progression	Death	07JAN2015
203-0010/74/ M/W2	26SEP2012/17SEP2012 /15DEC2014	26SEP2012/24OCT2014	Other	Unknown	15JUN2015*

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

[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.

[3] * means subject is on follow-up, the last telephone contacted date is used; + means subject is still ongoing at the time of database lock, the last dose date is used; # means subject is discontinued from treatment within 30-35 days before database lock, date of EOT visit is used.

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Listing 16.2.1
Disposition
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Date of Randomization/ First/ Last Visit	Date of First/ Last Dose	Reason for Discontinuation	Reason No Longer Followed	Date of Last Contact[3]
203-0014/73/ M/W2	23JAN2014/10JAN2014 /13MAR2014	23JAN2014/06MAR2014	Disease Progression	Death	29OCT2014
203-0016/57/ M/W2	04FEB2014/28JAN2014 /08AUG2014	04FEB2014/31JUL2014	Disease Progression	Death	08OCT2014
203-0019/68/ M/W2	22MAY2014/12MAY2014 /10JUL2014	22MAY2014/30JUN2014	Disease Progression	Death	16SEP2014
204-0003/64/ M/W2	08JUL2013/27JUN2013 /24OCT2013	08JUL2013/26SEP2013	Disease Progression	Death	20JAN2014
204-0004/76/ F/W2	15SEP2013/04SEP2013 /30JAN2014	16SEP2013/12DEC2013	Disease Progression	Death	23JUL2014
205-0002/71/ M/W2	24FEB2012/14FEB2012 /14JUN2012	24FEB2012/08MAY2012	Disease Progression	Death	06JUL2012
205-0003/79/ M/W2	27MAR2012/16MAR2012 /03JAN2013	27MAR2012/04DEC2012	Disease Progression	Death	17OCT2013

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

[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = 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 16.2.1
Disposition
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Date of Randomization/ First/ Last Visit	Date of First/ Last Dose	Reason for Discontinuation	Reason No Longer Followed	Date of Last Contact[3]
205-0005/71/ M/W2	20MAR2012/12MAR2012 /05JUL2012	20MAR2012/05JUN2012	Disease Progression	Death	13NOV2012
205-0014/70/ M/W2	18JUN2013/07JUN2013 /02AUG2013	18JUN2013/02AUG2013	Adverse Event	Death	02OCT2013
205-0023/72/ M/W2	08NOV2013/29OCT2013 /27FEB2014	08NOV2013/21JAN2014	Disease Progression	Death	25JUN2015
205-0026/61/ F/W2	09FEB2015/12JAN2015 /28APR2015	09FEB2015/28APR2015	Disease Progression	Unknown	15JUN2015*
205-0028/73/ F/W2	27JAN2015/15JAN2015 /10FEB2015	27JAN2015/03FEB2015	Adverse Event	Death	15FEB2015
207-0002/71/ M/W2	21MAR2012/08MAR2012 /20JUN2012	22MAR2012/11JUN2012	Disease Progression	Death	02OCT2012
207-0007/71/ M/W2	02JUL2012/14JUN2012 /15OCT2012	02JUL2012/17SEP2012	Disease Progression	Death	04JAN2013

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Listing 16.2.1
Disposition
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Date of Randomization/ First/ Last Visit	Date of First/ Last Dose	Reason for Discontinuation	Reason No Longer Followed	Date of Last Contact[3]
207-0012/66/ M/W2	21MAR2013/12MAR2013 /27FEB2014	21MAR2013/24JAN2014	Disease Progression	Death	19MAY2014
207-0016/82/ F/W2	10OCT2013/30SEP2013 /12FEB2014	10OCT2013/09JAN2014	Other	Death	19DEC2014
207-0017/81/ F/W2	22NOV2013/22NOV2013 /13FEB2014	29NOV2013/13FEB2014	Disease Progression	Death	09APR2014
207-0019/55/ M/W2	03JUN2014/27MAY2014 /17JUN2014	03JUN2014/17JUN2014	Adverse Event	Death	01AUG2014
209-0006/68/ M/W2	02MAY2013/18APR2013 /18FEB2014	02MAY2013/07JAN2014	Disease Progression	Death	17JUL2014
209-0011/69/ M/W2	03DEC2013/21NOV2013 /19MAR2014	03DEC2013/12FEB2014	Disease Progression	Unknown	15JUN2015*
209-0014/79/ M/W2	17MAR2014/04MAR2014 /23SEP2014	17MAR2014/26AUG2014	Disease Progression	Unknown	17JUN2015*

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Listing 16.2.1
Disposition
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Date of Randomization/ First/ Last Visit	Date of First/ Last Dose	Reason for Discontinuation	Reason No Longer Followed	Date of Last Contact[3]
210-0003/74/ M/W2	04NOV2013/30OCT2013 /06DEC2013	04NOV2013/06DEC2013	Adverse Event	Death	22JUL2014
210-0004/71/ M/W2	08JAN2014/02JAN2014 /21MAY2014	08JAN2014/26MAR2014	Disease Progression	Death	25AUG2014
210-0005/53/ M/W2	20FEB2014/12FEB2014 /29MAY2014	20FEB2014/07MAY2014	Disease Progression	Death	15JAN2015
210-0006/45/ M/W2	23JUN2014/26MAY2014 /03SEP2014	23JUN2014/03SEP2014	Disease Progression	Death	26NOV2014
251-0002/69/ M/W2	07AUG2013/06AUG2013 /15OCT2013	13AUG2013/08OCT2013	Disease Progression	Death	20NOV2013
251-0003/68/ M/W2	05NOV2013/29OCT2013 /04JUN2014	05NOV2013/15APR2014	Disease Progression	Death	22OCT2014
252-0001/65/ M/A3	08MAY2012/01MAY2012 /09JUL2012	08MAY2012/26JUN2012	Adverse Event	Death	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.

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Listing 16.2.1
Disposition
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Date of Randomization/ First/ Last Visit	Date of First/ Last Dose	Reason for Discontinuation	Reason No Longer Followed	Date of Last Contact[3]
252-0004/50/ M/A1	28MAY2013/21MAY2013 /20AUG2013	28MAY2013/23JUL2013	Disease Progression	Death	01SEP2013
252-0006/64/ M/W2	01OCT2013/17SEP2013 /22APR2014	01OCT2013/11MAR2014	Withdrew Consent	Death	24APR2015
252-0008/76/ M/W2	27MAY2014/20MAY2014 /23SEP2014	27MAY2014/12AUG2014	Disease Progression	Death	14JAN2015
252-0010/56/ F/W2	04NOV2014/28OCT2014 /27JAN2015	04NOV2014/20JAN2015	Disease Progression	Death	19MAR2015
253-0003/75/ M/W2	15JUN2012/25MAY2012 /08MAR2013	15JUN2012/08FEB2013	Disease Progression	Death	26JUN2013
253-0004/79/ M/W2	07SEP2012/04SEP2012 /21DEC2012	07SEP2012/16NOV2012	Disease Progression	Other	26FEB2013
253-0005/74/ F/W2	02NOV2012/26OCT2012 /28DEC2012	02NOV2012/02NOV2012	Other	Death	08JAN2013

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

[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = 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 16.2.1
Disposition
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Date of Randomization/ First/ Last Visit	Date of First/ Last Dose	Reason for Discontinuation	Reason No Longer Followed	Date of Last Contact[3]
253-0006/63/ M/A3	28DEC2012/21DEC2012 /21JUN2013	28DEC2012/17MAY2013	Disease Progression	Death	01SEP2014
253-0011/67/ M/W2	06OCT2014/22SEP2014 /Unknown	06OCT2014/06JUL2015		Unknown	06JUL2015+
253-0012/67/ M/W2	08DEC2014/24NOV2014 /20JAN2015	08DEC2014/05JAN2015	Disease Progression	Death	20JAN2015
257-0005/66/ M/W2	03JAN2013/13DEC2012 /19MAY2013	03JAN2013/14MAR2013	Death	Death	22MAY2013
257-0013/63/ M/W2	30MAY2013/23MAY2013 /01JUL2013	30MAY2013/27JUN2013	Disease Progression	Death	07AUG2013
257-0020/72/ M/A1	27OCT2014/20OCT2014 /08DEC2014	27OCT2014/17NOV2014	Disease Progression	Death	22DEC2014
258-0002/69/ F/W2	11APR2013/08APR2013 /15JAN2014	12APR2013/11DEC2013	Disease Progression	Death	14AUG2014

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

[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.

[3] * means subject is on follow-up, the last telephone contacted date is used; + means subject is still ongoing at the time of database lock, the last dose date is used; # means subject is discontinued from treatment within 30-35 days before database lock, date of EOT visit is used.

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Listing 16.2.1
Disposition
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Date of Randomization/ First/ Last Visit	Date of First/ Last Dose	Reason for Discontinuation	Reason No Longer Followed	Date of Last Contact[3]
258-0003/67/ F/W2	15MAY2013/09MAY2013 /27NOV2013	17MAY2013/23OCT2013	Disease Progression	Unknown	17JUN2015*
258-0004/65/ M/W2	21MAY2013/09MAY2013 /21JUN2013	22MAY2013/22MAY2013	Adverse Event	Death	21JUN2013
258-0006/69/ M/W2	15OCT2013/02OCT2013 /22NOV2013	15OCT2013/25OCT2013	Adverse Event	Death	12DEC2013
258-0013/59/ M/W2	11NOV2014/05NOV2014 /04MAR2015	12NOV2014/28JAN2015	Disease Progression	Death	09APR2015
259-0003/73/ M/W2	11JUN2014/09JUN2014 /Unknown	11JUN2014/06MAY2015		Death	06MAY2015
259-0004/52/ M/W2	21JUL2014/16JUL2014 /08SEP2014	23JUL2014/20AUG2014	Withdrew Consent	Voluntary Withdrawal	08SEP2014
260-0002/66/ M/W2	02OCT2013/18SEP2013 /11DEC2013	02OCT2013/30OCT2013	Disease Progression	Death	14JUL2014

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

[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.

[3] * means subject is on follow-up, the last telephone contacted date is used; + means subject is still ongoing at the time of database lock, the last dose date is used; # means subject is discontinued from treatment within 30-35 days before database lock, date of EOT visit is used.

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Listing 16.2.1
Disposition
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Date of Randomization/ First/ Last Visit	Date of First/ Last Dose	Reason for Discontinuation	Reason No Longer Followed	Date of Last Contact[3]
301-0001/47/ F/A2	01NOV2011/18OCT2011 /19FEB2012	01NOV2011/17JAN2012	Disease Progression	Death	13MAY2013
301-0003/61/ F/A2	01MAR2012/23FEB2012 /19JUN2012	01MAR2012/17MAY2012	Disease Progression	Death	19SEP2012
301-0008/53/ M/A2	04JAN2013/26DEC2012 /23MAR2013	04JAN2013/08MAR2013	Disease Progression	Death	10JUN2013
302-0006/49/ M/A2	10JAN2012/03JAN2012 /24MAR2012	10JAN2012/21FEB2012	Disease Progression	Death	27MAR2012
302-0009/73/ M/A2	17APR2012/11APR2012 /12JUN2012	17APR2012/29MAY2012	Withdrew Consent	Death	10JUL2012
302-0012/62/ M/A2	24APR2012/18APR2012 /14AUG2012	24APR2012/10JUL2012	Disease Progression	Death	11OCT2012
302-0013/62/ M/A2	26MAR2013/21MAR2013 /02JUL2013	26MAR2013/28MAY2013	Withdrew Consent	Death	17DEC2013

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

[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.

[3] * means subject is on follow-up, the last telephone contacted date is used; + means subject is still ongoing at the time of database lock, the last dose date is used; # means subject is discontinued from treatment within 30-35 days before database lock, date of EOT visit is used.

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Listing 16.2.1
Disposition
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Date of Randomization/ First/ Last Visit	Date of First/ Last Dose	Reason for Discontinuation	Reason No Longer Followed	Date of Last Contact[3]
302-0020/52/ M/A2	21MAY2013/16MAY2013 /15JUL2013	21MAY2013/11JUN2013	Withdrew Consent	Death	26NOV2013
302-0021/75/ F/A2	11JUN2013/06JUN2013 /26NOV2013	11JUN2013/19NOV2013	Disease Progression	Death	14FEB2014
304-0003/56/ F/A2	14MAR2013/07MAR2013 /03JUL2013	14MAR2013/30MAY2013	Disease Progression	Unknown	24JUN2015*
304-0004/69/ M/A2	03JUN2013/29MAY2013 /23JUL2013	03JUN2013/16JUL2013	Withdrew Consent	Death	07OCT2013
304-0007/72/ M/A2	13NOV2013/06NOV2013 /26FEB2014	13NOV2013/22JAN2014	Disease Progression	Death	20OCT2014
305-0004/79/ M/A2	24FEB2012/14FEB2012 /01JUN2012	24FEB2012/10MAY2012	Disease Progression	Death	03JUL2012
305-0007/67/ M/A2	09MAR2012/08MAR2012 /14SEP2012	09MAR2012/17AUG2012	Disease Progression	Death	08NOV2013

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

[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.

[3] * means subject is on follow-up, the last telephone contacted date is used; + means subject is still ongoing at the time of database lock, the last dose date is used; # means subject is discontinued from treatment within 30-35 days before database lock, date of EOT visit is used.

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Listing 16.2.1
Disposition
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Date of Randomization/ First/ Last Visit	Date of First/ Last Dose	Reason for Discontinuation	Reason No Longer Followed	Date of Last Contact[3]
305-0015/84/ M/A2	06JUL2012/03JUL2012 /18OCT2012	06JUL2012/13SEP2012	Disease Progression	Death	28NOV2012
305-0016/78/ M/A2	10JUL2012/04JUL2012 /26OCT2012	10JUL2012/02OCT2012	Adverse Event	Death	12NOV2012
305-0021/83/ F/A2	22NOV2012/06NOV2012 /15FEB2013	22NOV2012/05FEB2013	Disease Progression	Death	28APR2013
305-0024/68/ M/A2	15JAN2013/11JAN2013 /12APR2013	15JAN2013/03APR2013	Disease Progression	Death	08AUG2013
305-0033/37/ F/A2	02JUL2013/25JUN2013 /24SEP2013	02JUL2013/17SEP2013	Disease Progression	Death	22JUL2014
305-0035/60/ M/A2	28AUG2013/20AUG2013 /12FEB2014	28AUG2013/05FEB2014	Disease Progression	Death	29SEP2014
305-0046/60/ M/A2	07NOV2014/31OCT2014 /19MAY2015	07NOV2014/14APR2015	Disease Progression	Unknown	16JUN2015*

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

[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = ASIAN - MIXED, PI = NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, W1 = WHITE - ARABIC/NORTH AFRICAN HERITAGE, W2= WHITE - WHITE/CAUCASIAN/EUROPEAN HERITAGE, OTH = OTHER RACE.

[3] * means subject is on follow-up, the last telephone contacted date is used; + means subject is still ongoing at the time of database lock, the last dose date is used; # means subject is discontinued from treatment within 30-35 days before database lock, date of EOT visit is used.

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Listing 16.2.1
Disposition
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Date of Randomization/ First/ Last Visit	Date of First/ Last Dose	Reason for Discontinuation	Reason No Longer Followed	Date of Last Contact[3]
306-0004/46/ M/A2	21FEB2012/14FEB2012 /06APR2012	21FEB2012/27MAR2012	Disease Progression	Death	07APR2012
306-0010/69/ M/A2	21MAR2012/09MAR2012 /12JUN2012	21MAR2012/06JUN2012	Disease Progression	Death	10APR2013
306-0013/42/ M/A2	16APR2012/09APR2012 /18JUN2012	16APR2012/11JUN2012	Disease Progression	Death	18JUN2012
306-0015/73/ M/A2	17MAY2012/15MAY2012 /28JUN2012	17MAY2012/21JUN2012	Withdrew Consent	Death	27MAY2013
306-0016/58/ M/A2	25JUN2012/21JUN2012 /15OCT2012	25JUN2012/11SEP2012	Disease Progression	Death	14OCT2013
306-0022/56/ M/A2	13NOV2012/06NOV2012 /28MAY2013	13NOV2012/23APR2013	Disease Progression	Death	04FEB2014
306-0028/53/ M/A2	28MAR2013/18MAR2013 /04JUL2013	28MAR2013/03JUN2013	Disease Progression	Death	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.

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Listing 16.2.1
Disposition
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Date of Randomization/ First/ Last Visit	Date of First/ Last Dose	Reason for Discontinuation	Reason No Longer Followed	Date of Last Contact[3]
306-0045/60/ F/A1	20JUN2014/11JUN2014 /03OCT2014	20JUN2014/02SEP2014	Disease Progression	Death	30JUN2015
307-0006/72/ M/A2	29NOV2011/25NOV2011 /20DEC2011	29NOV2011/06DEC2011	Adverse Event	Death	23DEC2011
307-0009/53/ M/A2	03JAN2012/22DEC2011 /01MAR2012	03JAN2012/27JAN2012	Adverse Event	Death	12JUN2015
307-0012/42/ M/A2	07FEB2012/31JAN2012 /08MAR2012	07FEB2012/07FEB2012	Withdrew Consent	Death	10APR2012
307-0015/75/ M/A2	25APR2012/18APR2012 /08NOV2012	25APR2012/04OCT2012	Disease Progression	Death	28MAR2013
307-0021/68/ M/A2	21AUG2012/14AUG2012 /27DEC2012	21AUG2012/20DEC2012	Withdrew Consent	Death	21FEB2013
307-0028/69/ F/A2	14JAN2013/09JAN2013 /08APR2013	14JAN2013/01APR2013	Disease Progression	Death	01JUL2013

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Listing 16.2.1
Disposition
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Date of Randomization/ First/ Last Visit	Date of First/ Last Dose	Reason for Discontinuation	Reason No Longer Followed	Date of Last Contact[3]
307-0034/48/ M/A2	13AUG2013/08AUG2013 /31OCT2013	13AUG2013/29OCT2013	Disease Progression	Death	20FEB2014
307-0036/76/ M/A2	02OCT2013/27SEP2013 /21JAN2014	02OCT2013/18DEC2013	Disease Progression	Death	08JUL2014
307-0042/55/ M/A2	19JUN2014/10JUN2014 /18DEC2014	19JUN2014/13NOV2014	Disease Progression	Unknown	14MAY2015*
308-0002/36/ F/A2	31DEC2012/27DEC2012 /09APR2013	31DEC2012/19MAR2013	Disease Progression	Death	18FEB2014
308-0004/52/ M/A2	05FEB2013/29JAN2013 /01MAY2013	05FEB2013/23APR2013	Disease Progression	Death	30APR2015
308-0006/64/ M/A2	14MAY2013/07MAY2013 /30JUL2013	14MAY2013/26JUN2013	Disease Progression	Death	28NOV2014
308-0008/47/ M/A2	23JUL2013/11JUL2013 /05NOV2013	23JUL2013/16JUL2013	Disease Progression	Death	26DEC2013

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

[2] Race: MIX = Mixed Race, BL = BLACK OR AFRICAN AMERICA, AI = AMERICAN INDIAN OR ALASKA NATIVE, A1 = ASIAN - MAINLAND CHINA, A2 = ASIAN - TAIWAN, A3 = ASIAN - CENTRAL/SOUTH ASIAN HERITAGE, A4 = ASIAN - SOUTH EAST ASIAN HERITAGE, A5 = ASIAN - JAPANESE HERITAGE, A6 = ASIAN - EAST ASIAN HERITAGE, A7 = ASIAN - NORTH EAST ASIAN, A8 = ASIAN - ASIAN - OTHER, AMX = 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 16.2.1
Disposition
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Date of Randomization/ First/ Last Visit	Date of First/ Last Dose	Reason for Discontinuation	Reason No Longer Followed	Date of Last Contact[3]
308-0009/61/ M/A2	19JUL2013/11JUL2013 /12SEP2013	19JUL2013/05SEP2013	Death	Death	12SEP2013
309-0006/56/ M/A2	26NOV2012/19NOV2012 /22AUG2013	26NOV2012/22JUL2013	Disease Progression	Death	11JUN2015
309-0007/58/ M/A2	17DEC2012/04DEC2012 /28MAR2013	17DEC2012/25FEB2013	Disease Progression	Death	25JUN2013
309-0013/45/ M/A2	20JUN2013/11JUN2013 /30SEP2013	20JUN2013/29AUG2013	Disease Progression	Death	24NOV2014
309-0014/39/ M/A2	20JUN2013/14JUN2013 /03OCT2013	20JUN2013/29AUG2013	Disease Progression	Death	29JAN2014
309-0019/68/ M/A2	24JUN2014/17JUN2014 /Unknown	24JUN2014/20JUL2015		Unknown	20JUL2015+
309-0027/49/ M/A2	03NOV2014/22OCT2014 /16FEB2015	03NOV2014/12JAN2015	Disease Progression	Death	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.

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Listing 16.2.1
Disposition
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Date of Randomization/ First/ Last Visit	Date of First/ Last Dose	Reason for Discontinuation	Reason No Longer Followed	Date of Last Contact[3]
309-0029/50/ M/A2	01DEC2014/18NOV2014 /10FEB2015	01DEC2014/09FEB2015	Disease Progression	Death	11MAY2015
310-0004/50/ F/A2	06FEB2013/23JAN2013 /24APR2013	06FEB2013/17APR2013	Disease Progression	Death	19AUG2013
310-0005/58/ M/A2	27MAR2013/13MAR2013 /03JUL2013	27MAR2013/03JUN2013	Disease Progression	Death	30DEC2013
310-0006/50/ F/A2	01MAY2013/24APR2013 /27DEC2013	01MAY2013/23DEC2013	Disease Progression	Death	13OCT2014
310-0007/74/ M/A2	13JUN2013/30MAY2013 /06MAY2014	13JUN2013/01MAY2014	Disease Progression	Unknown	23JUN2015*
310-0009/46/ M/A2	07AUG2013/31JUL2013 /27SEP2013	07AUG2013/25SEP2013	Disease Progression	Death	24JAN2014
310-0010/34/ F/A2	26AUG2013/15AUG2013 /26SEP2013	26AUG2013/16SEP2013	Disease Progression	Death	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.

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Listing 16.2.1
Disposition
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Date of Randomization/ First/ Last Visit	Date of First/ Last Dose	Reason for Discontinuation	Reason No Longer Followed	Date of Last Contact[3]
310-0011/52/ M/A2	24OCT2013/17OCT2013 /08JAN2014	24OCT2013/02JAN2014	Disease Progression	Unknown	23JUN2015*
310-0014/64/ M/A2	24SEP2014/17SEP2014 /29DEC2014	24SEP2014/26NOV2014	Disease Progression	Death	25JUN2015
311-0003/44/ M/A2	25SEP2013/18SEP2013 /08JAN2014	25SEP2013/04DEC2013	Disease Progression	Death	03DEC2014
311-0004/68/ M/A2	30SEP2013/25SEP2013 /21OCT2013	30SEP2013/14OCT2013	Withdrew Consent	Voluntary Withdrawal	21OCT2013
311-0005/58/ M/A2	21OCT2013/07OCT2013 /22JAN2014	21OCT2013/23DEC2013	Disease Progression	Death	14AUG2014
311-0006/73/ F/A2	07NOV2013/04NOV2013 /16JAN2014	07NOV2013/09JAN2014	Disease Progression	Death	19MAR2014
311-0009/51/ F/A2	15JUL2014/01JUL2014 /04NOV2014	15JUL2014/30SEP2014	Disease Progression	Unknown	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] * means subject is on follow-up, the last telephone contacted date is used; + means subject is still ongoing at the time of database lock, the last dose date is used; # means subject is discontinued from treatment within 30-35 days before database lock, date of EOT visit is used.

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Listing 16.2.1
Disposition
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Date of Randomization/ First/ Last Visit	Date of First/ Last Dose	Reason for Discontinuation	Reason No Longer Followed	Date of Last Contact[3]
311-0010/47/ M/A2	02SEP2014/20AUG2014 /Unknown	02SEP2014/25JUN2015		Unknown	25JUN2015+
311-0011/46/ M/A2	30OCT2014/22OCT2014 /28JAN2015	30OCT2014/24DEC2014	Disease Progression	Unknown	18JUN2015*
311-0012/55/ M/A2	29JAN2015/15JAN2015 /Unknown	29JAN2015/25JUN2015		Unknown	25JUN2015+
401-0001/70/ M/A7	04JUN2013/03JUN2013 /07JUL2013	05JUN2013/05JUN2013	Other	Death	18AUG2013
401-0002/55/ M/A7	19JUN2013/12JUN2013 /05AUG2013	19JUN2013/03JUL2013	Withdrew Consent	Death	07MAY2015
402-0001/35/ M/A7	22APR2013/15APR2013 /24JUN2013	22APR2013/20MAY2013	Disease Progression	Death	24JUN2013
402-0002/58/ M/A7	23APR2013/15APR2013 /12AUG2013	23APR2013/09JUL2013	Disease Progression	Death	10JUN2014

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Listing 16.2.1
Disposition
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Date of Randomization/ First/ Last Visit	Date of First/ Last Dose	Reason for Discontinuation	Reason No Longer Followed	Date of Last Contact[3]
402-0005/70/ M/A7	09MAY2013/30APR2013 /22AUG2013	09MAY2013/23JUL2013	Disease Progression	Death	16OCT2013
402-0010/50/ M/A7	20MAY2013/10MAY2013 /08JUL2013	20MAY2013/17JUN2013	Disease Progression	Death	25JUL2013
402-0022/60/ F/A7	19AUG2013/09AUG2013 /19DEC2013	19AUG2013/11NOV2013	Disease Progression	Death	03MAR2014
402-0023/57/ M/A7	02SEP2013/22AUG2013 /26NOV2013	02SEP2013/19NOV2013	Disease Progression	Death	17JAN2014
402-0029/49/ M/A7	11NOV2013/06NOV2013 /Unknown	11NOV2013/30DEC2013	Disease Progression	Death	04JAN2014
402-0032/49/ F/A7	06DEC2013/28NOV2013 /27MAR2014	06DEC2013/20FEB2014	Disease Progression	Death	01JUL2014
402-0034/43/ F/A7	19DEC2013/11DEC2013 /26JUN2014	19DEC2013/29MAY2014	Disease Progression	Unknown	19JUN2015*

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Listing 16.2.1
Disposition
(Safety Population)

Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Date of Randomization/ First/ Last Visit	Date of First/ Last Dose	Reason for Discontinuation	Reason No Longer Followed	Date of Last Contact[3]
403-0004/37/ M/A7	11JUL2013/03JUL2013 /31OCT2013	12JUL2013/25SEP2013	Disease Progression	Death	07MAY2015
404-0003/53/ M/A7	10SEP2013/02SEP2013 /30SEP2013	10SEP2013/24SEP2013	Disease Progression	Death	07NOV2013
404-0004/61/ F/A7	15OCT2013/08OCT2013 /09DEC2013	15OCT2013/02DEC2013	Disease Progression	Death	25DEC2013
405-0001/55/ M/A7	22APR2013/22APR2013 /04SEP2013	22APR2013/03JUL2013	Disease Progression	Death	02APR2014
405-0005/35/ M/A6	24APR2013/19APR2013 /22JAN2014	24APR2013/23DEC2013	Disease Progression	Death	20MAY2015
405-0012/72/ M/A7	15MAY2013/09MAY2013 /21OCT2013	15MAY2013/21OCT2013	Disease Progression	Death	25DEC2013
405-0019/61/ M/A7	26JUN2013/19JUN2013 /05AUG2013	26JUN2013/24JUL2013	Death	Death	11AUG2013

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Disposition
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Treatment Group: Placebo

Subject No./ Age[1]/ Gender/ Race[2]	Date of Randomization/ First/ Last Visit	Date of First/ Last Dose	Reason for Discontinuation	Reason No Longer Followed	Date of Last Contact[3]
405-0024/69/ M/A7	03JUL2013/19JUN2013 /10JUL2013	03JUL2013/03JUL2013	Adverse Event	Death	05AUG2013
405-0026/67/ M/A7	08JUL2013/27JUN2013 /22OCT2013	08JUL2013/25SEP2013	Disease Progression	Death	24FEB2014
405-0036/70/ M/A7	19AUG2013/16AUG2013 /17DEC2013	19AUG2013/11NOV2013	Disease Progression	Death	15JAN2014
405-0041/57/ M/A7	13SEP2013/11SEP2013 /02JUN2014	13SEP2013/02MAY2014	Disease Progression	Unknown	03JUN2015*
501-0003/22/ M/A1	11DEC2013/05DEC2013 /27FEB2014	11DEC2013/19FEB2014	Disease Progression	Death	28JUL2014
501-0004/26/ M/A1	18DEC2013/14DEC2013 /08APR2014	18DEC2013/05MAR2014	Disease Progression	Death	08AUG2014
501-0011/61/ M/A1	25SEP2014/18SEP2014 /16DEC2014	25SEP2014/11DEC2014	Disease Progression	Death	12JAN2015

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Disposition
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Subject No./ Age[1]/ Gender/ Race[2]	Date of Randomization/ First/ Last Visit	Date of First/ Last Dose	Reason for Discontinuation	Reason No Longer Followed	Date of Last Contact[3]
502-0001/70/ M/A1	13DEC2013/11DEC2013 /16JAN2014	14DEC2013/10JAN2014	Death	Death	16JAN2014
502-0003/48/ M/A1	14JAN2014/13JAN2014 /05MAY2014	15JAN2014/04APR2014	Disease Progression	Death	05AUG2014
503-0002/71/ F/A1	20FEB2014/18FEB2014 /24NOV2014	20FEB2014/21OCT2014	Disease Progression	Death	18MAY2015
503-0003/47/ F/A1	07MAR2014/05MAR2014 /20MAY2014	07MAR2014/03APR2014	Withdrew Consent	Death	15JUL2014
503-0005/72/ M/A1	25MAR2014/18MAR2014 /19MAR2015	25MAR2014/15FEB2015	Disease Progression	Unknown	02JUL2015*
504-0003/53/ M/A1	13MAR2014/11MAR2014 /08MAY2014	13MAR2014/03APR2014	Disease Progression	Death	09JUN2014
504-0005/41/ F/A1	03SEP2014/02SEP2014 /11NOV2014	03SEP2014/09OCT2014	Death	Death	11NOV2014

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506-0001/43/ M/A1	15APR2014/14APR2014 /03JUL2014	15APR2014/21MAY2014	Disease Progression	Death	30JUL2014
506-0005/24/ M/A1	22DEC2014/19DEC2014 /20JAN2015	22DEC2014/07JAN2015	Adverse Event	Death	26JAN2015
507-0001/51/ M/A1	24JUL2014/18JUL2014 /11NOV2014	24JUL2014/09OCT2014	Disease Progression	Unknown	02JUL2015*
507-0002/44/ M/A1	29JUL2014/24JUL2014 /16OCT2014	29JUL2014/16SEP2014	Disease Progression	Death	10NOV2014
508-0002/64/ M/A1	19FEB2014/10FEB2014 /15APR2014	19FEB2014/11APR2014	Death	Death	16APR2014
508-0004/58/ M/A1	27AUG2014/25AUG2014 /30SEP2014	27AUG2014/10SEP2014	Other	Lost to Follow-up	30SEP2014
509-0003/39/ M/A1	24JUL2014/15JUL2014 /12NOV2014	24JUL2014/09OCT2014	Disease Progression	Death	12JAN2015

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510-0001/67/ M/A1	26FEB2014/25FEB2014 /10DEC2014	26FEB2014/03DEC2014	Disease Progression	Unknown	30JUN2015*
510-0003/43/ M/A1	05JUN2014/29MAY2014 /22AUG2014	05JUN2014/06AUG2014	Disease Progression	Death	27NOV2014
513-0003/46/ M/A1	30APR2014/22APR2014 /11JUN2014	30APR2014/07MAY2014	Adverse Event	Death	15JUN2014
515-0005/45/ M/A1	23JUN2014/09JUN2014 /10OCT2014	23JUN2014/09SEP2014	Disease Progression	Death	10OCT2014
517-0003/45/ M/A1	14MAY2014/09MAY2014 /29AUG2014	14MAY2014/30JUL2014	Disease Progression	Lost to Follow-up	18MAR2015
517-0010/67/ M/A1	12NOV2014/04NOV2014 /04MAR2015	12NOV2014/28JAN2015	Disease Progression	Death	08APR2015

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