Immune Tolerance Network
Protocol ITN020AI Zamvil

ADSTART0

One record per participant

Dataset for participant characteristics and demographics. Should be run before all analysis datasets.

	Variable Name	Variable Label	Type	Length	Format	Description
1	USUBJID*	ID	C	6	$6.	Unique Subject Identifier
2	INVID	Investigational Site	C	3	$3.	Site ID
3	SUBJL*	Inv.Site/Part. ID for listings	C	7	$7.	Unique Subject Identifier. Site and subject ID separated by a /.
4	STUDYID	Study Identifier	C	8	$8.	Study Identifier
5	TRTC*	Treatment Group (Char)	C	15	$15.	Randomized Treatment Group
6	ITT*	Intent To Treat Sample	C	3	$3.	Subject is in the Intent to Treat Sample. ITT is defined as all randomized subjects who received any dose of study drug.
7	PP*	Per Protocol Sample	C	3	$3.	Subject is in the Per-protocol Sample. PP is defined as all randomized subjects who receive at least 80% of planned dose of study drug and have no major protocol deviations that impact the efficacy assessments.
8	SAFETY*	Safety Sample	C	3	$3.	Subjects in the Safety Sample. Safety is defined as all subjects who receive at least one dose of study drug.
9	SAMP*	Analysis Sample	C	5	$5.	Subject's analysis sample. S= Safety, I= Intent to Treat, P= Per-Protocol
10	RAND*	Randomized	C	3	$3.	Subject was randomized
11	INFCDT	Date of Screening Informed Consent	N	8	DATE9.	Date of informed consent.
12	RANDT	Date of Randomization	N	8	DATE9.	Date of randomization
13	SCRDT	Date of Screening Visit	N	8	DATE9.	Date of screening visit
14	MNTH3DT*	Date of Month 3 visit	N	8	DATE9.	Date of actual 3 month visit.
15	MNTH6DT*	Date of Month 6 visit	N	8	DATE9.	Date of actual 6 month visit.
16	MNTH9DT*	Date of Month 9 visit	N	8	DATE9.	Date of actual 9 month visit.
17	MNTH12DT*	Date of Month 12 visit	N	8	DATE9.	Date of actual 12 month visit.
18	MNTH18DT*	Date of Month 18 visit	N	8	DATE9.	Date of actual 18 month visit.
19	DISCTDT	Date of Study Drug Discontinuation	N	8	DATE9.	Date study drug was discontinued. If the month and year were non-missing and the day was missing, the day was imputed as 15.
20	FDDT*	First Dose Date	N	8	DATE9.	First date receiving Atorvastatin or Placebo. It is assumed that the date the drug was dispensed is the first date the drug was taken by the subject.
21	LDDT	Last Dose Date	N	8	DATE9.	Last date drug was received. Equal to DISCTDT.
22	AVNXSTDT*	Start date of Avonex	N	8	DATE9.	First date receiving Avonex.

Note: Variables from the ADSTART0 dataset that are retained across all datasets are marked with an asterisk (*).

Based on derivations as of 20SEP2013. Some variables in the specifications may be excluded from datasets for de-indentification purposes.

Immune Tolerance Network
Protocol ITN020AI Zamvil

ADSTART0

One record per participant

Dataset for participant characteristics and demographics. Should be run before all analysis datasets.

	Variable Name	Variable Label	Type	Length	Format	Description
23	FUDT*	Date of Last Follow-up	N	8	DATE9.	Date of dropout or completion of study.
24	VISITNUM	Visit Number	C	10	$10.	Visit Number
25	BRTHDT	Date of Birth	N	8	DATE9.	Date of Birth (numeric).
26	AGE	Age (years)	N	8	8.0	Age in years at time of informed consent.
27	AGEGRP	Age Group (years)	C	7	$7.	Age group in years at time of informed consent.
28	RACEP	Primary Race	C	42	$42.	Primary race
29	RACEPL	Primary Race (List)	C	150	$150.	Primary race used for listings. If primary race is Other, then other race is specified.
30	RACES	Secondary Race	C	42	$42.	Secondary race
31	RACESL	Secondary Race (List)	C	150	$150.	Secondary race used for listings. If secondary race is Other, then other race is specified.
32	RACEIND	IND Race	C	42	$42.	Indicator of subject race. If both a primary and secondary race are specified, then = 'More than one race' . If primary race is Other, then 'Unknown'. Otherwise, = the primary race.
33	SEX	Sex	C	2	$2.	Sex (numeric)
34	SEXC	Sex (Char)	C	7	$7.	Sex (Character)
35	ETHNIC	Ethnicity	C	22	$22.	Ethnicity
36	COMPLTST	Completed Study	C	3	$3.	Subject completed study.
37	DISCSRS	Discontinued Study Reason	C	60	$60.	Reason for early discontinuation of study.
38	DISCSRSL	Discontinued Study Reason (List)	C	200	$200.	Reason for early discontinuation of study used for listings. If reason is Other, then other reason is specified.
39	COMPLTTR	Completed Study Therapy	C	7	$7.	Subject completed study therapy.
40	DISCTRS	Discontinued Therapy Reason	C	60	$60.	Reason for early discontinuation of study therapy.
41	DISCTRSL	Discontinued Therapy Reason (List)	C	250	$250.	Reason for early discontinuation of study therapy used for listings. If reason is Other, then other reason is specified.

Note: Variables from the ADSTART0 dataset that are retained across all datasets are marked with an asterisk (*).

Immune Tolerance Network
Protocol ITN020AI Zamvil

ADAE1

One record per participant and adverse event

Dataset for adverse events. No placeholders for participants without an AE.

	Variable Name	Variable Label	Type	Length	Format	Description
1	USUBJID*	ID	C	6	$6.	Unique Subject Identifier
2	SUBJL*	Inv.Site/Part. ID for listings	C	7	$7.	Unique Subject Identifier. Site and subject ID separated by a /.
3	TRTC*	Treatment Group (Char)	C	15	$15.	Randomized Treatment Group
4	ITT*	Intent To Treat Sample	C	3	$3.	Subject is in the Intent to Treat Sample. ITT is defined as all randomized subjects who received any dose of study drug.
5	PP*	Per Protocol Sample	C	3	$3.	Subject is in the Per-protocol Sample. PP is defined as all randomized subjects who receive at least 80% of planned dose of study drug and have no major protocol deviations that impact the efficacy assessments.
6	SAFETY*	Safety Sample	C	3	$3.	Subjects in the Safety Sample. Safety is defined as all subjects who receive at least one dose of study drug.
7	SAMP*	Analysis Sample	C	5	$5.	Subject's analysis sample. S= Safety, I= Intent to Treat, P= Per-Protocol
8	RAND*	Randomized	C	3	$3.	Subject was randomized
9	MNTH3DT*	Date of Month 3 visit	N	8	DATE9.	Date of actual 3 month visit.
10	MNTH6DT*	Date of Month 6 visit	N	8	DATE9.	Date of actual 6 month visit.
11	MNTH9DT*	Date of Month 9 visit	N	8	DATE9.	Date of actual 9 month visit.
12	MNTH12DT*	Date of Month 12 visit	N	8	DATE9.	Date of actual 12 month visit.
13	MNTH18DT*	Date of Month 18 visit	N	8	DATE9.	Date of actual 18 month visit.
14	FDDT*	First Dose Date	N	8	DATE9.	First date receiving Atorvastatin or Placebo. It is assumed that the date the drug was dispensed is the first date the drug was taken by the subject.
15	AVNXSTDT*	Start date of Avonex	N	8	DATE9.	First date receiving Avonex.
16	FUDT*	Date of Last Follow-up	N	8	DATE9.	Date of dropout or completion of study.
17	AETERM	Reported Term for the Adverse Event	C	100	$100.	Site reported verbatim term for the adverse event.
18	AESTDT	Start Date of Adverse Event	N	8	DATE9.	Date adverse event started.
19	AESTDTC	Start Date of Adverse Event (Char)	C	9	$9.	Date adverse event started (character).
20	AESTDY	AE Start Date Study Day	N	8	8.	Days from Day 1 (first dose date) to start of adverse event.
21	AEENDT	Stop Date of Adverse Event	N	8	DATE9.	Date adverse event ended.
22	AEENDTC	Stop Date of Adverse Event (Char)	C	9	$9.	Date adverse event ended (character).
23	AEENDY	AE Stop Date Study Day	N	8	8.	Days from Day 1 (first dose date) to end of adverse event.

Note: Variables from the ADSTART0 dataset that are retained across all datasets are marked with an asterisk (*).

Immune Tolerance Network
Protocol ITN020AI Zamvil

ADAE1

One record per participant and adverse event

Dataset for adverse events. No placeholders for participants without an AE.

	Variable Name	Variable Label	Type	Length	Format	Description
24	AEONGO	AE Ongoing	C	3	$3.	Adverse event ongoing at study termination/completion.
25	AEDUR	Duration of Adverse Event	N	8	8.	Number of days between the start and end of the adverse event. Duration is missing if the start or stop dates are missing or the adverse event was ongoing at end of study.
26	AEOUT	Outcome of Adverse Event	C	2	$2.	Outcome of adverse event.
27	AEOUTC	Outcome of Adverse Event (Char)	C	22	$22.	Outcome of adverse event (character). Outcome is unresolved for adverse events ongoing at end of study.
28	AESEV	Severity/Intensity of Adverse Event	C	2	$2.	Severity of adverse event.
29	AESEVC	Severity/Intensity of AE (Char)	C	16	$16.	Severity of adverse event (character).
30	AESEVCI	Imputed Severity/Intensity of AE (Char)	C	16	$16.	Imputed severity of adverse event. A severity of 'Severe' is imputed for missing severity.
31	AEREL	Causality	C	2	$2.	Causality/relationship of adverse event.
32	AERELC	Causality (Char)	C	15	$15.	Causality/relationship of adverse event (character).
33	AESER	Serious Adverse Event	C	3	$3.	Adverse event serious.
34	AESERC	Serious Adverse Event (Char)	C	3	$3.	Adverse event serious (character).
35	AETRT	Treatment Required	C	2	$2.	Treatment required for adverse event.
36	AETRTC	Treatment Required (Char)	C	50	$50.	Treatment required for adverse event (character).
37	AEACT	Action Taken	C	2	$2.	Action taken with study drug due to adverse event.
38	AEACTC	Action Taken (Char)	C	25	$25.	Action taken with study drug due to adverse event (character).
39	AETEAE	Treatment Emergent Adverse Event	C	3	$3.	Adverse event treatment emergent. Considered treatment emergent if adverse event started after Day 1 (first dosing date). If the start date is missing or partially missing and it cannot be determined whether the start date is after the first dose was administered the adverse event is treated as treatment emergent as long as the adverse event did not stop prior to the first dose date.
40	AEPT	Preferred Term	C	200	$200.	Adverse event preferred term.
41	AESOC	System Organ Class	C	200	$200.	Adverse event system organ class.
42	VISITNUM	Visit Number	C	10	$10.	Visit Number

Note: Variables from the ADSTART0 dataset that are retained across all datasets are marked with an asterisk (*).

Immune Tolerance Network
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ADAV1

One record per participant per dose

Dataset for the analysis of Avonex medication.

	Variable Name	Variable Label	Type	Length	Format	Description
1	USUBJID*	ID	C	6	$6.	Unique Subject Identifier
2	SUBJL*	Inv.Site/Part. ID for listings	C	7	$7.	Unique Subject Identifier. Site and subject ID separated by a /.
3	TRTC*	Treatment Group (Char)	C	15	$15.	Randomized Treatment Group
4	ITT*	Intent To Treat Sample	C	3	$3.	Subject is in the Intent to Treat Sample. ITT is defined as all randomized subjects who received any dose of study drug.
5	PP*	Per Protocol Sample	C	3	$3.	Subject is in the Per-protocol Sample. PP is defined as all randomized subjects who receive at least 80% of planned dose of study drug and have no major protocol deviations that impact the efficacy assessments.
6	SAFETY*	Safety Sample	C	3	$3.	Subjects in the Safety Sample. Safety is defined as all subjects who receive at least one dose of study drug.
7	SAMP*	Analysis Sample	C	5	$5.	Subject's analysis sample. S= Safety, I= Intent to Treat, P= Per-Protocol
8	RAND*	Randomized	C	3	$3.	Subject was randomized
9	MNTH3DT*	Date of Month 3 visit	N	8	DATE9.	Date of actual 3 month visit.
10	MNTH6DT*	Date of Month 6 visit	N	8	DATE9.	Date of actual 6 month visit.
11	MNTH9DT*	Date of Month 9 visit	N	8	DATE9.	Date of actual 9 month visit.
12	MNTH12DT*	Date of Month 12 visit	N	8	DATE9.	Date of actual 12 month visit.
13	MNTH18DT*	Date of Month 18 visit	N	8	DATE9.	Date of actual 18 month visit.
14	FDDT*	First Dose Date	N	8	DATE9.	First date receiving Atorvastatin or Placebo. It is assumed that the date the drug was dispensed is the first date the drug was taken by the subject.
15	AVNXSTDT*	Start date of Avonex	N	8	DATE9.	First date receiving Avonex.
16	FUDT*	Date of Last Follow-up	N	8	DATE9.	Date of dropout or completion of study.
17	MTENDPT	Met Primary Endpoint	C	3	$3.	Primary endpoint met. The primary endpoint criteria are met if the subject develops at least 3 new T2 lesions or one clinical exacerbation.
18	AVNXOFR	Avonex Offered to Participant	C	3	$3.	Avonex offered to the subject.
19	AVNXACP	Avonex Accepted by Participant	C	3	$3.	Avonex accepted by the subject.
20	AVDOSE	Avonex Dose	C	20	$20.	Dose of Avonex administered.
21	AVSTDT	Avonex Start Date	N	8	DATE9.	Avonex start date.
22	AVSTDY	Avonex Start Study Day	N	8	8.	Days from Day 1 (first dose date) to start of Avonex dose.

Note: Variables from the ADSTART0 dataset that are retained across all datasets are marked with an asterisk (*).

Based on derivations as of 20SEP2013. Some variables in the specifications may be excluded from datasets for de-indentification purposes.

Immune Tolerance Network
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ADAV1

One record per participant per dose

Dataset for the analysis of Avonex medication.

	Variable Name	Variable Label	Type	Length	Format	Description
23	AVSTDTC	Avonex Start Date (Char)	C	9	$9.	Avonex start date (character).
24	AVENDT	Avonex End Date	N	8	DATE9.	Avonex end date.
25	AVENDY	Avonex End Study Day	N	8	8.	Days from Day 1 (first dose date) to end of Avonex dose.
26	AVENDTC	Avonex End Date (Char)	C	9	$9.	Avonex end date (character).
27	AVENDTI	Avonex End Date (Imputed)	N	8	DATE9.	Imputed Avonex end date. June is imputed for missing month and 15 is imputed for missing day. No imputation was performed if the entire stop date was missing.
28	AVONGO	Avonex Ongoing	C	3	$3.	Avonex ongoing at study termination/completion.
29	VISITNUM	Visit Number	C	10	$10.	Visit Number

Note: Variables from the ADSTART0 dataset that are retained across all datasets are marked with an asterisk (*).

Immune Tolerance Network
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ADCEXR1

One record per participant and clinical exacerbation visit

Dataset for the analysis of clinical exacerbations.

	Variable Name	Variable Label	Type	Length	Format	Description
1	USUBJID*	ID	C	6	$6.	Unique Subject Identifier
2	SUBJL*	Inv.Site/Part. ID for listings	C	7	$7.	Unique Subject Identifier. Site and subject ID separated by a /.
3	TRTC*	Treatment Group (Char)	C	15	$15.	Randomized Treatment Group
4	ITT*	Intent To Treat Sample	C	3	$3.	Subject is in the Intent to Treat Sample. ITT is defined as all randomized subjects who received any dose of study drug.
5	PP*	Per Protocol Sample	C	3	$3.	Subject is in the Per-protocol Sample. PP is defined as all randomized subjects who receive at least 80% of planned dose of study drug and have no major protocol deviations that impact the efficacy assessments.
6	SAFETY*	Safety Sample	C	3	$3.	Subjects in the Safety Sample. Safety is defined as all subjects who receive at least one dose of study drug.
7	SAMP*	Analysis Sample	C	5	$5.	Subject's analysis sample. S= Safety, I= Intent to Treat, P= Per-Protocol
8	RAND*	Randomized	C	3	$3.	Subject was randomized
9	MNTH3DT*	Date of Month 3 visit	N	8	DATE9.	Date of actual 3 month visit.
10	MNTH6DT*	Date of Month 6 visit	N	8	DATE9.	Date of actual 6 month visit.
11	MNTH9DT*	Date of Month 9 visit	N	8	DATE9.	Date of actual 9 month visit.
12	MNTH12DT*	Date of Month 12 visit	N	8	DATE9.	Date of actual 12 month visit.
13	MNTH18DT*	Date of Month 18 visit	N	8	DATE9.	Date of actual 18 month visit.
14	FDDT*	First Dose Date	N	8	DATE9.	First date receiving Atorvastatin or Placebo. It is assumed that the date the drug was dispensed is the first date the drug was taken by the subject.
15	AVNXSTDT*	Start date of Avonex	N	8	DATE9.	First date receiving Avonex.
16	FUDT*	Date of Last Follow-up	N	8	DATE9.	Date of dropout or completion of study.
17	VISIT	Visit Number	N	8	8.	Visit number.
18	VISITNUM	Visit Number	C	10	$10.	Visit number.
19	VISITC	Visit Name (Char)	C	15	$15.	Visit.
20	CEDT	Date of Clinical Exacerbation Visit	N	8	DATE9.	Date of clinical exacerbation visit.
21	CEDY	Day of Clinical Exacerbation Visit	N	8	8.	Days from Day 1 (first dose date) to clinical exacerbation visit.
22	SYMPYN	Any New or Recurrent Neuro Symptoms	C	3	$3.	New or recurrent neurological symptoms, not associated with fever or infection, consistent with multiple sclerosis.

Note: Variables from the ADSTART0 dataset that are retained across all datasets are marked with an asterisk (*).

Based on derivations as of 20SEP2013. Some variables in the specifications may be excluded from datasets for de-indentification purposes.

Immune Tolerance Network
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ADCEXR1

One record per participant and clinical exacerbation visit

Dataset for the analysis of clinical exacerbations.

	Variable Name	Variable Label	Type	Length	Format	Description
23	CETYPE	Type of Clinical Exacerbation Symptoms	C	20	$20.	Type of clinical exacerbation symptoms.
24	CESYMG48	Symptoms Last >= 48 Hours	C	3	$3.	Symptoms last >= 48 hours.
25	SYMPLST	List of Symptoms	C	200	$200.	List of symptoms experienced.
26	SYMIDNT	Identical to Symptoms at Study Start	C	3	$3.	Symptoms identical in nature and severity to the symptoms at the start of the study.
27	SYMLT48	Symptoms Last <= 48 Hours	C	3	$3.	Symptoms last <= 48 hours
28	PRIMEND	Met Primary Endpoint (to Month 12)	C	3	$3.	Primary endpoint met between Day 1 (first dosing date) and Month 12. The primary endpoint criteria are met if the subject develops at least 3 new T2 lesions or has one clinical exacerbation.
29	PRIMENDX	Met Primary Endpoint (to Month 18)	C	3	$3.	Primary endpoint criteria met between Day 1 (first dosing date) and Month 18. The primary endpoint criteria are met if the subject develops at least 3 new T2 lesions or has one clinical exacerbation.
30	CISFORM	Form of CIS (Primary Endpoint)	C	200	$200.	Form of clinically isolated syndrome (CIS). Primary endpoint met if non-missing.
31	OPTLMYN	Has Opthalmologist Rules out Other Poss	C	3	$3.	If CIS is optic neuritis has an ophthalmologist ruled out other possibilities.
32	OPTLDT	Date of Opthalmologist Assessment	N	8	DATE9.	If CIS is optic neuritis, date of ophthalmologist assessment.
33	DB	Indicator: Double-blind treatment phase	N	8	1.0	Indicator for double-blind treatment phase (Day 1 through Month 12). Month 12 expected visit date is used if the visit is missing. 1 = double blind treatment phase. 0 = other.
34	M3_12	Indicator: Month 3 - Month 12	N	8	3.0	Indicator for Month 3 - Month 12. Expected visit dates are used if the visits are missing. 1 = Month 3 - Month 12. 0 = other.
35	D1_M3	Indicator: Day 1 - Month 3	N	8	3.0	Indicator for Day 1 - Month 3. Month 3 expected visit date is used if the visit is missing. 1 = Day 1 - Month 3. 0 = other.
36	D1_M6	Indicator: Day 1 - Month 6	N	8	3.0	Indicator for Day 1 - Month 6. Month 6 expected date is used if the visit is missing. 1 = Day 1 - Month 6. 0 = other.
37	D1_M9	Indicator: Day 1 - Month 9	N	8	1.0	Indicator for Day 1 - Month 9. Month 9 expected date is used if the visit is missing. 1 = Day 1 - Month 9. 0 = other.
38	EXT	Indicator: Extension phase	N	8	1.0	Indicator for extension phase (>Month 12 - Month 18). Expected visit dates are used if the visits are missing. 1 = extension phase. 0 = other.
39	CISFORML	Form of CIS (Primary Endpoint) Specified	C	200	$200.	Form of clinically isolated syndrome (CIS). Primary endpoint met if non-missing. Variable for listings which includes ophthalmologist findings.

Note: Variables from the ADSTART0 dataset that are retained across all datasets are marked with an asterisk (*).

Immune Tolerance Network
Protocol ITN020AI Zamvil

ADCIS1

One record per participant

Dataset for the anlaysis of clinically isolated syndrome

	Variable Name	Variable Label	Type	Length	Format	Description
1	USUBJID*	ID	C	6	$6.	Unique Subject Identifier
2	SUBJL*	Inv.Site/Part. ID for listings	C	7	$7.	Unique Subject Identifier. Site and subject ID separated by a /.
3	TRTC*	Treatment Group (Char)	C	15	$15.	Randomized Treatment Group
4	ITT*	Intent To Treat Sample	C	3	$3.	Subject is in the Intent to Treat Sample. ITT is defined as all randomized subjects who received any dose of study drug.
5	PP*	Per Protocol Sample	C	3	$3.	Subject is in the Per-protocol Sample. PP is defined as all randomized subjects who receive at least 80% of planned dose of study drug and have no major protocol deviations that impact the efficacy assessments.
6	SAFETY*	Safety Sample	C	3	$3.	Subjects in the Safety Sample. Safety is defined as all subjects who receive at least one dose of study drug.
7	SAMP*	Analysis Sample	C	5	$5.	Subject's analysis sample. S= Safety, I= Intent to Treat, P= Per-Protocol
8	RAND*	Randomized	C	3	$3.	Subject was randomized
9	MNTH3DT*	Date of Month 3 visit	N	8	DATE9.	Date of actual 3 month visit.
10	MNTH6DT*	Date of Month 6 visit	N	8	DATE9.	Date of actual 6 month visit.
11	MNTH9DT*	Date of Month 9 visit	N	8	DATE9.	Date of actual 9 month visit.
12	MNTH12DT*	Date of Month 12 visit	N	8	DATE9.	Date of actual 12 month visit.
13	MNTH18DT*	Date of Month 18 visit	N	8	DATE9.	Date of actual 18 month visit.
14	FDDT*	First Dose Date	N	8	DATE9.	First date receiving Atorvastatin or Placebo. It is assumed that the date the drug was dispensed is the first date the drug was taken by the subject.
15	AVNXSTDT*	Start date of Avonex	N	8	DATE9.	First date receiving Avonex.
16	FUDT*	Date of Last Follow-up	N	8	DATE9.	Date of dropout or completion of study.
17	VISIT	Visit Number	N	8	8.	Visit number.
18	VISITNUM	Visit Number	C	10	$10.	Visit number.
19	VISITC	Visit Name (Char)	C	15	$15.	Visit.
20	CISFORM	Form of CIS	C	30	$30.	Form of clinically isolated syndrome (CIS). Primary endpoint met if non-missing. Note that this data is from the CRF form called 'Clinically Isolated Syndrome - CIS.' The ADCEXR1 dataset information is from the 'Clinical Exacerbation' CRF form.

Note: Variables from the ADSTART0 dataset that are retained across all datasets are marked with an asterisk (*).

Immune Tolerance Network
Protocol ITN020AI Zamvil

ADCIS1

One record per participant

Dataset for the anlaysis of clinically isolated syndrome

	Variable Name	Variable Label	Type	Length	Format	Description
21	CISFORML	Form of CIS (List)	C	200	$200.	Form of clinically isolated syndrome (CIS). Primary endpoint met if non-missing. Variable for listings which includes other findings.
22	OPTLMYN	Ophthalmologist Rules Out Other Poss	C	3	$3.	If CIS is optic neuritis has an ophthalmologist ruled out other possibilities.
23	OPTLDT	Date of Ophthalmologist Assessment	N	8	DATE9.	If CIS is optic neuritis, date of ophthalmologist assessment.
24	OPTLDTC	Date of Ophthalmologist Assess (Char)	C	9	$9.	If CIS is optic neuritis, date of ophthalmologist assessment (character).
25	CISDT	Date of Symptoms Onset	N	8	DATE9.	Date of CIS symptoms onset.
26	CISDY	Study Day of Symptoms Onset	N	8	8.	Days from Day 1 (first dose date) to start of CIS symptoms.
27	CISDTC	Date of Symptoms Onset (Char)	C	9	$9.	Date of CIS symptoms onset (character)
28	CISDUR	Duration of CIS	N	8	8.	Number of days between screening and CIS symptoms onset.
29	CISSEV	Severity of Symptoms	C	8	$8.	Severity of symptoms. Mild = EDSS range 0 to 1.5 inclusive. Moderate = EDSS range 2.0 to 2.5 inclusive. Severe = EDSS of 3.0 or more.
30	CIVISUL	Visual Functional System	C	3	$3.	Visual functional system symptoms present.
31	CIPYRAM	Pyramidal Functional System	C	3	$3.	Pyramidal functional system symptoms present.
32	CISENS	Sensory Functional System	C	3	$3.	Sensory functional system symptoms present.
33	CIBRAIN	Cranial Nerves/Brainstem Functional Sys	C	3	$3.	Cranial nerves/brainstem functional system symptoms present.
34	CICBELL	Cerebellar Functional System	C	3	$3.	Cerebellar functional system symptoms present.
35	CISPNCT	Sphincters Functional System	C	3	$3.	Sphincters functional system symptoms present.
36	CICGNFT	Cognition/Fatigue Functional System	C	3	$3.	Cognition/fatigue functional system symptoms present
37	CISSYMP	Functional Systems of Symptoms	C	200	$200.	Comma delimited list of all functional system symptoms present.

Note: Variables from the ADSTART0 dataset that are retained across all datasets are marked with an asterisk (*).

Immune Tolerance Network
Protocol ITN020AI Zamvil

ADCMED1

One record per participant, medication, and start date

Dataset for concomitant medications.

	Variable Name	Variable Label	Type	Length	Format	Description
1	USUBJID*	ID	C	6	$6.	Unique Subject Identifier
2	SUBJL*	Inv.Site/Part. ID for listings	C	7	$7.	Unique Subject Identifier. Site and subject ID separated by a /.
3	TRTC*	Treatment Group (Char)	C	15	$15.	Randomized Treatment Group
4	ITT*	Intent To Treat Sample	C	3	$3.	Subject is in the Intent to Treat Sample. ITT is defined as all randomized subjects who received any dose of study drug.
5	PP*	Per Protocol Sample	C	3	$3.	Subject is in the Per-protocol Sample. PP is defined as all randomized subjects who receive at least 80% of planned dose of study drug and have no major protocol deviations that impact the efficacy assessments.
6	SAFETY*	Safety Sample	C	3	$3.	Subjects in the Safety Sample. Safety is defined as all subjects who receive at least one dose of study drug.
7	SAMP*	Analysis Sample	C	5	$5.	Subject's analysis sample. S= Safety, I= Intent to Treat, P= Per-Protocol
8	RAND*	Randomized	C	3	$3.	Subject was randomized
9	MNTH3DT*	Date of Month 3 visit	N	8	DATE9.	Date of actual 3 month visit.
10	MNTH6DT*	Date of Month 6 visit	N	8	DATE9.	Date of actual 6 month visit.
11	MNTH9DT*	Date of Month 9 visit	N	8	DATE9.	Date of actual 9 month visit.
12	MNTH12DT*	Date of Month 12 visit	N	8	DATE9.	Date of actual 12 month visit.
13	MNTH18DT*	Date of Month 18 visit	N	8	DATE9.	Date of actual 18 month visit.
14	FDDT*	First Dose Date	N	8	DATE9.	First date receiving Atorvastatin or Placebo. It is assumed that the date the drug was dispensed is the first date the drug was taken by the subject.
15	AVNXSTDT*	Start date of Avonex	N	8	DATE9.	First date receiving Avonex.
16	FUDT*	Date of Last Follow-up	N	8	DATE9.	Date of dropout or completion of study.
17	CMSTDT	Start Date of Con Med	N	8	date9.	Date concomitant medication was started.
18	CMSTDTC	Start Date of Con Med (Char)	C	10	$10.	Date concomitant medication was started (character).
19	CMSTDY	Start Day of Con Med	N	8	8.	Days from Day 1 (first dose date) to start of concomitant medication.
20	CMENDT	Stop Date of Con Med	N	8	date9.	Date concomitant medication was stopped.
21	CMENDTC	Stop Date of Con Med (Char)	C	10	$10.	Date concomitant medication was stopped (character).
22	CMENDY	Stop Day of Con Med	N	8	8.	Days from Day 1 (first dose date) to stop date of concomitant medication.

Note: Variables from the ADSTART0 dataset that are retained across all datasets are marked with an asterisk (*).

ADCMED1

One record per participant, medication, and start date

Dataset for concomitant medications.

	Variable Name	Variable Label	Type	Length	Format	Description
23	CMTERM	Con Med Description	C	100	$100.	Site verbatim description of concomitant medication.
24	CMIND	Con Med Indication	C	100	$100.	Indication of concomitant medication.
25	CMDOSE	Con Med Dose	C	20	$20.	Dose of concomitant medication.
26	CMUNIT	Con Med Unit	C	20	$20.	Unit of concomitant medication.
27	CMFREQ	Con Med Frequency	C	40	$40.	Frequency of concomitant medication.
28	CMROUTE	Con Med Route	C	40	$40.	Route of concomitant medication.
29	CMONGO	Con Med Ongoing	C	3	$3.	Concomitant medication ongoing at study termination/completion.
30	CMPT	Con Med Preferred Term	C	200	$200.	Concomitant medication preferred term.
31	CMDUR	Con Med Duration	N	8	8.0	Number of days between the start and stop dates of the concomitant medication. Duration is missing if the start or stop dates are missing or the medication was ongoing at end of study.
32	CORTI	Indicator for Corticosteroids	N	8	8.	Indicator for medication being a corticosteroid. 1 = corticosteroid.
33	INFBI	Indicator for Interferon Beta	N	8	8.	Indicator for medication being Interferon Beta. 1 = Interferon Beta.
34	VISITNUM	Visit Number	C	10	$10.	Visit Number

Note: Variables from the ADSTART0 dataset that are retained across all datasets are marked with an asterisk (*).

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ADCORT1

One record per participant, corticosteroid, start day

Dataset for the analysis of Corticosteroid use.

	Variable Name	Variable Label	Type	Length	Format	Description
1	USUBJID*	ID	C	6	$6.	Unique Subject Identifier
2	SUBJL*	Inv.Site/Part. ID for listings	C	7	$7.	Unique Subject Identifier. Site and subject ID separated by a /.
3	TRTC*	Treatment Group (Char)	C	15	$15.	Randomized Treatment Group
4	ITT*	Intent To Treat Sample	C	3	$3.	Subject is in the Intent to Treat Sample. ITT is defined as all randomized subjects who received any dose of study drug.
5	PP*	Per Protocol Sample	C	3	$3.	Subject is in the Per-protocol Sample. PP is defined as all randomized subjects who receive at least 80% of planned dose of study drug and have no major protocol deviations that impact the efficacy assessments.
6	SAFETY*	Safety Sample	C	3	$3.	Subjects in the Safety Sample. Safety is defined as all subjects who receive at least one dose of study drug.
7	SAMP*	Analysis Sample	C	5	$5.	Subject's analysis sample. S= Safety, I= Intent to Treat, P= Per-Protocol
8	RAND*	Randomized	C	3	$3.	Subject was randomized
9	MNTH3DT*	Date of Month 3 visit	N	8	DATE9.	Date of actual 3 month visit.
10	MNTH6DT*	Date of Month 6 visit	N	8	DATE9.	Date of actual 6 month visit.
11	MNTH9DT*	Date of Month 9 visit	N	8	DATE9.	Date of actual 9 month visit.
12	MNTH12DT*	Date of Month 12 visit	N	8	DATE9.	Date of actual 12 month visit.
13	MNTH18DT*	Date of Month 18 visit	N	8	DATE9.	Date of actual 18 month visit.
14	FDDT*	First Dose Date	N	8	DATE9.	First date receiving Atorvastatin or Placebo. It is assumed that the date the drug was dispensed is the first date the drug was taken by the subject.
15	AVNXSTDT*	Start date of Avonex	N	8	DATE9.	First date receiving Avonex.
16	FUDT*	Date of Last Follow-up	N	8	DATE9.	Date of dropout or completion of study.
17	PP3SC	Received 3-5 Day Course Prior Screening	C	3	$3.	Participant received a complete 3 to 5-day course of IV corticosteroid (equivalent to 3 grams) for their clinically isolated syndrome (CIS) as per protocol before screening.
18	PP3DT	Date 3-5 Day Course Completed	N	8	DATE9.	Date IV corticosteroid 3 to 5-day course completed.
19	CCSTYP	Type of Corticosteroid	C	20	$20.	Type of corticosteroid.
20	CCSSTDT	Corticosteroid Start Date	N	8	DATE9.	Date corticosteroid started.

Note: Variables from the ADSTART0 dataset that are retained across all datasets are marked with an asterisk (*).

ADCORT1

One record per participant, corticosteroid, start day

Dataset for the analysis of Corticosteroid use.

	Variable Name	Variable Label	Type	Length	Format	Description
21	CCSSTDY	Corticosteroid Start Study Day	N	8	8.	Days from day 1 (first dose date) to start of corticosteroid dosing. Duration will be negative because drug was administered prior to start of study therapy.
22	CCSSTDTC	Corticosteroid Start Date (Char)	C	9	$9.	Date corticosteroid started (character).
23	CCSENDT	Corticosteroid End Date	N	8	DATE9.	Date corticosteroid stopped.
24	CCSENDY	Corticosteroid End Study Day	N	8	8.	Days from day 1 (first dose date) to stop of corticosteroid dosing. Duration will be negative because drug was administered prior to start of study therapy.
25	CCSENDTC	Corticosteroid End Date (Char)	C	9	$9.	Date corticosteroid stopped (character).
26	CCSIND	Indication for Corticosteroid	C	100	$100.	Indication for corticosteroid.
27	CCSDOSE	Corticosteroid Dose	C	20	$20.	Dose for corticosteroid.
28	CCSUNIT	Corticosteroid Unit	C	20	$20.	Unit of corticosteroid.
29	CCSNUM	Corticosteroid Course Number	N	8	8.	Corticosteroid course number. Corresponds to record on CRF.
30	VISITNUM	Visit Number	C	10	$10.	Visit Number

Note: Variables from the ADSTART0 dataset that are retained across all datasets are marked with an asterisk (*).

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ADEDSS1

One record per participant, EDSS visit and functional system

Dataset for the analysis of EDSS

	Variable Name	Variable Label	Type	Length	Format	Description
1	USUBJID*	ID	C	6	$6.	Unique Subject Identifier
2	SUBJL*	Inv.Site/Part. ID for listings	C	7	$7.	Unique Subject Identifier. Site and subject ID separated by a /.
3	TRTC*	Treatment Group (Char)	C	15	$15.	Randomized Treatment Group
4	ITT*	Intent To Treat Sample	C	3	$3.	Subject is in the Intent to Treat Sample. ITT is defined as all randomized subjects who received any dose of study drug.
5	PP*	Per Protocol Sample	C	3	$3.	Subject is in the Per-protocol Sample. PP is defined as all randomized subjects who receive at least 80% of planned dose of study drug and have no major protocol deviations that impact the efficacy assessments.
6	SAFETY*	Safety Sample	C	3	$3.	Subjects in the Safety Sample. Safety is defined as all subjects who receive at least one dose of study drug.
7	SAMP*	Analysis Sample	C	5	$5.	Subject's analysis sample. S= Safety, I= Intent to Treat, P= Per-Protocol
8	RAND*	Randomized	C	3	$3.	Subject was randomized
9	MNTH3DT*	Date of Month 3 visit	N	8	DATE9.	Date of actual 3 month visit.
10	MNTH6DT*	Date of Month 6 visit	N	8	DATE9.	Date of actual 6 month visit.
11	MNTH9DT*	Date of Month 9 visit	N	8	DATE9.	Date of actual 9 month visit.
12	MNTH12DT*	Date of Month 12 visit	N	8	DATE9.	Date of actual 12 month visit.
13	MNTH18DT*	Date of Month 18 visit	N	8	DATE9.	Date of actual 18 month visit.
14	FDDT*	First Dose Date	N	8	DATE9.	First date receiving Atorvastatin or Placebo. It is assumed that the date the drug was dispensed is the first date the drug was taken by the subject.
15	AVNXSTDT*	Start date of Avonex	N	8	DATE9.	First date receiving Avonex.
16	FUDT*	Date of Last Follow-up	N	8	DATE9.	Date of dropout or completion of study.
17	VISIT	Visit Number	N	8	8.	Visit number.
18	VISITNUM	Visit Number	C	10	$10.	Visit number
19	VISITC	Visit Name	C	15	$15.	Visit.
20	EDSSYN	Was EDSS Assessment Performed?	C	3	$3.	EDSS Assessment performed.
21	EDSSDT	Date EDSS Assessment Performed	N	8	DATE9.	Date EDSS assessment performed.
22	EDSSDY	Day EDSS Assessment Performed	N	8	8.	Days from Day 1 (first dose date) to EDSS assessment date.
23	EDSSTM	Time EDSS Assessment Performed	C	8	$5.	Time EDSS assessment performed.

Note: Variables from the ADSTART0 dataset that are retained across all datasets are marked with an asterisk (*).

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ADEDSS1

One record per participant, EDSS visit and functional system

Dataset for the analysis of EDSS

	Variable Name	Variable Label	Type	Length	Format	Description
24	FNCTSYS	Functional System	C	20	$20.	Functional system the corresponding scores are for. Note: this dataset is structured to have one record per visit and functional system.
25	FSSCOR	Functional System Score	N	8	4.1	Functional system score.
26	NOTDONE	Functional System Score Not Done	C	8	$8.	Indicator for functional system score not done.
27	AMBDSTN	Farthest Ambulation Distance	C	29	$29.	Ambulation. Farthest distance the subject is able to walk without rest or assistance.
28	AMBDSTNB	Farthest Ambulation Distance Baseline	C	29	$29.	Ambulation score at baseline. Baseline measurement is the last non-missing observation on or before Day 1 (first day of dosing).
29	EDSSCOR	EDSS Score	N	8	4.1	EDSS score.
30	FSSCORB	Functional System Score Baseline	N	8	4.1	Functional system score at baseline. Baseline measurement is the last non-missing observation on or before Day 1 (first day of dosing).
31	FSSCORC	Functional System Score Change from Base	N	8	4.1	Functional system score change from baseline.
32	EDSSCORB	EDSS Score Baseline	N	8	4.1	EDSS score at baseline. Baseline measurement is the last non-missing observation on or before Day 1 (first day of dosing).
33	EDSSCORC	EDSS Score Change from Baseline	N	8	4.1	EDSS score change from baseline. Baseline measurement is the last non-missing observation on or before Day 1 (first day of dosing).
34	EDSSSUM	Flag for inclusion in Tables	N	8	8.	This variable was never derived and is missing on all records.

Note: Variables from the ADSTART0 dataset that are retained across all datasets are marked with an asterisk (*).

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ADLB1

One record per participant, laboratory visit, and laboratory test

Dataset for the analysis of laboratory tests

	Variable Name	Variable Label	Type	Length	Format	Description
1	USUBJID*	ID	C	6	$6.	Unique Subject Identifier
2	SUBJL*	Inv.Site/Part. ID for listings	C	7	$7.	Unique Subject Identifier. Site and subject ID separated by a /.
3	TRTC*	Treatment Group (Char)	C	15	$15.	Randomized Treatment Group
4	ITT*	Intent To Treat Sample	C	3	$3.	Subject is in the Intent to Treat Sample. ITT is defined as all randomized subjects who received any dose of study drug.
5	PP*	Per Protocol Sample	C	3	$3.	Subject is in the Per-protocol Sample. PP is defined as all randomized subjects who receive at least 80% of planned dose of study drug and have no major protocol deviations that impact the efficacy assessments.
6	SAFETY*	Safety Sample	C	3	$3.	Subjects in the Safety Sample. Safety is defined as all subjects who receive at least one dose of study drug.
7	SAMP*	Analysis Sample	C	5	$5.	Subject's analysis sample. S= Safety, I= Intent to Treat, P= Per-Protocol
8	RAND*	Randomized	C	3	$3.	Subject was randomized
9	MNTH3DT*	Date of Month 3 visit	N	8	DATE9.	Date of actual 3 month visit.
10	MNTH6DT*	Date of Month 6 visit	N	8	DATE9.	Date of actual 6 month visit.
11	MNTH9DT*	Date of Month 9 visit	N	8	DATE9.	Date of actual 9 month visit.
12	MNTH12DT*	Date of Month 12 visit	N	8	DATE9.	Date of actual 12 month visit.
13	MNTH18DT*	Date of Month 18 visit	N	8	DATE9.	Date of actual 18 month visit.
14	FDDT*	First Dose Date	N	8	DATE9.	First date receiving Atorvastatin or Placebo. It is assumed that the date the drug was dispensed is the first date the drug was taken by the subject.
15	AVNXSTDT*	Start date of Avonex	N	8	DATE9.	First date receiving Avonex.
16	FUDT*	Date of Last Follow-up	N	8	DATE9.	Date of dropout or completion of study.
17	VISIT	Visit Number	N	8	8.	Visit number.
18	VISITNUM	Visit Number	C	10	$10.	Visit number
19	VISITC	Visit Name (Char)	C	15	$15.	Visit.
20	LBDT	Laboratory Date	N	8	DATE9.	Date of laboratory assessment.
21	LBDY	Laboratory Study Day	N	8	8.	Days from Day 1 (first dose date) to laboratory assessment date.
22	LBNAME	Laboratory Name	C	100	$100.	Laboratory name.
23	LABID	Laboratory ID	C	100	$100.	Laboratory ID. This equals the site number if the location is PI Lab.

Note: Variables from the ADSTART0 dataset that are retained across all datasets are marked with an asterisk (*).

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ADLB1

One record per participant, laboratory visit, and laboratory test

Dataset for the analysis of laboratory tests

	Variable Name	Variable Label	Type	Length	Format	Description
24	LBGROUP	Group of Laboratory Tests	C	25	$25.	Group of laboratory tests.
25	LBTEST	Laboratory Test Name	C	30	$30.	Laboratory test name.
26	LBSTRESU	Standard Units	C	15	$15.	Standard Units.
27	LBORRESU	Original Units	C	15	$15.	Original Units result reported in.
28	LBORRESC	Result in Original Units (Char)	C	10	$10.	Result in original units (character).
29	LBORRES	Result in Original Units	N	8	BEST12.	Result in original units.
30	LBSTRES	Result in Standard Units	N	8	BEST12.	Result in standard units.
31	LBSTRESC	Result in Standard Units (Char)	C	15	$15.	Result in standard units (character).
32	LBLLN	Lower Limit of Normal	N	8	BEST12.	Lower limit of normal. Harrisons normal ranges used.
33	LBLLNC	Lower Limit of Normal (Char)	C	15	$15.	Lower limit of normal (character). Harrisons normal ranges used.
34	LBULN	Upper Limit of Normal	N	8	BEST12.	Upper limit of normal. Harrisons normal ranges used.
35	LBULNC	Upper Limit of Normal (Char)	C	15	$15.	Upper limit of normal (character). Harrisons normal ranges used.
36	LBFLAG	Outside Normal Range	C	4	$4.	Flag for results outside of the normal range.
37	LBCSYN	Clinically Significant	C	3	$3.	Lab result clinically significant.
38	OVRESLT	Overall Urinalysis Result	C	36	$36.	Overall urinalysis result.
39	FASTYNU	Fasting Since Midnight	C	7	$7.	Fasting since midnight.
40	LBSTRBL	BL Lab Value (Standard units)	N	8	BEST12.	Baseline laboratory result. Baseline measurement is the last non-missing observation on or before Day 1 (first day of dosing).
41	LBSTRCH	Change from BL Lab Value (STD Units)	N	8	BEST12.	Change from baseline in laboratory result. Calculated only for results in standard units. Baseline measurement is the last non-missing observation on or before Day 1 (first day of dosing).
42	LBSTPCBL	Percent Change from Baseline (STD Units)	N	8	BEST12.	Percent change from baseline in laboratory result. Calculated only for results in standard units. Baseline measurement is the last non-missing observation on or before Day 1 (first day of dosing).
43	LBSTPOBL	Percent of Baseline (Standard Units)	N	8	BEST12.	Percent of baseline. Calculated only for results in standard units. Baseline measurement is the last non-missing observation on or before Day 1 (first day of dosing).
44	EXCLUDE	Indicator to Exclude from Display	N	8	8.0	Indicator for which lab values to exclude from displays. 1 = exclude result.
45	LBAGE	Laboratory Age (years)	N	8	8.	Age of subject at time laboratory tests were performed.

Note: Variables from the ADSTART0 dataset that are retained across all datasets are marked with an asterisk (*).

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ADLB1

One record per participant, laboratory visit, and laboratory test

Dataset for the analysis of laboratory tests

	Variable Name	Variable Label	Type	Length	Format	Description
46	LBFLAG2	Laboratory Flag - Protocol Criteria	C	20	$20.	Flags for laboratory results that meet specific criteria specified in the protocol (e.g. CPK results >= 10 ULN).
47	LBFLAG2B	Laboratory Flag - Protocol Criteria Base	C	20	$20.	Baseline value for flags of laboratory results that meet specific criteria specified in the protocol. Baseline measurement is the last non-missing observation on or before Day 1 (first day of dosing).

Note: Variables from the ADSTART0 dataset that are retained across all datasets are marked with an asterisk (*).

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ADMH1

One record per participant per medical history finding.

Dataset for the analysis of medical history.

	Variable Name	Variable Label	Type	Length	Format	Description
1	USUBJID*	ID	C	6	$6.	Unique Subject Identifier
2	SUBJL*	Inv.Site/Part. ID for listings	C	7	$7.	Unique Subject Identifier. Site and subject ID separated by a /.
3	TRTC*	Treatment Group (Char)	C	15	$15.	Randomized Treatment Group
4	ITT*	Intent To Treat Sample	C	3	$3.	Subject is in the Intent to Treat Sample. ITT is defined as all randomized subjects who received any dose of study drug.
5	PP*	Per Protocol Sample	C	3	$3.	Subject is in the Per-protocol Sample. PP is defined as all randomized subjects who receive at least 80% of planned dose of study drug and have no major protocol deviations that impact the efficacy assessments.
6	SAFETY*	Safety Sample	C	3	$3.	Subjects in the Safety Sample. Safety is defined as all subjects who receive at least one dose of study drug.
7	SAMP*	Analysis Sample	C	5	$5.	Subject's analysis sample. S= Safety, I= Intent to Treat, P= Per-Protocol
8	RAND*	Randomized	C	3	$3.	Subject was randomized
9	MNTH3DT*	Date of Month 3 visit	N	8	DATE9.	Date of actual 3 month visit.
10	MNTH6DT*	Date of Month 6 visit	N	8	DATE9.	Date of actual 6 month visit.
11	MNTH9DT*	Date of Month 9 visit	N	8	DATE9.	Date of actual 9 month visit.
12	MNTH12DT*	Date of Month 12 visit	N	8	DATE9.	Date of actual 12 month visit.
13	MNTH18DT*	Date of Month 18 visit	N	8	DATE9.	Date of actual 18 month visit.
14	FDDT*	First Dose Date	N	8	DATE9.	First date receiving Atorvastatin or Placebo. It is assumed that the date the drug was dispensed is the first date the drug was taken by the subject.
15	AVNXSTDT*	Start date of Avonex	N	8	DATE9.	First date receiving Avonex.
16	FUDT*	Date of Last Follow-up	N	8	DATE9.	Date of dropout or completion of study.
17	MHDT	Date of Medical History Collection	N	8	DATE9.	Date medical history collected.
18	MHDY	Day of Medical History Collection	N	8	8.	Days from Day 1 (first dose date) to medical history collection date.
19	MHYN	Any Clin Sign Medical History	C	3	$3.	Any clinically significant medical history.
20	MHBDSYS	Body System	C	200	$200.	Body system.
21	MHBDSYSC	Body System (Char)	C	200	$200.	Body system (character). Note dataset has one record per subject and body system.
22	MHSTAT	Serious or Chronic Body System	C	3	$3.	Significant or chronic medical history.

Note: Variables from the ADSTART0 dataset that are retained across all datasets are marked with an asterisk (*).

ADMH1

One record per participant per medical history finding.

Dataset for the analysis of medical history.

	Variable Name	Variable Label	Type	Length	Format	Description
23	MHTERM	Reported Condition	C	200	$200.	Reported condition if significant or chronic medical history.
24	VISITNUM	Visit Number	C	10	$10.	Visit Number

Note: Variables from the ADSTART0 dataset that are retained across all datasets are marked with an asterisk (*).

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ADMRI1

One record per participant and MRI visit.

Dataset for the analysis of MRI evaluations.

	Variable Name	Variable Label	Type	Length	Format	Description
1	USUBJID*	ID	C	6	$6.	Unique Subject Identifier
2	SUBJL*	Inv.Site/Part. ID for listings	C	7	$7.	Unique Subject Identifier. Site and subject ID separated by a /.
3	TRTC*	Treatment Group (Char)	C	15	$15.	Randomized Treatment Group
4	ITT*	Intent To Treat Sample	C	3	$3.	Subject is in the Intent to Treat Sample. ITT is defined as all randomized subjects who received any dose of study drug.
5	PP*	Per Protocol Sample	C	3	$3.	Subject is in the Per-protocol Sample. PP is defined as all randomized subjects who receive at least 80% of planned dose of study drug and have no major protocol deviations that impact the efficacy assessments.
6	SAFETY*	Safety Sample	C	3	$3.	Subjects in the Safety Sample. Safety is defined as all subjects who receive at least one dose of study drug.
7	SAMP*	Analysis Sample	C	5	$5.	Subject's analysis sample. S= Safety, I= Intent to Treat, P= Per-Protocol
8	RAND*	Randomized	C	3	$3.	Subject was randomized
9	MNTH3DT*	Date of Month 3 visit	N	8	DATE9.	Date of actual 3 month visit.
10	MNTH6DT*	Date of Month 6 visit	N	8	DATE9.	Date of actual 6 month visit.
11	MNTH9DT*	Date of Month 9 visit	N	8	DATE9.	Date of actual 9 month visit.
12	MNTH12DT*	Date of Month 12 visit	N	8	DATE9.	Date of actual 12 month visit.
13	MNTH18DT*	Date of Month 18 visit	N	8	DATE9.	Date of actual 18 month visit.
14	FDDT*	First Dose Date	N	8	DATE9.	First date receiving Atorvastatin or Placebo. It is assumed that the date the drug was dispensed is the first date the drug was taken by the subject.
15	AVNXSTDT*	Start date of Avonex	N	8	DATE9.	First date receiving Avonex.
16	FUDT*	Date of Last Follow-up	N	8	DATE9.	Date of dropout or completion of study.
17	VISIT	Visit Number	N	8	8.	Visit Number
18	VISITNUM	Visit Number	C	10	$10.	Visit Number
19	VISITC	Visit Name (Char)	C	16	$16.	Visit name
20	MRIDT	Date of MRI Scan	N	8	DATE9.	Date of MRI Scan
21	MRIDTC	Date of MRI Scan (Char)	C	9	$9.	Date of MRI Scan Character. U's are imputed for missing values.

Note: Variables from the ADSTART0 dataset that are retained across all datasets are marked with an asterisk (*).

Based on derivations as of 20SEP2013. Some variables in the specifications may be excluded from datasets for de-indentification purposes.

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ADMRI1

One record per participant and MRI visit.

Dataset for the analysis of MRI evaluations.

	Variable Name	Variable Label	Type	Length	Format	Description
22	MRIDY	Day of MRI Scan	N	8	8.	Study day of MRI scan, defined as the number of days between first dose date and date of MRI scan plus 1 day. The first dose date is considered study day 1.
23	T2SLNT	Clinically Silent T2 Lesions	C	3	$3.	Clinically silent T2 lesions at screening. Data from CRF form.
24	T1LLN	T1 lesion load at Baseline (ml)	N	8	7.3	T1 lesion load at Baseline (ml). Data from central lab.
25	T2LLN	T2 lesion load at Baseline (ml)	N	8	7.3	T2 lesion load at Baseline (ml). Data from central lab.
26	GADN	# Gd+ lesions (# new, if post-BL)	N	8	3.0	Number of Gd+ lesions. If assessment is post-baseline, variable is the number of new Gd+ lesions. Data from central lab.
27	T2N	# T2 lesions (# new, if post-BL)	N	8	3.0	Number of T2 lesions. If assessment is post-baseline, variable is the number of new T2 lesions. Data from central lab.
28	NEWLSN1	1 or 2 New Lesions Since Baseline	C	3	$3.	1 or 2 new lesions since baseline. Data from central lab.
29	NEWLSN3	3 or More New Lesions Since Baseline	C	3	$3.	3 or more new lesions since baseline. Data from central lab.
30	DB	Indicator: Double-blind treatment phase	N	8	1.0	Indicator for double-blind treatment phase (Day 1 through Month 12). Month 12 expected visit date is used if the visit is missing. 1 = double blind treatment phase. 0 = other.
31	M3_12	Indicator: Month 3 - Month 12	N	8	1.0	Indicator for Month 3 - Month 12. Expected visit dates are used if the visits are missing. 1 = Month 3 - Month 12. 0 = other.
32	D1_M3	Indicator: Day 1 - Month 3	N	8	1.0	Indicator for Day 1 - Month 3. Month 3 expected visit date is used if the visit is missing. 1 = Day 1 - Month 3. 0 = other.
33	D1_M6	Indicator: Day 1 - Month 6	N	8	1.0	Indicator for Day 1 - Month 6. Month 6 expected date is used if the visit is missing. 1 = Day 1 - Month 6. 0 = other.
34	D1_M9	Indicator: Day 1 - Month 9	N	8	1.0	Indicator for Day 1 - Month 9. Month 9 expected date is used if the visit is missing. 1 = Day 1 - Month 9. 0 = other.
35	EXT	Indicator: Extension phase	N	8	1.0	Indicator for extension phase (>Month 12 - Month 18). Expected visit dates are used if the visits are missing. 1 = extension phase. 0 = other.
36	PREAVNX	MRI date before Avonex start date	C	3	$3.	Indicator for whether MRI occurred prior to starting Avonex.
37	POSTAVNX	MRI date after Avonex start date	C	3	$3.	Indicator for whether MRI occurred after starting Avonex.
38	T2NDBEX	Cumulative # T2 Pre-Avonex	N	8	3.0	Cumulative sum of number of new T2 lesions occurring prior to starting Avonex. Data from central lab.
39	T2NDBEXX	Cum # T2 Day 1-M18 (No Avonex Req.)	N	8	3.0	Cumulative sum of number of new T2 lesions through Month 18. Variable includes all new lesions, regardless of Avonex status. Data from central lab.

Note: Variables from the ADSTART0 dataset that are retained across all datasets are marked with an asterisk (*).

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ADMRI1

One record per participant and MRI visit.

Dataset for the analysis of MRI evaluations.

	Variable Name	Variable Label	Type	Length	Format	Description
40	GADNDBEX	Cumulative # Gd+ Day 1-Month 18	N	8	3.0	Cumulative sum of number of new Gd+ lesions through Month 18. Variable includes all new lesions, regardless of Avonex status. Data from central lab.
41	PEPDBEX	Met PEP Day 1-M18 Pre-Avonex	C	3	$3.	Subject met primary endpoint criteria Day 1 through Month 18 prior to starting Avonex. Data from central lab.
42	PEPDBEXX	Met PEP Day 1-M18 (No Avonex Req.)	C	3	$3.	Subject met primary endpoint criteria Day 1 through Month 18 regardless of Avonex status. Data from central lab.
43	LSN312	Cumulative # lesions M3-M12 Pre-Avonex	N	8	3.0	Cumulative sum of number of new lesions Month 3 through Month 12 occurring prior to starting Avonex. Data from central lab.
44	PEP312	Met PEP Month 3-Month 12	C	3	$3.	Subject met primary endpoint criteria Month 3 through Month 12. Data from central lab.
45	TOTGADDB	Total # Gd+ lesions Months 1-12	N	8	4.0	Total number of new Gd+ lesions occurring prior to Month 12 and prior to starting Avonex. This variable is the same across all records for a subject. Data from central lab.
46	TOTT2DB	Total # T2 lesions Months 1-12	N	8	4.0	Total number of new T2 lesions occurring prior to Month 12 and prior to starting Avonex. This variable is the same across all records for a subject. Data from central lab.
47	TOTGAD12	Total # Gd+ lesions Months 3-12	N	8	4.0	Total number of new Gd+ lesions from Month 3 through Month 12 and prior to starting Avonex. This variable is the same across all records for a subject. Data from central lab.
48	TOTT212	Total # T2 lesions Months 3-12	N	8	4.0	Total number of new T2 lesions from Month 3 through Month 12 and prior to starting Avonex. This variable is the same across all records for a subject. Data from central lab.
49	TOTGADEX	Total # Gd+ lesions Months 15-18	N	8	4.0	Total number of Gd+ lesions from Month 15 through Month 18 (inclusive) and prior to starting Avonex. This variable is the same across all records for a subject. This variable is missing for subjects with no extension phase visits and subjects that started Avonex prior to Month 12. Data from central lab.
50	TOTT2EX	Total # T2 lesions Months 15-18	N	8	4.0	Total number of T2 lesions from Month 15 through Month 18 (inclusive) and prior to starting Avonex. This variable is the same across all records for a subject. This variable is missing for subjects with no extension phase visits and subjects that started Avonex prior to Month 12. Data from central lab.
51	MTENDPT	Met Primary Endpoint by MRI criteria	C	3	$3.	Met primary endpoint criteria by MRI criteria. Subject developed at least 3 new T2 lesions prior to starting Avonex. This variable looks at MRIs up to Month 18. Data from central lab.

Note: Variables from the ADSTART0 dataset that are retained across all datasets are marked with an asterisk (*).

ADMRI1

One record per participant and MRI visit.

Dataset for the analysis of MRI evaluations.

	Variable Name	Variable Label	Type	Length	Format	Description
52	CBAVBL	Chg brain atrophy vs. Baseline (%)	N	8	12.8	Change in brain atrophy measure versus baseline (%). This variable is only populated at Month 12 and Month 18. Data from central lab.
53	CBAV12	Chg brain atrophy vs. Month 12 (%)	N	8	12.8	Change in brain atrophy measure vs. Month 12 (%). This variable is only populated at Month 18. Data from central lab.
54	VSCALEN	Scaling Factor for Normalization	N	8	6.3	Scaling factor for normalization. Data from central lab.
55	GREYMATN	Normalized Grey Matter Volume (mm^3)	N	8	15.3	Normalized grey matter volume (mm^3). Data from central lab.
56	WHITEMTN	Normalized White Matter Volume (mm^3)	N	8	15.3	Normalized white matter volume (mm^3). Data from central lab.
57	NLSNVOLN	Normalized Lesion Volume (mm^3)	N	8	15.3	Normalized lesion volume (mm^3). Data from central lab.
58	NBRAINN	Normalized Brain Parenchyma Vol. (mm^3)	N	8	15.3	Normalized brain parenchyma volume (mm^3). Data from central lab.
59	NCSFVOLN	Normalized CSF Volume (mm^3)	N	8	15.3	Normalized CSF volume (mm^3). Data from central lab.

Note: Variables from the ADSTART0 dataset that are retained across all datasets are marked with an asterisk (*).

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ADMSFC1

One record per participant and MSFC visit

Dataset for the analysis of MSFC score

	Variable Name	Variable Label	Type	Length	Format	Description
1	USUBJID*	ID	C	6	$6.	Unique Subject Identifier
2	SUBJL*	Inv.Site/Part. ID for listings	C	7	$7.	Unique Subject Identifier. Site and subject ID separated by a /.
3	TRTC*	Treatment Group (Char)	C	15	$15.	Randomized Treatment Group
4	ITT*	Intent To Treat Sample	C	3	$3.	Subject is in the Intent to Treat Sample. ITT is defined as all randomized subjects who received any dose of study drug.
5	PP*	Per Protocol Sample	C	3	$3.	Subject is in the Per-protocol Sample. PP is defined as all randomized subjects who receive at least 80% of planned dose of study drug and have no major protocol deviations that impact the efficacy assessments.
6	SAFETY*	Safety Sample	C	3	$3.	Subjects in the Safety Sample. Safety is defined as all subjects who receive at least one dose of study drug.
7	SAMP*	Analysis Sample	C	5	$5.	Subject's analysis sample. S= Safety, I= Intent to Treat, P= Per-Protocol
8	RAND*	Randomized	C	3	$3.	Subject was randomized
9	MNTH3DT*	Date of Month 3 visit	N	8	DATE9.	Date of actual 3 month visit.
10	MNTH6DT*	Date of Month 6 visit	N	8	DATE9.	Date of actual 6 month visit.
11	MNTH9DT*	Date of Month 9 visit	N	8	DATE9.	Date of actual 9 month visit.
12	MNTH12DT*	Date of Month 12 visit	N	8	DATE9.	Date of actual 12 month visit.
13	MNTH18DT*	Date of Month 18 visit	N	8	DATE9.	Date of actual 18 month visit.
14	FDDT*	First Dose Date	N	8	DATE9.	First date receiving Atorvastatin or Placebo. It is assumed that the date the drug was dispensed is the first date the drug was taken by the subject.
15	AVNXSTDT*	Start date of Avonex	N	8	DATE9.	First date receiving Avonex.
16	FUDT*	Date of Last Follow-up	N	8	DATE9.	Date of dropout or completion of study.
17	VISIT	Visit Number	N	8	8.	Visit number.
18	VISITNUM	Visit Number	C	10	$10.	Visit number
19	VISITC	Visit Name	C	15	$15.	Visit.
20	WLKYN	Was 25-Foot Walk Test Performed?	C	3	$3.	25-foot walk test performed.
21	WLKDT	Date Walk Test Performed	N	8	DATE9.	Date 25-foot walk test performed.
22	WLKDY	Day of Walk Test	N	8	8.	Days from Day 1 (first dose date) to date walk test was performed.
23	WLKTM	Time 25-Foot Walk Test Performed	C	5	$5.	Time (24 hour clock) the 25-foot walk test was started.

Note: Variables from the ADSTART0 dataset that are retained across all datasets are marked with an asterisk (*).

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ADMSFC1

One record per participant and MSFC visit

Dataset for the analysis of MSFC score

	Variable Name	Variable Label	Type	Length	Format	Description
24	AFOYN	Did Participant Wear an AFO?	C	3	$3.	Did subject wear an AFO (ankle-foot orthosis).
25	ASTDVYN	Was Assistive Device Used?	C	3	$3.	Was assistive device used.
26	ASTDVSP	Assistive Device Specified	C	200	$200.	Specific assistive device used.
27	WTRL1TM	Walk Trial 1 Time, seconds	N	8	6.1	Trial 1: time for the 25-foot walk in seconds.
28	WTRL1TXT	Walk Trial 1 Circumstances	C	200	$200.	Any circumstances that affected the subject's performance in trial 1.
29	WTRL1NC	Reason Walk Trial 1 Not Completed	C	200	$200.	Reason the walk in trial 1 was not completed.
30	WTRL2TM	Walk Trial 2 Time, seconds	N	8	6.1	Trial 2: time for 25-foot walk in seconds.
31	WTRL2TXT	Walk Trial 2 Circumstances	C	200	$200.	Any circumstances that affected the subject's performance in trial 2.
32	WTRL2NC	Reason Walk Trial 2 Not Completed	C	200	$200.	Reason the walk in trial 2 was not completed.
33	WLKMTR	More Than Two Attempts - Walk Test	C	3	$3.	If two trials were completed, did it take more than two attempts to get the two successful trials.
34	WLKAVE	Average Walk Trial Time, seconds	N	8	6.2	Mean walk time in seconds of trial 1 and trial 2.
35	WLKAVEB	Average Walk Trial Time, seconds Base	N	8	6.2	Baseline measure of the mean walk time in seconds of the baseline trial 1 and trial 2. Baseline measurement is the last non-missing observation on or before Day 1 (first day of dosing).
36	WLKZ	Walk Test Z-score	N	8	10.6	Z-score for the 25-foot walk test.
37	WLKZB	Walk Test Z-score - Base	N	8	10.6	Baseline Z-score for the 25-foot walk test. Baseline measurement is the last non-missing observation on or before Day 1 (first day of dosing).
38	WLKZC	Walk Test Z-score - Change from Base	N	8	10.6	Change from baseline in the 25-foot walk test z-score.
39	PEGYN	Was 9 Hole Peg Test Performed	C	3	$3.	Nine hole peg test performed.
40	PEGDT	Date 9 Hole Peg Test Performed	N	8	DATE9.	Date nine hole peg test performed.
41	PEGDY	Day of Nine Hole Peg Test	N	8	8.	Days from Day 1 (first dose date) to date nine hole peg test was performed.
42	DMNHND	Dominant Hand	C	6	$6.	Dominant hand.
43	PTRL1TMD	Peg Trial 1 Time, sec - Dom	N	8	6.1	Trial 1 dominant hand: Seconds till completion of nine hole peg test.
44	PTRL1NCD	Reason Peg Trial 1 Not Completed - Dom	C	200	$200.	Reason nine hole peg test trial 1 for the dominant hand was not completed.
45	PTRL2TMD	Peg Trial 2 Time, sec - Dom	N	8	6.1	Trial 2 dominant hand: Seconds till completion of nine hole peg test.
46	PTRL2NCD	Reason Peg Trial 2 Not Completed - Dom	C	200	$200.	Reason nine hole peg test trial 2 for the dominant hand was not completed.

Note: Variables from the ADSTART0 dataset that are retained across all datasets are marked with an asterisk (*).

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ADMSFC1

One record per participant and MSFC visit

Dataset for the analysis of MSFC score

	Variable Name	Variable Label	Type	Length	Format	Description
47	PEGMTRD	More Than Two Attempts - Peg - Dom.	C	3	$3.	Did it take more than two attempts with the dominant hand to get two successful trials.
48	PTRL1TMN	Peg Trial 1 Time, sec - Non-dom	N	8	6.1	Trial 1 non-dominant hand: Seconds till completion of nine hole peg test.
49	PTRL1NCN	Reason Peg Trial 1 Not Comp. - Non-dom	C	200	$200.	Reason nine hole peg test trial 1 for the non-dominant hand was not completed.
50	PTRL2TMN	Peg Trial 2 Time, sec - Non-dom	N	8	6.1	Trial 2 non-dominant hand: Seconds till completion of nine hole peg test.
51	PTRL2NCN	Reason Peg Trial 2 Not Comp. - Non-dom	C	200	$200.	Reason nine hole peg test trial 2 for the non-dominant hand was not completed.
52	PEGMTRN	More Than Two Attempts - Peg - Non-dom.	C	3	$3.	Did it take more than two attempts with the non-dominant hand to get two successful trials.
53	PEGSCOR	Peg Score, seconds	N	8	12.8	Nine hole peg score in seconds.
54	PEGSCORB	Peg Score Time, seconds Base	N	8	12.8	Baseline nine hole peg score in seconds. Baseline measurement is the last non-missing observation on or before Day 1 (first day of dosing).
55	PEGZ	Nine Hole Peg Test Z-score	N	8	12.8	Nine hole peg test Z-score.
56	PEGZB	Nine Hole Peg Test Z-score - Base	N	8	12.8	Baseline nine hole peg test Z-score. Baseline measurement is the last non-missing observation on or before Day 1 (first day of dosing).
57	PEGZC	Peg Test Z-score - Change from Base	N	8	12.8	Change from baseline in the nine hole peg test Z-score. Baseline measurement is the last non-missing observation on or before Day 1 (first day of dosing).
58	PST2PRFM	Was PASAT 2 Performed?	C	3	$3.	PASAT 2" test performed.
59	PST2DT	Date PASAT 2 Test Performed	N	8	DATE9.	Date PASAT 2" test performed.
60	PST2DY	Day of PASAT 2 Test	N	8	8.	Days from Day 1 (first dose date) to date PASAT 2" test was performed.
61	PST2CMPL	Was PASAT 2 Completed?	C	3	$3.	PASAT 2" completed.
62	PST2TOTL	PASAT 2 Total Correct	N	8	2.	PASAT 2" total correct.
63	PST2TXT	PASAT 2 Circumstances	C	200	$200.	Any circumstances that affected the subjects performance on the PASAT 2".
64	PST2UNCM	Reason PASAT 2 Not Completed	C	200	$200.	Reason the subject was unable to complete the PASAT 2".
65	PST2MTRN	More Than Two Attempts - PASAT 2	C	3	$3.	Did it take more than one attempt to get one successful PASAT 2" trial.

Note: Variables from the ADSTART0 dataset that are retained across all datasets are marked with an asterisk (*).

ADMSFC1

One record per participant and MSFC visit

Dataset for the analysis of MSFC score

	Variable Name	Variable Label	Type	Length	Format	Description
66	PST2TOTB	PASAT 2 Total Correct - Base	N	8	2.0	Baseline PASAT 2" total correct. Baseline measurement is the last non-missing observation on or before Day 1 (first day of dosing).
67	PST2Z	PASAT 2 Test Z-score	N	8	12.8	Z-score for PASAT 2" test.
68	PST2ZB	PASAT 2 Test Z-score - Base	N	8	12.8	Baseline Z-score for PASAT 2" test. Baseline measurement is the last non-missing observation on or before Day 1 (first day of dosing).
69	PST2ZC	PASAT 2 Test Z-score - Change from Base	N	8	12.8	Change from baseline in Z-Score for PASAT 2" test. Baseline measurement is the last non-missing observation on or before Day 1 (first day of dosing).
70	PST3PRFM	Was PASAT 3 Performed?	C	3	$3.	PASAT 3" test performed.
71	PST3DT	Date PASAT 3 Test Performed	N	8	DATE9.	Date PASAT 3" test performed.
72	PST3DY	Day of PASAT 3 Test	N	8	8.	Days from Day 1 (first dose date) to date PASAT 3" test was performed.
73	PST3CMPL	Was PASAT 3 Completed?	C	3	$3.	PASAT 3" completed.
74	PST3TOTL	PASAT 3 Total Correct	N	8	2.	PASAT 3" total correct.
75	PST3TXT	PASAT 3 Circumstances	C	200	$200.	Any circumstances that affected the subject's performance of the PASAT 3" test.
76	PST3UNCM	Reason PASAT 3 Not Completed	C	200	$200.	Reason the subject was unable to complete the PASAT 3" trial.
77	PST3MTRN	More Than Two Attempts - PASAT 3	C	3	$3.	Did it take more than one attempt to get one successful PASAT 3" trial.
78	PST3TOTB	PASAT 3 Total Correct - Base	N	8	2.0	Baseline PASAT 2" total correct. Baseline measurement is the last non-missing observation on or before Day 1 (first day of dosing).
79	PST3Z	PASAT 3 Test Z-score	N	8	12.8	Z-score for PASAT 3" test.
80	PST3ZB	PASAT 3 Test Z-score - Base	N	8	12.8	Baseline Z-score for PASAT 3" test.
81	PST3ZC	PASAT 3 Test Z-score - Change Base	N	8	12.8	Z-score change from baseline for PASAT 3" test.
82	MSFCZ	MSFC Z-score	N	8	12.8	MSFC Z-score.
83	MSFCZB	MSFC Z-score - Base	N	8	12.8	Baseline MSFC Z-score.
84	MSFCZC	MSFC Z-score - Change from Base	N	8	12.8	Change from baseline in the MSFC Z-score.
85	MSFCSUM	Flag for inclusion in Tables	N	8	8.	This variable was not derived and is therefore missing on all records.

Note: Variables from the ADSTART0 dataset that are retained across all datasets are marked with an asterisk (*).

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ADPV1

One record per participant and protocol deviation

Used for the analysis of protocol deviations. Only participants with protocol deviations will be in the dataset.

	Variable Name	Variable Label	Type	Length	Format	Description
1	USUBJID*	ID	C	6	$6.	Unique Subject Identifier
2	SUBJL*	Inv.Site/Part. ID for listings	C	7	$7.	Unique Subject Identifier. Site and subject ID separated by a /.
3	TRTC*	Treatment Group (Char)	C	15	$15.	Randomized Treatment Group
4	ITT*	Intent To Treat Sample	C	3	$3.	Subject is in the Intent to Treat Sample. ITT is defined as all randomized subjects who received any dose of study drug.
5	PP*	Per Protocol Sample	C	3	$3.	Subject is in the Per-protocol Sample. PP is defined as all randomized subjects who receive at least 80% of planned dose of study drug and have no major protocol deviations that impact the efficacy assessments.
6	SAFETY*	Safety Sample	C	3	$3.	Subjects in the Safety Sample. Safety is defined as all subjects who receive at least one dose of study drug.
7	SAMP*	Analysis Sample	C	5	$5.	Subject's analysis sample. S= Safety, I= Intent to Treat, P= Per-Protocol
8	RAND*	Randomized	C	3	$3.	Subject was randomized
9	MNTH3DT*	Date of Month 3 visit	N	8	DATE9.	Date of actual 3 month visit.
10	MNTH6DT*	Date of Month 6 visit	N	8	DATE9.	Date of actual 6 month visit.
11	MNTH9DT*	Date of Month 9 visit	N	8	DATE9.	Date of actual 9 month visit.
12	MNTH12DT*	Date of Month 12 visit	N	8	DATE9.	Date of actual 12 month visit.
13	MNTH18DT*	Date of Month 18 visit	N	8	DATE9.	Date of actual 18 month visit.
14	FDDT*	First Dose Date	N	8	DATE9.	First date receiving Atorvastatin or Placebo. It is assumed that the date the drug was dispensed is the first date the drug was taken by the subject.
15	AVNXSTDT*	Start date of Avonex	N	8	DATE9.	First date receiving Avonex.
16	FUDT*	Date of Last Follow-up	N	8	DATE9.	Date of dropout or completion of study.
17	DEVDT	Protocol Deviation Date	N	8	DATE9.	Date of protocol deviation.
18	DEVDTC	Protocol Deviation Date (Char)	C	9	$9.	Date of protocol deviation (character).
19	DEVIDBYC	Deviation Identified By (Char)	C	22	$22.	Individual who identified the protocol deviation (e.g. study coordinator, site monitor, etc.)
20	DEVCAT	Deviation Category	C	30	$30.	Category of deviation (e.g. inclusion, exclusion, etc.)
21	DEVCATL	Deviation Category (List)	C	200	$200.	Category of deviation (e.g. inclusion, exclusion, etc.) with inclusion or exclusion number concatenated and the specifics for the other category. This variable is used for listings.

Note: Variables from the ADSTART0 dataset that are retained across all datasets are marked with an asterisk (*).

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ADPV1

One record per participant and protocol deviation

Used for the analysis of protocol deviations. Only participants with protocol deviations will be in the dataset.

	Variable Name	Variable Label	Type	Length	Format	Description
22	DEVIMP	Deviation Impact	C	200	$200.	Site determined impact of protocol deviation.
23	DEVTXT	Details of Protocol Deviation	C	200	$200.	Site verbatim details of the protocol deviation.
24	DEVRESL	Steps to Resolve Protocol Deviation	C	200	$200.	Steps taken to resolve the protocol deviation.
25	DEVIC	Inclusion/Exclusion Deviation	C	3	$3.	Indicator for inclusion/exclusion criteria protocol deviation.
26	SPNTFY	Sponsor Notified	C	3	$3.	Sponsor notified.
27	SPNTFYDT	Date Sponsor Notified	N	8	DATE9.	Date the sponsor was notified.
28	DEVCONTC	Participant Continue in Trial (Char)	C	34	$34.	Subject will continue in trial.
29	PISIGNDT	PI Date of Signature	N	8	DATE9.	Date principal investigator signed the protocol deviation.
30	VISITNUM	Visit Number	C	10	$10.	Visit Number

Note: Variables from the ADSTART0 dataset that are retained across all datasets are marked with an asterisk (*).

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ADSL2

One record per participant

Summary dataset that compiles information from other derived datasets (rather than from the clinical data).

	Variable Name	Variable Label	Type	Length	Format	Description
1	USUBJID*	ID	C	6	$6.	Unique Subject Identifier
2	SUBJL*	Inv.Site/Part. ID for listings	C	7	$7.	Unique Subject Identifier. Site and subject ID separated by a /.
3	TRTC*	Treatment Group (Char)	C	15	$15.	Randomized Treatment Group
4	ITT*	Intent To Treat Sample	C	3	$3.	Subject is in the Intent to Treat Sample. ITT is defined as all randomized subjects who received any dose of study drug.
5	PP*	Per Protocol Sample	C	3	$3.	Subject is in the Per-protocol Sample. PP is defined as all randomized subjects who receive at least 80% of planned dose of study drug and have no major protocol deviations that impact the efficacy assessments.
6	SAFETY*	Safety Sample	C	3	$3.	Subjects in the Safety Sample. Safety is defined as all subjects who receive at least one dose of study drug.
7	SAMP*	Analysis Sample	C	5	$5.	Subject's analysis sample. S= Safety, I= Intent to Treat, P= Per-Protocol
8	RAND*	Randomized	C	3	$3.	Subject was randomized
9	MNTH3DT*	Date of Month 3 visit	N	8	DATE9.	Date of actual 3 month visit.
10	MNTH6DT*	Date of Month 6 visit	N	8	DATE9.	Date of actual 6 month visit.
11	MNTH9DT*	Date of Month 9 visit	N	8	DATE9.	Date of actual 9 month visit.
12	MNTH12DT*	Date of Month 12 visit	N	8	DATE9.	Date of actual 12 month visit.
13	MNTH18DT*	Date of Month 18 visit	N	8	DATE9.	Date of actual 18 month visit.
14	FDDT*	First Dose Date	N	8	DATE9.	First date receiving Atorvastatin or Placebo. It is assumed that the date the drug was dispensed is the first date the drug was taken by the subject.
15	AVNXSTDT*	Start date of Avonex	N	8	DATE9.	First date receiving Avonex.
16	FUDT*	Date of Last Follow-up	N	8	DATE9.	Date of dropout or completion of study.
17	FDDT	First Dose Date	N	8	DATE9.	First date receiving Atorvastatin or Placebo. It is assumed that the date the drug was dispensed is the first date the drug was taken by the subject.
18	MEETPEP	Did patient meet primary endpoint?	C	3	$3.	Subject met the primary endpoint between Day 1 (first dosing date) and Month 12. The primary endpoint criteria are met if the subject develops at least 3 new T2 lesions or one clinical exacerbation.
19	MEETPEPX	Had patient met primary endpoint at M18?	C	3	$3.	Subject met the primary endpoint criteria between Day 1 (first dosing date) and Month 18. The primary endpoint criteria are met if the subject develops at least 3 new T2 lesions or one clinical exacerbation.

Note: Variables from the ADSTART0 dataset that are retained across all datasets are marked with an asterisk (*).

Based on derivations as of 20SEP2013. Some variables in the specifications may be excluded from datasets for de-indentification purposes.

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ADSL2

One record per participant

Summary dataset that compiles information from other derived datasets (rather than from the clinical data).

	Variable Name	Variable Label	Type	Length	Format	Description
20	PEPDT	Date subject met PEP (Day 1-M12)	N	8	DATE9.	The date the subject met the primary endpoint criteria between Day 1 (first dosing date) and Month 12.
21	PEPDTX	Date subject met PEP (thru M18)	N	8	DATE9.	The date the subject met the primary endpoint criteria between Day 1 (first dosing date) and Month 18.
22	PEPPHASE	Phase when subject met primary endpoint	C	45	$45.	Category for the time point the subject met the primary endpoint. Categories are 'Subject Did Not Meet Primary Endpoint', 'Treatment Phase (Day 1 - Month 12)', 'Extension Phase (Months 12-18)'.
23	PEPEVT12	Event Leading to PEP	C	45	$45.	Indicator of whether the primary endpoint was met because of a clinical exacerbation or imaging criteria (at least 3 new T2 lesions).
24	PEP3_12	Meet PEP Months 3-12	C	3	$3.	Subject met the primary endpoint criteria between Month 3 and 12. The primary endpoint criteria are met if the subject develops at least 3 new T2 lesions or one clinical exacerbation. Note that a subject can meet the primary endpoint prior to 3 months and still meet the endpoint criteria months 3-12 if they have another event.
25	PEPDT312	Date subject met PEP (M3-12)	N	8	DATE9.	The date the subject met the primary endpoint criteria between Month 3 and 12.
26	PEP1_3	Meet PEP Day 1 - Month 3	C	3	$3.	Subject met the primary endpoint criteria between Day 1 (first dosing date) and Month 3.
27	PEP1_6	Meet PEP Day 1 - Month 6	C	3	$3.	Subject met the primary endpoint criteria between Day 1 (first dosing date) and Month 6.
28	PEP1_9	Meet PEP Day 1 - Month 9	C	3	$3.	Subject met the primary endpoint criteria between Day 1 (first dosing date) and Month 9.
29	PEPTM12K	Time primary endpoint(Day 1-Month 12)	N	8	8.	Number of days from Day 1 (first dosing date) to meeting the primary endpoint for subjects meeting the endpoint by Month 12. Otherwise, it's the number of days from Day 1 (first dosing date) to the minimum of the date Avonex started, 12 month visit date, and study termination date. This variable is used for Kaplan-Meier plots.
30	PEP12KC	Primary Endpoint Censor(Day 1-Month 12)	N	8	8.	Indicator for whether the primary endpoint was met by Month 12. 1 = primary endpoint met. 0 = primary endpoint not met.
31	PEPTM3K	Time primary endpoint(Months 3-12)	N	8	8.	Number of days from the 3 month visit date to meeting the primary endpoint for subjects meeting the endpoint by Month 12. Otherwise, it's the number of days from the 3 month visit date to the minimum of the date Avonex started, 12 month visit date, and study termination date. This variable is used for Kaplan-Meier plots and subjects with values < 0 should be excluded.

Note: Variables from the ADSTART0 dataset that are retained across all datasets are marked with an asterisk (*).

ADSL2

One record per participant

Summary dataset that compiles information from other derived datasets (rather than from the clinical data).

	Variable Name	Variable Label	Type	Length	Format	Description
32	PEP3KC	Primary Endpoint Censor(Months 3-12)	N	8	8.	Indicator for whether the primary endpoint criteria were met between month 3 and 12. 1 = primary endpoint criteria met. 0 = primary endpoint criteria not met.
33	PEPTM18K	Time Primary Endpoint(Day 1-Month 18)	N	8	8.	Number of days from Day 1 (first dosing date) to meeting the primary endpoint for subjects meeting the endpoint by Month 18. Otherwise, it's the number of days from Day 1 (first dosing date) to the minimum of the date Avonex started, 18 month visit date, and study termination date. This variable is used for Kaplan-Meier plots.
34	PEP18KC	Primary Endpoint Censor(Day 1-Month 18)	N	8	8.	Indicator for whether the primary endpoint was met by Month 18. 1 = primary endpoint criteria met. 0 = primary endpoint criteria not met.
35	TOTT2B	Total # T2 lesions before Avonex	N	8	3.0	Total number of new T2 lesions that occurred prior to starting Avonex for subjects that met the primary endpoint prior to Month 12 and started Avonex. Note that this variable is calculated for subjects that started Avonex after Month 12.
36	TOTGADB	Total # Gd+ lesions before Avonex	N	8	3.0	Total number of new Gd+ lesions that occurred prior to starting Avonex for subjects that met the primary endpoint prior to Month 12 and started Avonex.
37	TOTT2A	Total # T2 lesions after Avonex	N	8	3.0	Total number of new T2 lesions that occurred after starting Avonex up to and including Month 12 for subjects that met the primary endpoint prior to Month 12 and started Avonex. Note that this variable is calculated for subjects that started Avonex after Month 12.
38	TOTGADA	Total # Gd+ lesions after Avonex	N	8	3.0	Total number of new Gd+ lesions that occurred after starting Avonex up to and including Month 12 for subjects that met the primary endpoint prior to Month 12 and started Avonex.
39	NUMMRIB	# of MRI reads before Avonex	N	8	2.0	Number of MRI readings that occurred prior to starting Avonex for subjects that met the primary endpoint prior to Month 12 and started Avonex. Note that this variable is calculated for subjects that started Avonex after Month 12.
40	NUMMRIA	# of MRI reads after Avonex	N	8	2.0	Number of MRI readings that occurred after starting Avonex up to and including Month 12 for subjects that met the primary endpoint prior to Month 12 and started Avonex.
41	MNT2B	Mean # T2 lesions/MRI before Avonex	N	8	5.2	Mean number of new T2 lesions that occurred per MRI reading prior to starting Avonex for subjects that met the primary endpoint prior to Month 12 and started Avonex. Note that this variable is calculated for subjects that started Avonex after Month 12.
42	MNT2A	Mean # T2 lesions/MRI after Avonex	N	8	5.2	Mean number of new T2 lesions that occurred per MRI reading after starting Avonex and up to and including Month 12 for subjects that met the primary endpoint prior to Month 12 and started Avonex.

Note: Variables from the ADSTART0 dataset that are retained across all datasets are marked with an asterisk (*).

Immune Tolerance Network
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ADSL2

One record per participant

Summary dataset that compiles information from other derived datasets (rather than from the clinical data).

	Variable Name	Variable Label	Type	Length	Format	Description
43	MNGADB	Mean # Gd+ lesions/MRI before Avonex	N	8	5.2	Mean number of new Gd+ lesions that occurred per MRI reading prior to starting Avonex for subjects that met the primary endpoint prior to Month 12 and started Avonex. Note that this variable is calculated for subjects that started Avonex after Month 12.
44	MNGADA	Mean # Gd+ lesions/MRI after Avonex	N	8	5.2	Mean number of new Gd+ lesions that occurred per MRI reading after starting Avonex and up to and including Month 12 for subjects that met the primary endpoint prior to Month 12 and started Avonex
45	MNLSNB	Mean # total lesions/MRI before Avonex	N	8	5.2	Mean number of new T2 lesions that occurred per MRI reading prior to starting Avonex for subjects that met the primary endpoint prior to Month 12 and started Avonex. This variable is the same as MNT2B. Note that this variable is calculated for subjects that started Avonex after Month 12.
46	MNLSNA	Mean # total lesions/MRI after Avonex	N	8	5.2	Mean number of new T2 lesions that occurred per MRI reading after starting Avonex and up to and including Month 12 for subjects that met the primary endpoint prior to Month 12 and started Avonex. This variable is the same as MNT2A.
47	TOTCEB	# clinical exacer before Avonex-Month 12	C	3	$3.	Number of clinical exacerbations experienced prior to starting Avonex for subjects meeting the primary endpoint and starting Avonex before Month 12. If the Month 12 visit date was missing the date of the first dose + 372 days was used.
48	TOTCEA	# clinical exacer after Avonex-Month 12	C	3	$3.	Number of clinical exacerbations experienced after starting Avonex through Month 12 for subjects meeting the primary endpoint and starting Avonex before Month 12. If the Month 12 visit date was missing the date of the first dose + 372 days was used.
49	TMCEA	Time from Avonex to exacer or Month 12	N	8	8.0	Number of days from starting Avonex to a clinical exacerbation for subjects experiencing a clinical exacerbation after starting Avonex and before Month 12. For subjects starting Avonex prior to Month 12 without a clinical exacerbation before Month 12, the number of days between starting Avonex and the earliest of a subject's Month 12 visit date or termination date.
50	NUMMNTHB	Total # months before Avonex	N	8	5.2	Number of months from Day 1 (first dosing date) to the day Avonex was started for subjects meeting the primary endpoint before Month 12. This variable is calculated for all subjects starting Avonex even if Avonex was started after Month 12.
51	NUMMNTHA	Total # months after Avonex	N	8	5.2	Number of months from starting Avonex to either Month 12 or study termination (whichever is earliest) for subjects meeting the primary endpoint before Month 12. This variable is calculated for all subjects starting Avonex even if Avonex started after Month 12.

Note: Variables from the ADSTART0 dataset that are retained across all datasets are marked with an asterisk (*).

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ADSL2

One record per participant

Summary dataset that compiles information from other derived datasets (rather than from the clinical data).

	Variable Name	Variable Label	Type	Length	Format	Description
52	HEIGHTB	Height (cm) Baseline	N	8	8.1	Baseline measurement of subject height in centimeters. Baseline measurement is the last non-missing observation on or before Day 1 (first day of dosing).
53	WEIGHTB	Weight (kg) Baseline	N	8	8.1	Baseline measurement of subject weight in kilograms. Baseline measurement is the last non-missing observation on or before Day 1 (first day of dosing).
54	WGTGRP	Weight (kg) Group Baseline	C	6	$6.	Subject weight category based on baseline weight. Baseline measurement is the last non-missing observation on or before Day 1 (first day of dosing).
55	BMIB	BMI (kg/m^2) Baseline	N	8	8.2	Baseline measurement of body mass index. Baseline measurement is the last non-missing observation on or before Day 1 (first day of dosing).
56	AVNXDUR	Duration of Avonex	N	8	8.0	Number of days between the day the first Avonex dose was administered and either study termination or the last day Avonex was administered.
57	AVNXDURM	Duration of Avonex (months)	N	8	8.0	Months between the day the first Avonex dose was administered and either study termination or the last day Avonex was administered.
58	AVDUR12	Duration of Avonex up to Month 12	N	8	8.0	Number of days between the day the first Avonex dose was administered and the Month 12 visit date if Avonex was ongoing, the last day Avonex was administered if drug was stopped or study termination if prior to Month 12.
59	ATRVDUR	Duration of Atorvastatin	N	8	8.0	Number of days between the first dose of Atorvastatin/Placebo and the last dose of Atorvastatin/Placebo.
60	BLT2N	# of T2 lesions at Baseline	N	8	3.0	Number of T2 lesions on the baseline MRI reading. Baseline measurement is the last non-missing observation on or before Day 1 (first day of dosing).
61	BLGADN	# of Gd+ lesions at Baseline	N	8	3.0	Number of Gd+ lesions on the baseline MRI reading. Baseline measurement is the last non-missing observation on or before Day 1 (first day of dosing).
62	T2PREDB	# T2 before Avonex (M1-12)	N	8	3.0	Cumulative number of new T2 lesions occurring prior to starting Avonex or Month 12, whichever is earliest.
63	T2PREEX	# T2 before Avonex (M12-18)	N	8	3.0	Cumulative number of new T2 lesions occurring from Month 12 (exclusive) until starting Avonex or Month 18, whichever is earliest.
64	GADPREDB	# Gd+ before Avonex (M1-12)	N	8	3.0	Cumulative number of new Gd+ lesions occurring prior to starting Avonex or Month 12, whichever is earliest.
65	GADPREEX	# Gd+ before Avonex (M12-18)	N	8	3.0	Cumulative number of new Gd+ lesions occurring from Month 12 (exclusive) until starting Avonex or Month 18, whichever is earliest.

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ADSL2

One record per participant

Summary dataset that compiles information from other derived datasets (rather than from the clinical data).

	Variable Name	Variable Label	Type	Length	Format	Description
66	MEETCE	Any clinical exacerbations?	C	3	$3.	Experienced any clinical exacerbations (first dose through Month 18).
67	FCEDT	Date of first clinical exacerbation	N	8	DATE9.	Date of first clinical exacerbation.
68	CEPHASE	Phase of first clinical exacerbation	C	50	$50.	Category for the timepoint the subject experienced their first clinical exacerbation. Categories are 'Subject Did Not Experience Clinical Exacerbation', 'Treatment Phase (Day 1 - Month 12)', 'Extension Phase (Months 12-18)'.
69	CETM12K	Time first clin. exac. (Day 1-Month12)	N	8	8.	Kaplan-Meier time variable for time to first clinical exacerbation. For subjects having a clinical exacerbation prior to Month 12 and prior to starting Avonex it is the days from the Day 1 (first dose) through the date of the clinical exacerbation. For subjects starting Avonex prior Month 12 or experiencing a clinical exacerbation it's the days from Day 1 (first dose) through starting Avonex. For all other subjects it's the days between Day 1 (first dose) and Month 12 visit date if non-missing or study termination date.
70	CE12KC	Clin. exac. censor (Day 1-Month 12)	N	8	8.	Kaplan-Meier indicator for first clinical exacerbation. 1 = subject experienced a clinical exacerbation prior to Month 12 and prior to starting Avonex. 0 = subject did not experience a clinical exacerbation.
71	CETM18K	Time first clin. exac. (Day 1-Month 18)	N	8	8.	Kaplan-Meier time variable for time to first clinical exacerbation. For subjects having a clinical exacerbation prior to starting Avonex it is the days from Day 1 (first dose) through the date of the clinical exacerbation. For subjects starting Avonex prior to a clinical exacerbation, it's the days from Day 1 (first dose) through starting Avonex. For all other subjects it's the days between Day 1 (first dose) and Month 18 visit if non-missing or study termination date.
72	CE18KC	Clin. exac. censor (Day 1-Month 18)	N	8	8.	Kaplan-Meier indicator for first clinical exacerbation. 1= subject experienced a clinical exacerbation prior to starting Avonex. 0 = subject did not experience a clinical exacerbation.
73	MEETMS	Was subject diagnosed with MS?	C	3	$3.	Subject diagnosed with MS according to the McDonald criteria (defined as having one or more new lesions or experiencing a clinical exacerbation).
74	MSDT	Date subject diagnosed with MS	N	8	DATE9.	Date subject was first diagnosed with MS according to the McDonald criteria.
75	MSPHASE	Phase when MS diagnosed	C	45	$45.	Category for the timepoint the subject was diagnosed with MS. Categories are 'Subject Not Diagnosed with MS', 'Treatment Phase (Day 1 - Month 12)', 'Extension Phase (Months 12-18)'.

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One record per participant

Summary dataset that compiles information from other derived datasets (rather than from the clinical data).

	Variable Name	Variable Label	Type	Length	Format	Description
76	MSTM12K	Time MS diagnosis(Day 1-Month 12)	N	8	8.	Kaplan-Meier time variable for time to MS diagnosis. For subjects diagnosed with MS prior to Month 12 and prior to starting Avonex it is the number of days from the Day 1 (first dose) through the date of MS diagnosis. For subjects starting Avonex prior Month 12 or being diagnosed with MS it's the days from Day 1 (first dose) through starting Avonex. For all other subjects it's the days between Day 1 (first dose) and Month 12 visit date if non-missing or study termination date.
77	MS1_3	MS Diagnosed Day 1 - Month 3	C	3	$3.	Subject diagnosed with MS between Day 1 (first dosing date) and Month 3.
78	MS1_6	MS Diagnosed Day 1 - Month 6	C	3	$3.	Subject diagnosed with MS between Day 1 (first dosing date) and Month 6.
79	MS1_9	MS Diagnosed Day 1 - Month 9	C	3	$3.	Subject diagnosed with MS between Day 1 (first dosing date) and Month 9.
80	MS12KC	MS diagnosis censor (Day 1-Month 12)	N	8	8.	Subject diagnosed with MS between Day 1 (first dosing date) and Month 12.
81	MSTM18K	Time MS diagnosis (Day 1-Month 18)	N	8	8.	Subject diagnosed with MS between Day 1 (first dosing date) and Month 18.
82	MS18KC	MS diagnosis censor (Day 1-Month 18)	N	8	8.	Indicator for whether subject was diagnosed with MS prior to starting Avonex. 1 = subject diagnosed with MS prior to staring Avonex. 0 = subject not diagnosed with MS prior to starting Avonex.
83	LSN312	Any Lesions Months 3-12	C	3	$3.	New Lesions on MRI reads between Months 3 (exclusive) and Month 12 (inclusive).
84	GADEX	Any GD+ Lesion Months 12-18	C	3	$3.	New Gd+ lesions on MRI reads between Month 12 (exclusive) and Month 18 (inclusive) prior to starting Avonex.
85	T2EX	Any T2 Lesion Months 12-18	C	3	$3.	New T2 lesions on MRI reads between Month 12 (exclusive) and Month 18 (inclusive) prior to starting Avonex.
86	CEEX	Any Clin. exac. Months 12 - 18	C	3	$3.	First clinical exacerbation during Months 12 (exclusive) and Month 18 (inclusive) prior to starting Avonex.
87	GDT2CEEX	Any T2, GD+, Clin. Exac. Months 12 - 18	C	3	$3.	Subject experienced their first clinical exacerbation, had any new T2 lesions, or any new Gd+ lesions during Months 12 (exclusive) and Month 18 (inclusive) prior to starting Avonex.
88	TOLERANC	Did patient exhibit tolerance at M18?	C	3	$3.	Subject exhibited tolerance by not meeting the primary endpoint criteria by Month 18. If the subject did not have their Month 18 visit and did not meet the primary endpoint criteria earlier this variable is missing.
89	FUDY	Time on Study (days)	N	8	8.0	Days from Day 1 (first dose date) to study termination or completion.

Note: Variables from the ADSTART0 dataset that are retained across all datasets are marked with an asterisk (*).

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ADSL2

One record per participant

Summary dataset that compiles information from other derived datasets (rather than from the clinical data).

	Variable Name	Variable Label	Type	Length	Format	Description
90	FUDYM	Time on Study (months)	N	8	8.0	Months from Day 1 (first dose date) to study termination or completion.
91	UNBLYN	Unmasked During Study	C	3	$3.	Subject unmasked during the trial.
92	UNBLDT	Date of Unmasking	N	8	DATE9.	Date subject was unmasked.
93	UNBLTM	Time of Unmasking	N	8	TIME5.	Time subject was unmasked using the 24-hour clock.
94	UNCOM1	Unmasking Reason - part 1	C	200	$200.	Reason subject was unmasked - part 1
95	UNCOM2	Unmasking Reason - part 2	C	200	$200.	Reason subject was unmasked - part 2
96	UNCOM3	Unmasking Reason - part 3	C	200	$200.	Reason subject was unmasked - part 3
97	VISITNUM	Visit Number	C	10	$10.	Visit Number

Note: Variables from the ADSTART0 dataset that are retained across all datasets are marked with an asterisk (*).

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ADVS1

One record per participant and vital sign visit

Dataset for the analysis of vital signs.

	Variable Name	Variable Label	Type	Length	Format	Description
1	USUBJID*	ID	C	6	$6.	Unique Subject Identifier
2	SUBJL*	Inv.Site/Part. ID for listings	C	7	$7.	Unique Subject Identifier. Site and subject ID separated by a /.
3	TRTC*	Treatment Group (Char)	C	15	$15.	Randomized Treatment Group
4	ITT*	Intent To Treat Sample	C	3	$3.	Subject is in the Intent to Treat Sample. ITT is defined as all randomized subjects who received any dose of study drug.
5	PP*	Per Protocol Sample	C	3	$3.	Subject is in the Per-protocol Sample. PP is defined as all randomized subjects who receive at least 80% of planned dose of study drug and have no major protocol deviations that impact the efficacy assessments.
6	SAFETY*	Safety Sample	C	3	$3.	Subjects in the Safety Sample. Safety is defined as all subjects who receive at least one dose of study drug.
7	SAMP*	Analysis Sample	C	5	$5.	Subject's analysis sample. S= Safety, I= Intent to Treat, P= Per-Protocol
8	RAND*	Randomized	C	3	$3.	Subject was randomized
9	MNTH3DT*	Date of Month 3 visit	N	8	DATE9.	Date of actual 3 month visit.
10	MNTH6DT*	Date of Month 6 visit	N	8	DATE9.	Date of actual 6 month visit.
11	MNTH9DT*	Date of Month 9 visit	N	8	DATE9.	Date of actual 9 month visit.
12	MNTH12DT*	Date of Month 12 visit	N	8	DATE9.	Date of actual 12 month visit.
13	MNTH18DT*	Date of Month 18 visit	N	8	DATE9.	Date of actual 18 month visit.
14	FDDT*	First Dose Date	N	8	DATE9.	First date receiving Atorvastatin or Placebo. It is assumed that the date the drug was dispensed is the first date the drug was taken by the subject.
15	AVNXSTDT*	Start date of Avonex	N	8	DATE9.	First date receiving Avonex.
16	FUDT*	Date of Last Follow-up	N	8	DATE9.	Date of dropout or completion of study.
17	VISIT	Visit Number	N	8	8.	Visit number.
18	VISITNUM	Visit Number	C	10	$10.	Visit number
19	VISITC	Visit Name (Char)	C	15	$15.	Visit.
20	VSDT	Vital Signs Date	N	8	DATE9.	Date vital signs visit.
21	VSDY	Study Day of Vital Signs	N	8	8.	Days from Day 1 (first dose date) to date of vital signs visit.
22	DIABP	Diastolic Blood Pressure (mmHg)	N	8	8.	Diastolic blood pressure (mmHg).

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ADVS1

One record per participant and vital sign visit

Dataset for the analysis of vital signs.

	Variable Name	Variable Label	Type	Length	Format	Description
23	DIABPB	Diastolic Blood Pressure (mmHg) Baseline	N	8	8.	Baseline diastolic blood pressure (mmHg). Baseline measurement is the last non-missing observation on or before Day 1 (first day of dosing).
24	DIABPC	Diastolic BP (mmHg) Change from Baseline	N	8	8.	Change from baseline in diastolic blood pressure (mmHg). Baseline measurement is the last non-missing observation on or before Day 1 (first day of dosing).
25	SYSBP	Systolic Blood Pressure (mmHg)	N	8	8.	Systolic blood pressure (mmHg).
26	SYSBPB	Systolic Blood Pressure (mmHg) Baseline	N	8	8.	Baseline systolic blood pressure (mmHg). Baseline measurement is the last non-missing observation on or before Day 1 (first day of dosing).
27	SYSBPC	Systolic BP (mmHg) Change from Baseline	N	8	8.	Change from baseline in systolic blood pressure (mmHg). Baseline measurement is the last non-missing observation on or before Day 1 (first day of dosing).
28	TEMP	Temperature (C)	N	8	8.1	Temperature in Celsius.
29	TEMPB	Temperature (C) Baseline	N	8	8.1	Baseline temperature in Celsius. Baseline measurement is the last non-missing observation on or before Day 1 (first day of dosing).
30	TEMPC	Temperature (C) Change from Baseline	N	8	8.1	Change from baseline in temperature in Celsius. Baseline measurement is the last non-missing observation on or before Day 1 (first day of dosing).
31	PULSE	Pulse (beats/min)	N	8	8.	Pulse (beats/min).
32	PULSEB	Pulse (beats/min) Baseline	N	8	8.	Baseline pulse (beats/min). Baseline measurement is the last non-missing observation on or before Day 1 (first day of dosing).
33	PULSEC	Pulse (beats/min) Change from Baseline	N	8	8.	Change from baseline in pulse (beats/min). Baseline measurement is the last non-missing observation on or before Day 1 (first day of dosing).
34	HEIGHT	Height (cm)	N	8	8.1	Height (cm).
35	HEIGHTB	Height (cm) Baseline	N	8	8.1	Baseline height (cm). Baseline measurement is the last non-missing observation on or before Day 1 (first day of dosing).
36	WEIGHT	Weight (kg)	N	8	8.1	Weight (kg).
37	WEIGHTB	Weight (kg) Baseline	N	8	8.1	Baseline weight (kg). Baseline measurement is the last non-missing observation on or before Day 1 (first day of dosing).
38	WEIGHTC	Weight (kg) Change from Baseline	N	8	8.1	Change from baseline in weight (kg). Baseline measurement is the last non-missing observation on or before Day 1 (first day of dosing).
39	RESP	Respirations (breaths/min)	N	8	8.	Respirations (breaths/min).

Note: Variables from the ADSTART0 dataset that are retained across all datasets are marked with an asterisk (*).

ADVS1

One record per participant and vital sign visit

Dataset for the analysis of vital signs.

	Variable Name	Variable Label	Type	Length	Format	Description
40	RESPB	Respirations (breaths/min) Baseline	N	8	8.	Baseline respirations (breaths/min). Baseline measurement is the last non-missing observation on or before Day 1 (first day of dosing).
41	RESPC	Resp (breaths/min) Change from Base	N	8	8.	Change from baseline in respirations (breaths/min). Baseline measurement is the last non-missing observation on or before Day 1 (first day of dosing).
42	VSSUM	Flag for inclusion in Tables	N	8	8.	This variable was not calculated and is therefore blank on all records.

Note: Variables from the ADSTART0 dataset that are retained across all datasets are marked with an asterisk (*).

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ADVSLA1

One record per participant and VAS visit

Dataset for the analysis of Visual Analog Scale (VAS)

	Variable Name	Variable Label	Type	Length	Format	Description
1	USUBJID*	ID	C	6	$6.	Unique Subject Identifier
2	SUBJL*	Inv.Site/Part. ID for listings	C	7	$7.	Unique Subject Identifier. Site and subject ID separated by a /.
3	TRTC*	Treatment Group (Char)	C	15	$15.	Randomized Treatment Group
4	ITT*	Intent To Treat Sample	C	3	$3.	Subject is in the Intent to Treat Sample. ITT is defined as all randomized subjects who received any dose of study drug.
5	PP*	Per Protocol Sample	C	3	$3.	Subject is in the Per-protocol Sample. PP is defined as all randomized subjects who receive at least 80% of planned dose of study drug and have no major protocol deviations that impact the efficacy assessments.
6	SAFETY*	Safety Sample	C	3	$3.	Subjects in the Safety Sample. Safety is defined as all subjects who receive at least one dose of study drug.
7	SAMP*	Analysis Sample	C	5	$5.	Subject's analysis sample. S= Safety, I= Intent to Treat, P= Per-Protocol
8	RAND*	Randomized	C	3	$3.	Subject was randomized
9	MNTH3DT*	Date of Month 3 visit	N	8	DATE9.	Date of actual 3 month visit.
10	MNTH6DT*	Date of Month 6 visit	N	8	DATE9.	Date of actual 6 month visit.
11	MNTH9DT*	Date of Month 9 visit	N	8	DATE9.	Date of actual 9 month visit.
12	MNTH12DT*	Date of Month 12 visit	N	8	DATE9.	Date of actual 12 month visit.
13	MNTH18DT*	Date of Month 18 visit	N	8	DATE9.	Date of actual 18 month visit.
14	FDDT*	First Dose Date	N	8	DATE9.	First date receiving Atorvastatin or Placebo. It is assumed that the date the drug was dispensed is the first date the drug was taken by the subject.
15	AVNXSTDT*	Start date of Avonex	N	8	DATE9.	First date receiving Avonex.
16	FUDT*	Date of Last Follow-up	N	8	DATE9.	Date of dropout or completion of study.
17	VISIT	Visit Number	N	8	8.	Visit number.
18	VISITC	Visit Name	C	15	$15.	Visit.
19	VSLADT	Date of VAS Evaluation	N	8	DATE9.	Date of visual analog scale (VAS) evaluation.
20	VSLADY	Day of VAS Evaluation	N	8	8.	Days from Day 1 (first dose date) to date of VAS evaluation.
21	VSLASCR	Visual Analog Score	N	8	8.	Visual Analog Score. Score is from 0 to 100.

Note: Variables from the ADSTART0 dataset that are retained across all datasets are marked with an asterisk (*).

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ADVSLA1

One record per participant and VAS visit

Dataset for the analysis of Visual Analog Scale (VAS)

	Variable Name	Variable Label	Type	Length	Format	Description
22	VSLASCRB	Visual Analog Score Baseline	N	8	8.	Baseline visual analog score. Score is from 0 to 100. Baseline measurement is the last non-missing observation on or before Day 1 (first day of dosing). This variable is the same across all records for a subject.
23	VSLASCRC	Visual Analog Score Change from Baseline	N	8	8.	Change from baseline in visual analog score. Baseline measurement is the last non-missing observation on or before Day 1 (first day of dosing).
24	VSLASUM	Flag for inclusion in Tables	N	8	8.	This variable was not derived and is missing on all records.
25	VISITNUM	Visit Number	C	10	$10.	Visit Number

Note: Variables from the ADSTART0 dataset that are retained across all datasets are marked with an asterisk (*).