Data Set Name: ae.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	PatientKey	Num	8	11.	11.	Unique subject identifier
2	LineNo	Num	8	11.	11.	AE Number
3	HighLevelTerm	Char	200	$200.	$200.	High Level MedDRA Term
4	SOC	Char	200	$200.	$200.	System Organ Class
5	Ongoing	Num	8	YN.		Was AE ongoing?
6	Serious	Num	8	YN.		Was AE Serious
7	Severity	Num	8	SEV.		Severity
8	Relate	Num	8	RELATE.		Relationship to study drug
9	Outcome	Num	8	OUTCOME.		Outcome
10	DrugAdj	Num	8	DRUGADJ.		Change in the use of the study drug
11	AE_StDt	Num	8			Onset date
12	AE_EndDt	Num	8			End date
13	Treatment	Num	8	TREAT.		Did AE require treatment?

Data Set Name: events.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	RevasType	Num	8	REVTYPE.	4.	Type of revascularization
2	CardRevasc	Num	8	CARDREV.	4.	Type of cardiac revascularization
3	RevasSympt	Num	8	REVSYMPT.	4.	Was revascularization symptom-driven?
4	PatientKey	Num	8	11.	11.	Patient Key
5	Event	Num	8	EVENT.		Type of event
6	StrokeType	Num	8	STROKE.		Stroke etiology
7	FatalStroke	Num	8	FSTROKE.		Was stroke fatal?
8	StudyPeriod	Num	8	PERIOD.		Study period for event
9	IsPrimary	Num	8	ISPRIM.		Is this the primary endpoint
10	dtevent	Num	8			Date of event

Data Set Name: formats.sas7bdat

Num	Variable	Type	Len	Label
1	FMTNAME	Char	32	Format name
2	START	Char	16	Starting value for format
3	END	Char	16	Ending value for format
4	LABEL	Char	53	Format value label
5	MIN	Num	3	Minimum length
6	MAX	Num	3	Maximum length
7	DEFAULT	Num	3	Default length
8	LENGTH	Num	3	Format length
9	FUZZ	Num	8	Fuzz value
10	PREFIX	Char	2	Prefix characters
11	MULT	Num	8	Multiplier
12	FILL	Char	1	Fill character
13	NOEDIT	Num	3	Is picture string noedit?
14	TYPE	Char	1	Type of format
15	SEXCL	Char	1	Start exclusion
16	EEXCL	Char	1	End exclusion
17	HLO	Char	13	Additional information
18	DECSEP	Char	1	Decimal separator
19	DIG3SEP	Char	1	Three-digit separator
20	DATATYPE	Char	8	Date/time/datetime?
21	LANGUAGE	Char	8	Language for date strings

Data Set Name: lab.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	PatientKey	Num	8	11.	11.	Unique subject identifier
2	Test	Char	25	$25.	$25.	name of Lab Test
3	Visit	Num	8	VISIT.		Nominal visit
4	Result	Num	8			Lab test results converted to numeric
5	CrCl	Num	8			Creatinine clearance. Computed for Test='Creat'
6	eGFR	Num	8			MDRD estimate of glomerular filtration rate (eGFR). Computed only for test='Creat'
7	base	Num	8	BASE.		Indicator for baseline value
8	dtdraw	Num	8			Date of draw relative to randomization

Data Set Name: patient.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	PatientKey	Num	8	11.	11.	Unique subject identifier
2	RandDose	Num	8	DOSE.		Dose of study drug at randomization
3	Sex	Num	8	SEX.		Sex
4	Race	Num	8	RACE.		Race
5	Smoke	Num	8	SMOKE.		Smoking Status at Baseline
6	Age	Num	8			Age
7	Age65	Num	8	AGE65CAT.		Age65
8	HxDiab	Num	8			History of Diabetes
9	MetabSyn	Num	8			Metabolic Syndrome
10	TypePrimary	Num	8	TP.		Type of endpoint for primary
11	StatinDuration	Num	8	DURATION.		StatinDuration
12	ETSecondary_4	Num	8			Time to four-component secondary outcome
13	VSSecondary_4	Num	8	EVENTYN.		Four-component secondary outcome: CAD death, MI, ischemic stroke, hosp for "high risk" ACS
14	ETSecondary_3	Num	8			Time to three-component secondary outcome
15	VSSecondary_3	Num	8	EVENTYN.		Three-component secondary outcome: CAD death, MI, ischemic stroke
16	ETPrimary	Num	8			Time to primary endpoint or censoring
17	VSPrimary	Num	8	EVENTYN.		Primary Endpoint indicator
18	ETIsch	Num	8			Time to ischemic stroke or censoring
19	VSIsch	Num	8	EVENTYN.		Ischemic Stroke indicator
20	VSDth	Num	8	DEAD.		Death during main trial
21	causeDth	Num	8	CDTH.		Cause of death
22	SysBP	Num	8			Systolic BP
23	DiasBP	Num	8			Diastolic BP
24	StudyStatus	Num	8	STATUS.		Study Status
25	TypePrimaryA6	Num	8	TP.		Type of endpoint for primary main trial or Amend 6 Follow-up
26	ETSecondary_4_A6	Num	8			Time to four-component secondary outcome, main trial or Amend 6 follow-up
27	VSSecondary_4_A6	Num	8	EVENTYN.		Four-component secondary outcome: CAD death, MI, ischemic stroke, hosp for "high risk" ACS, main trial or Amend 6 follow-up
28	ETSecondary_3_A6	Num	8			Time to three-component secondary outcome; main trial or Amend 6 follow-up
29	VSSecondary_3_A6	Num	8	EVENTYN.		Three-component secondary outcome: CAD death, MI, ischemic stroke; main trial or Amend 6 follow-up
30	ETPrimaryA6	Num	8			Time to primary endpoint or censoring, main trial or Amend 6 follow-up
31	VSPrimaryA6	Num	8	EVENTYN.		Primary Endpoint indicator, main trial or Amend 6 follow-up

Num	Variable	Type	Len	Format	Informat	Label
32	ETIschA6	Num	8			Time to ischemic stroke or censoring, main trial or Amend 6 follow-up
33	VSIschA6	Num	8	EVENTYN.		Ischemic Stroke indicator, main trial or Amend 6 follow-up
34	VSDthA6	Num	8	DEAD.		Death during main trial or Amend 6 follow-up
35	Glucose_Base	Num	8			Baseline Glucose
36	HDL_C_Base	Num	8			Baseline HDL-C
37	LDL_C_Base	Num	8			Baseline LDL-C
38	Lpa	Num	8			Baseline Lp(a)
39	Trig_Base	Num	8			Baseline Trig
40	RandAssi	Num	8	RAND.	4.	Treatment assignment
41	BMI	Num	8			Body Mass Index
42	DtEnroll	Num	8			Date of enrollment
43	DtCensor	Num	8			Last observation, main trial
44	DtCensorA6	Num	8			Last observation, Amend 6 follow-up
45	ethn	Num	8	TABETHN.		Ethnicity

Data Set Name: statindose.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	PatientKey	Num	8	11.	11.	Patient Key
2	StatinDose	Num	8	STADOSE.		Statin Dose
3	OnEze	Num	8	YN.		On ezetimibe

Data Set Name: studydrugadj.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	PatientKey	Num	8	11.	11.	Patient Key
2	DrugStopped	Num	8	YN.		Study drug discontinued
3	ETDiscontinue	Num	8			Days from randomization to drug discontinuation
4	DrugStopReason	Num	8	ADJREAS.		Primary reason study drug discontinued
5	Restart	Num	8	RESTART.		Patient restarted blinded therapy after discontinuation
6	DoseReduced	Num	8			Study drug dose lowered
7	NewDose	Num	8	DOSE.		New Dose
8	DoseAdjReason	Num	8	ADJREAS.		Primary reason for dose reduction
9	DtRestart	Num	8			Date restarted

Data Set Name: acs.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	PatientKey	Num	8	11.	11.	Unique subject identifier
2	ACS_OnsetDt	Num	8			Date of onset of ACS event
3	ACS_AdmDt	Num	8			Date of hospital admission
4	ACS_DiscDt	Num	8			Date of hospital discharge
5	ACS_event	Num	8	ACEVENT.		Type of event
6	ACS_angina	Num	8	YN.		Did patient experience angina or angina equivalent symptoms with 24 hours prior to event
7	ACS_anginaduration	Num	8	ANGDURAT.		If angina symptoms, duration of symptoms
8	ACS_enzyme	Num	8	YN.		Were cardiac enzymes taken?
9	ACS_ecg	Num	8	YN.		Were ECGs obtained
10	ACS_revascpreacs	Num	8	PREPOACS.		Did patient undergo PCI within 24 hours or CABG within 72 hours of onset of symptoms?
11	ACS_revascpostacs	Num	8	PREPOACS.		Was revascularization procedure performed FOLLOWING the event?
12	ACS_fatal	Num	8	YN.		Did the patient die within 30 days of this event?

Data Set Name: base.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	PatientKey	Num	8	11.	11.	Unique Subject Identifier
2	bl_bldDate	Num	8			Date of baseline blood draw (days from date of enrollment)
3	BL_Fasting	Num	8	YN.		Was blood drawn in fasting state?
4	BL_LDL	Num	8			Screening LDL-C
5	BL_LDLUnit	Num	8	LABUNIT.		Units for LDL-C
6	BL_HDL	Num	8			Screening HDL-C
7	BL_HDLUnit	Num	8	LABUNIT.		Units for HDL-C
8	BL_Trig	Num	8			Screening Triglycerides
9	BL_TGUnit	Num	8	LABUNIT.		Units for triglycerides
10	BL_LipidOnStatin	Num	8	YN.		Was patient taking statins prior to screening?
11	BL_PriorNiacin	Num	8	YN.		Has pateint ever taken niacin or Niaspan?
12	BL_Statin	Num	8	YN.		Statins taken in prior month
13	BL_BileAcid	Num	8	YN.		Bile acid sequestrates taken in prior month
14	BL_Nicotin	Num	8	YN.		Nicontinic acid other than niacin or Niaspan taken in prior month
15	BL_Fibric	Num	8	YN.		Fibric acids taken in prior month
16	BL_Absorb	Num	8	YN.		Cholesterol absorption inhibitors taken in prior month
17	BL_OtherDrug	Num	8	YN.		Other lipid modifying agents taken in prior month
18	BL_TLC	Num	8	YN.		Therapeutic lifestyle changes ONLY in prior month
19	BL_Counsel	Num	8	YN.		Patient counseled regarding diet and exercise for lipid control?

Data Set Name: cenz.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	PatientKey	Num	8	11.	11.	Unique Subject Identifier
2	ENZ_CK_ULN	Char	4	$4.	$4.	CK upper limit of normal
3	ENZ_CKMB_ULN	Char	4	$4.	$4.	CK-MB upper limit of normal
4	ENZ_Trop	Char	6	$6.	$6.	Troponin
5	ENZ_Trop_ULN	Char	5	$5.	$5.	Troponin upper limit of normal
6	ENZ_Date	Num	8			Date enzymes drawn
7	ENZ_TimeHH	Num	8			Time enzymes drawn - hour
8	ENZ_TimeMin	Num	8			Time enzymes drawn - minute
9	ENZ_CKUnit	Num	8	CKU.		CK units
10	ENZ_CK_ULNUnit	Num	8	CKU.		CK upper limit of normal units
11	ENZ_CKMBUnit	Num	8	CKMBU.		CK-MB units
12	ENZ_CKMB_ULNUnit	Num	8	CKMBU.		CK-MB upper limit of normal units
13	ENZ_TropUnit	Num	8	TROPU.		Troponin units
14	ENZ_Trop_ULNUnit	Num	8	TROPU.		Troponin upper limit of normal units
15	ENZ_CK	Char	4			CK value
16	ENZ_CKMB	Char	4			CK-MB value

Data Set Name: cns.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	PatientKey	Num	8	11.	11.	Unique subject identifier
2	CNS_SymDt	Num	8			Date of onset of CNS event
3	CNS_AdmDt	Num	8			If hospitalized, admission date
4	CNS_DiscDt	Num	8			If hospitalized, discharge date
5	CNS_Type	Num	8	CNSTYPE.		Primary etiology
6	CNS_hospital	Num	8	YN.		Did event require hospitalization?
7	CNS_24hr	Num	8	YN.		Did symptoms persis for more than 24 hrs?
8	CNS_CT	Num	8	YN.		CT obtained
9	CNS_MRI	Num	8	YN.		MRI obtained
10	CNS_Echo	Num	8	YN.		Cardiac echo obtained
11	CNS_Doppler	Num	8	YN.		Carotid doppler obtained
12	CNS_MRA	Num	8	YN.		MRA/angiography obtained

Data Set Name: conmed.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	PatientKey	Num	8	11.	11.	Unique Subject Identifier
2	visit	Char	200	$200.	$200.	Visit
3	CM_Beta	Num	8	YN.		Beta-blocker
4	CM_Ace	Num	8	YN.		ACE inhibitor
5	CM_ATII	Num	8	YN.		Angiotensin II receptor blocker
6	CM_CCB	Num	8	YN.		Calcium channel blocker
7	CM_Diu	Num	8	YN.		Diuretic
8	CM_Digitalis	Num	8	YN.		Digitalis
9	CM_Nit	Num	8	YN.		Nitrates
10	CM_Warfarin	Num	8	YN.		Warfarin or heparin analog
11	CM_Aspirin	Num	8	YN.		Aspirin regularly
12	CM_NSAID	Num	8	YN.		NSAIDs regularly
13	CM_Cox2	Num	8	YN.		Cox-2 inhibitor
14	CM_Plavix	Num	8	YN.		Clopidogrel
15	CM_Metformin	Num	8	YN.		Metformin
16	CM_TZD	Num	8	YN.		Thiazolidnediones
17	CM_SulU	Num	8	YN.		Sulfa Urea
18	CM_Insulin	Num	8	YN.		Insulin
19	CM_OtDiab	Num	8	YN.		Other diabetes treatments
20	CM_HRT	Num	8	YN.		Hormone replacement therapy
21	CM_HRTEs	Num	8	YN.		Estrogens
22	CM_HRTpro	Num	8	YN.		Progestins
23	CM_Cort	Num	8	YN.		Corticosteroids
24	CM_Anitbac	Num	8	YN.		Antibacterial
25	CM_Serzone	Num	8	YN.		Mefazodone
26	CM_Antifun	Num	8	YN.		Antifungal
27	CM_Fibric	Num	8	YN.		Fibric acide derivative
28	CM_Cyclo	Num	8	YN.		Cyclosporine
29	CM_HighVit	Num	8	YN.		High dose vitamins
30	CM_Vit_C_E	Num	8	YN.		High dose vitamin C (> 500 mg) or E (> 400 IU)
31	CM_Niacin	Num	8	YN.		Niacin or nicotinic acid
32	CM_NiacDose	Num	8	DOSE.		Dose
33	CM_FishOil	Num	8	YN.		Fish oil or derivatives or any n-3 fatty acids

Data Set Name: dadh.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	PatientKey	Num	8	11.	11.	Unique Subject Identifier
2	Visit	Char	200	$200.	$200.	Visit
3	DADH_VisDt	Num	8			Date of Visit
4	DADH_KitNumDt	Num	8			Date patient starting taking drugs in this kit
5	DAdh_NiaspanDose	Num	8			Number of Niaspan/placebo pills per day?
6	DAdh_StatinDose	Num	8			Number of simvastatin pills per day?
7	DAdh_Niaspan_Return	Num	8			Approximate number of Niaspan/placebo pills returned
8	DAdh_Statin_Return	Num	8			Approximate number of simvasatin pills returned?
9	DAdh_Ezt	Num	8	YN.		Was ezetimibe prescribed
10	DAdh_Ezt_Return	Num	8			Approximate number of ezetimibe pills returned
11	DAdh_Adhere	Num	8	YN.		Did patient report taking drugs as prescribed?
12	DAdh_NoAdhereNia	Num	8	YN.		If no, was it Niaspan/Placebo?
13	DAdh_NoAdhereZocor	Num	8	YN.		If no, was it simvastatin?
14	DAdh_NoAdhereEze	Num	8	YN.		if no, was it ezetimibe
15	DAdh_BadWhy	Num	8	BADREAS.		What was primary reason for poor adherence

Data Set Name: dadj.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	PatientKey	Num	8	11.	11.	Unique Subject Identifier
2	visit	Char	200	$200.	$200.	Visit
3	DADJ_VisDt	Num	8			Date of Visit
4	DADJ_DoseAdj	Num	8	DOSEADJ.		Was the dose of Niaspan/placebo adjusted or drug discontinued?
5	DADJ_NiaspanDoseNewLevel	Num	8	DOSE.		New dose level
6	DADJ_NiaspanDoseAdjReason	Num	8	ADJREAS.		If dose adjusted or discontinued, what was the primary reason?
7	DADJ_StatinDoseAdj	Num	8	DOSEADJ.		Was dose of simvastatin adjusted or discontinued?
8	DADJ_StatinDoseNewLevel	Num	8	STADOSE.		What was new dose of simvastatin?
9	DADJ_StatinDoseAdjReason	Num	8	SADJREAS.		What was primary reason for adjusting simvastatin?
10	DADJ_AnotherStatin	Num	8	YN.		If not on simvastatin, is patient taking another statin?
11	DADJ_StatinType	Num	8	STTYPE.		If yes, which?
12	DADJ_StatinDose	Num	8			Dose level of other statin (mg)?
13	DADJ_EzDoseAdj	Num	8	EZADJ.		What is current ezetimibe use?
14	DADJ_EzDoseAdjReason	Num	8	EZADJRSN.		If ezetimibe discontinued, primary reason

Data Set Name: death.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	PatientKey	Num	8	11.	11.	Unique subject identifier
2	DTH_Date	Num	8			Date of death
3	DTH_cause	Num	8	DTHCAUS.		Presumed cause of death
4	DTH_cardiaccause	Num	8	CARDCAUS.		If cardiac, cause of death
5	DTH_vascause	Num	8	VASCAUS.		If vascular, cause of death
6	DTH_noncause	Num	8	NONCAUS.		If non-vascular, cause of death
7	DTH_hospital	Num	8	YN.		Was patient in the ED or hospitalized at time of death?
8	DTH_autopsy	Num	8	YN.		Was an autopsy performed?
9	DTH_revas	Num	8	YN.		Did death occur within 30 days of cardiac surgery or revascularization?

Data Set Name: demo.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	PatientKey	Num	8	11.	11.	Unique Subject Identifier
2	Demo_TobNm	Char	70	$70.	$70.	If current or former tobacco user, estimated pack-years
3	Demo_Age	Num	8			Age at enrollment
4	Demo_Sex	Num	8	SEX.		Gender
5	Demo_Ethn	Num	8	TABETHN.		Ethnicity
6	Demo_Race	Num	8	RACE.		Race
7	Demo_Smoke	Num	8	SMOKE.		Tobacco use
8	Demo_Alcohol	Num	8	YN.		Does patient consume alcohol?
9	Demo_Alcnum	Num	8			If yes, average number of drinks per week.
10	Demo_Employ	Num	8	TABEMP.		Employment status
11	Demo_Edu	Num	8	TABEDU.		Education level
12	Demo_Job	Num	8	TABJOB.		Field describing patients work category

Data Set Name: disp.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	PatientKey	Num	8	11.	11.	Unique Subject Identifier
2	Visit	Char	200	$200.	$200.	Visit
3	Disp_VisDt	Num	8			Date of Visit
4	Disp_Dose	Num	8	DOSE.		Dose of Niaspan/Placebo dispensed
5	Disp_StatinDose	Num	8	STADOSE.		Daily dose of statin dispensed
6	Disp_Ezetimibe	Num	8			Number of ezetimibe bottles dispensed
7	Disp_StatinBottles_10	Num	8			Number of 10 mg simvastatin bottles dispensed
8	Disp_StatinBottles_20	Num	8			Number of 20 mg simvastatin bottles dispensed
9	Disp_StatinBottles_40	Num	8			Number of 40 mg simvastatin bottles dispensed

Data Set Name: exc.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	PatientKey	Num	8	11.	11.	Unique Subject Identifier
2	Exc_ACS	Num	8	YN.		Has patient been hospitalized for ACS with discharge <= 4 weeks ago?
3	Exc_CAB	Num	8	YN.		Has patient had CABG within the past 1 year?
4	Exc_PCI	Num	8	YN.		Has patient had PCI <= 4 weeks ago?
5	Exc_Strokek8wk	Num	8	YN.		Has patient had stroke or TIA <= 8 weeks ago?
6	Exc_Glu	Num	8	YN.		Is fasting glucose >= 180 mg/dL or HbA1c > 9.0%?
7	Exc_Glucometer	Num	8	YN.		Is patient diabetic and unable to or refuses to use glucometer for home glucose monitoring?
8	Exc_PostMIvax	Num	8	YN.		Is the need/liklihood of urgent revascularization high?
9	Exc_LfCAD	Num	8	YN.		Does patient have left main coronary disease >= 50% and no prior CABG
10	Exc_Ejc	Num	8	YN.		Is the patients ejection fraction < 30%
11	Exc_Unresp	Num	8	YN.		Does the patient have cardiogenic shock, pulmonary edema, angina or CHF unresponsive to standard medical therapy (CCS Class IV)
12	Exc_CVD	Num	8	YN.		Does patient have concomitant valvular disease likely to require surgery or affect prognosis
13	Exc_CardMy	Num	8	YN.		Does patient have congenital or primary cardiomyopathy likely to affect prognosis
14	Exc_ICD	Num	8	YN.		Has the patient experienced resuscitated out-of-hospital sudden death or symptomatic sustained or non-sustained ventricular tachycardia and does NOT now have an ICD?
15	Exc_Hyper	Num	8	YN.		Does patient have significant systemic hypertension unresponsive to medical therapy?
16	Exc_Peptic	Num	8	YN.		Does patient have active peptic ulcer disease?
17	Exc_Liver	Num	8	YN.		Does patient have AST or ALT > 2 x upper limit of normal or active liver disease?
18	Exc_Gout	Num	8	YN.		Does patient have recent history of acute gout?
19	Exc_Creat	Num	8	YN.		Does patient have chronic renal insufficiency with creatinine >= 2.5 mg/dL
20	Exc_Meds	Num	8	YN.		Must patient continue any of the excluded medications?
21	Exc_Preg	Num	8	YN.		If female, is patient pregnant or likely to become pregnant?
22	Exc_Comorb	Num	8	YN.		Does patient have any significant comorbidity likely to cause death in the 3-5 year follow-up period?
23	Exc_HIV	Num	8	YN.		Does patient have AIDS or active HIV infection?
24	Exc_abuse	Num	8	YN.		Does patient have significant active history of substance abuse within past 5 years?
25	Exc_Clintrial	Num	8	YN.		Is pateint currently participating in another long-term clinical trial?
26	Exc_patient	Num	8	YN.		Is the patient unwilling to participate?
27	Exc_Physcian	Num	8	YN.		Is the physician or other non-study physician unwilling to allow patient to participate?

Data Set Name: folla6.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	PatientKey	Num	8	11.	11.	Unique Subject Identifier
2	Visit	Char	200	$200.	$200.	Visit
3	AFUP_VisitDt	Num	8			Date of visit
4	AFUP_VisitTp	Num	8	VISIT_.		Type of visit
5	AFUP_VisitNtDn	Num	8	VISREAS.		If not done, reason
6	AFUP_MI	Num	8	YN.		Did participant have an MI
7	AFUP_ACS	Num	8	YN.		Was participant hospitalized for ACS
8	AFUP_CardRevas	Num	8	YN.		Did participant have cardiac revascularization?
9	AFUP_CerebRevas	Num	8	YN.		Did participant have carotid revascularization?
10	AFUP_PeriRevas	Num	8	YN.		Did participant have peripheral revascularization?
11	AFUP_StrokeTIA	Num	8	YN.		Did participant have peripheral revascularization?

Data Set Name: followup.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	PatientKey	Num	8	11.	11.	Unique Subject Identifier
2	visit	Char	200	$200.	$200.	Visit
3	Fol_Date	Num	8			Date of Visit
4	Fol_VisitType	Num	8	VISTYPE.		Type of visit
5	Fol_Reason	Num	8	VISREAS_.		Reason for follow-up
6	Fol_DrugDC	Num	8	YN.		Was study drug dose adjusted or discontinued
7	Fol_MI	Num	8	YN.		Screen for endpoints: MI
8	Fol_Stroke	Num	8	YN.		Screen for endpoints: Stroke
9	Fol_ACS	Num	8	YN.		Screen for endpoints: Hospitalization for ACS
10	Fol_CardRevasc	Num	8	YN.		Screen for endpoints: Cardiac revascularization
11	Fol_CerebRevasc	Num	8	YN.		Screen for endpoints: Cerebral revascularization
12	Fol_PeriphRevasc	Num	8	YN.		Screen for endpoints: Peripheral revascularization
13	Fol_Flush	Num	8	TABFLUSH.		Frequency of flushing
14	Fol_Flush2	Num	8	SEV.		Severity of flushing
15	Fol_Prior	Num	8	YN.		Did patient take aspirin prior to Niaspan/placebo
16	Fol_Prior2	Num	8	YN.		Was it generally effective in preventing or reducing incidence or severity of flush
17	Fol_Itch	Num	8	SEV.		Itching?
18	Fol_Nausea	Num	8	SEV.		Nausea?
19	Fol_HeartBurn	Num	8	SEV.		Other gastro-intestinal symptoms?
20	Fol_Muscle	Num	8	SEV.		Muscle aches or weakness?
21	Fol_Fatigue	Num	8	SEV.		Fatigue?
22	Fol_Vision	Num	8	SEV.		Marked changes in eyesight?
23	Fol_Gout	Num	8	SEV.		Development of gout or severe symptoms of arthritis?
24	Fol_Glucose	Num	8	YN.		Fasting glucometer measurements rise by > 15 mg/dL?
25	Fol_Diabetic	Num	8	YN.		For diabetics, did they use a glucometer?
26	Fol_AEs	Num	8	YN.		Any other adverse events?

Data Set Name: hcu.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	PatientKey	Num	8	11.	11.	Unique Subject Identifier
2	Visit	Char	200	$200.	$200.	Visit
3	HU_Date	Num	8			Date of Visit
4	HU_Outpatient	Num	8			Number of outpatient doctor visits since last follow-up contact
5	HU_HomeHealth	Num	8			Number of home health care days since last follow-up contact
6	HU_Rehab	Num	8			Number of days in nursing or rehab facility since last follow-up
7	HU_WorkStatus	Num	8	TABEMP.		Current work status
8	HU_WorkChg	Num	8	WRKCHG.		Has work status changed since last follow-up due to health issues?
9	HU_WorkLost	Num	8			If still working, number of days unable to work because of health issues
10	HU_Cath	Num	8	YN.		Cardiac outpatient procedures: cardiac catheterization
11	HU_Cardiov	Num	8	YN.		Cardiac outpatient procedures: cardioversion
12	HU_Pacemaker	Num	8	YN.		Cardiac outpatient procedures: pacemaker implant
13	HU_EP	Num	8	TABFLUSH.		Cardiac outpatient procedures: electrophysiology study
14	HU_echo	Num	8	SEV.		Cardiac outpatient procedures: transthoracic cardiac echo
15	HU_TEE	Num	8	YN.		Cardiac outpatient procedures: transesophageal cardiac echo
16	HU_NucScan	Num	8	YN.		Cardiac outpatient procedures: radionuclide scan
17	HU_CT	Num	8	SEV.		Cardiac outpatient procedures: CT scan (cardiac or other)
18	HU_MRI	Num	8	SEV.		Cardiac outpatient procedures: MRI scan (cardiac or other)

Data Set Name: hosp.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	PatientKey	Num	8	11.	11.	Unique Subject Identifier
2	Hosp_DischDt	Num	8			Date of discharge
3	Hosp_AdmDt	Num	8			Date of admission
4	Hosp_ED	Num	8	HOSPED.		Type of admission
5	Hosp_ICU	Num	8			Number of days in ICU
6	Hosp_Death	Num	8	YN.		Did patient die during this admission?
7	Hosp_Revasc	Num	8	YN.		Did patient undergo revascularization during this hospitalization?
8	Hosp_MI	Num	8	YN.		Did patient suffer an MI during this admission?
9	Hosp_Cath	Num	8	YN.		Procedures performed: cardiac catheterization
10	Hosp_Cardiov	Num	8	YN.		Procedures performed: cardioversion
11	Hosp_Pace	Num	8	YN.		Procedures performed: pacemaker implant
12	Hosp_ICD	Num	8	YN.		Procedures performed: ICD implant
13	Hosp_Aneur	Num	8	YN.		Procedures performed: aneurysm resection
14	Hosp_Valve	Num	8	YN.		Procedures performed: valve repair or replacement
15	Hosp_EP	Num	8	YN.		Procedures performed: electrophysiology study
16	Hosp_echo	Num	8	YN.		Procedures performed: transthoracic cardiac echo
17	Hosp_TEE	Num	8	YN.		Procedures performed: transesophageal cardiac echo
18	Hosp_Nucscan	Num	8	YN.		Procedures performed: radionuclide scan
19	Hosp_CT	Num	8	YN.		Procedures performed: CT scan (cardiac or other)
20	Hosp_MRI	Num	8	YN.		Procedures performed: MRI scan (cardiac or other)

Data Set Name: hx.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	PatientKey	Num	8	11.	11.	Unique Subject Identifier
2	HX_Angina	Num	8	YN.		Angina
3	HX_ACS	Num	8	YN.		Hospitalization for ACS
4	Hx_MI	Num	8	YN.		MMI
5	Hx_VenArr	Num	8	YN.		Ventricular arrhythmia
6	Hx_Afib	Num	8	YN.		Atrial fibrillation
7	Hx_CHF	Num	8	YN.		CHF
8	Hx_EF	Num	8	YN.		Ejection fraction (%)
9	Hx_PE	Num	8	YN.		Pulmonary embolism
10	Hx_DVT	Num	8	YN.		DVT requiring anticoagulation
11	Hx_IDC	Num	8	YN.		Ischemic dilated cardiomyopathy
12	Hx_aorsten	Num	8	YN.		Moderate - severe mitral or aortic stenosis
13	Hx_mitregurg	Num	8	YN.		Moderate - severe mitral regurgitation
14	Hx_Hyper	Num	8	YN.		Hypertension
15	Hx_TIA	Num	8	YN.		TIA
16	Hx_Stroke	Num	8	YN.		Stroke
17	HX_StrokeDef	Num	8	STROKE.		Stroke etiology
18	Hx_AAA	Num	8	YN.		Abdominal aortic aneurysm
19	Hx_PVD	Num	8	YN.		Peripheral vascular disease
20	Hx_Carotid	Num	8	YN.		Carotid artery disesase
21	Hx_famCVD	Num	8	YN.		Family history of premature cardiovascular disease (prior to 65 yr for women, 55 year for men) in first degree relative
22	Hx_CABG	Num	8	YN.		CABG
23	Hx_PCI	Num	8	YN.		PCI
24	HX_PCIStent	Num	8	YN.		Was a stent placed?
25	Hx_valve	Num	8	YN.		Valve repair or replacement
26	Hx_AAArepair	Num	8	YN.		AAA repair
27	Hx_edart	Num	8	YN.		Carotid endarterectomy
28	Hx_CarotidStent	Num	8	YN.		Carotid stent placed
29	Hx_PeriRevas	Num	8	YN.		Peripheral revascularization
30	Hx_ICD	Num	8	YN.		ICD implant
31	Hx_Pace	Num	8	YN.		Pacemaker implant
32	Hx_CPD	Num	8	YN.		Chronic pulmonary disease
33	Hx_HepC	Num	8	YN.		Hepatic disease
34	Hx_Renal	Num	8	YN.		Renal disease
35	Hx_Diabetes	Num	8	YN.		Diabetes mellitus
36	Hx_Dtype	Num	8	TABDTYPE.		Type of diabetes

Num	Variable	Type	Len	Format	Informat	Label
37	Hx_DtreatDiet	Num	8	YN.		Current treatment ONLY dietary counseling
38	Hx_DtreatOral	Num	8	YN.		Treatment includes oral hypoglycemic
39	Hx_DtreatInsulin	Num	8	YN.		Treatment includes insulin
40	HX_Glucometer	Num	8	YN.		Patient uses glucometer
41	HX_ACSdateMM	Num	8			Most recent hospitalization (months prior to enrollment)
42	HX_MIDateMM	Num	8			Most recent MI (months prior to enrollment)
43	HX_EFdateMM	Num	8			Most recent EF measurement (months prior to enrollment)
44	HX_StrokedateMM	Num	8			Most recent stroke (months prior to enrollment)
45	HX_CABGdateMM	Num	8			Most recent CABG (months prior to enrollment)
46	Hx_PCIdateMM	Num	8			Most recent PCI
47	Hx_DiabetesYY	Num	8			Years since onset

Data Set Name: incl.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	PatientKey	Num	8	11.	11.	Unique Subject Identifier
2	Incl_age	Num	8	YN.		Was patient at least 45 years old?
3	Incl_cad	Num	8	YN.		Does patient have documented multi-vessel CAD?
4	Incl_MI	Num	8	YN.		Has patient experienced a documented MI?
5	Incl_ACS	Num	8	YN.		Has patient been hospitalized for ACS with objective evidence of ischemia?
6	Incl_CVD	Num	8	YN.		Does Patient have documented cerebrovascular or carotid disease?
7	Incl_PAD	Num	8	YN.		Does patient have documented symptomatic PAD?
8	Incl_LDL	Num	8	YN.		Is LDL-C in protocol specified range?
9	Incl_HDL	Num	8	YN.		Is HDL-C in protocol specified range?
10	Incl_TG	Num	8	YN.		Are triglycerides in protocol specified range?
11	Incl_Onstatin	Num	8	YN.		Was patient on a statin at time of screening?
12	Incl_Ezetimibe	Num	8	YN.		Was patient on ezetimibe at time of screening?
13	Incl_StatinType	Num	8	STTYPE.		If yes, which type?
14	Incl_StatinDose	Num	8			Dose level of statin

Data Set Name: liptx.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	PatientKey	Num	8	11.	11.	Unique subject identifier
2	Visit	Char	200	$200.	$200.	Visit
3	LI_AdviDose	Char	20	$20.	$20.	Lovastatin dose (mg/day)
4	LI_CaduDose	Char	20	$20.	$20.	Atorvastatin dose (mg/day)
5	LI_VytoDose	Char	20	$20.	$20.	Simvastatin + ezetimibe dose (mg/day)
6	LI_PraviDose	Char	20	$20.	$20.	Pravastatin + aspirin dose (mg/day)
7	LI_SimcDose	Char	20	$20.	$20.	Simvastatin + niacin dose (mg/day)
8	LI_OthComDose	Char	20	$20.	$20.	Other combination medication dose (mg/day)
9	LI_Ator	Num	8	YN.		Atorvastatin
10	LI_AtorDose	Num	8			Atorvastatin dose (mg/day)
11	LI_Fluv	Num	8	YN.		Fluvastatin
12	LI_FluvDose	Num	8			Fluvastatin dose (mg/day)
13	LI_Lova	Num	8	YN.		Lovastatin
14	LI_LovaDose	Num	8			Lovastatin dose (mg/day)
15	LI_Prava	Num	8	YN.		Pravastatin
16	LI_PravaDose	Num	8			Pravastatin dose (mg/day)
17	LI_Rosu	Num	8	YN.		Rosuvastatin
18	LI_RosuDose	Num	8			Rosuvastatin dose (mg/day)
19	LI_Simv	Num	8	YN.		Simvastatin
20	LI_SimvDose	Num	8			Simvastatin dose (mg/day)
21	LI_OthSta	Num	8	YN.		Other statin
22	LI_OthStaDose	Num	8			Other statin dose (mg/day)
23	LI_Advi	Num	8	YN.		Lovastatin
24	LI_Cadu	Num	8	YN.		Atorvastatin
25	LI_Vyto	Num	8	YN.		Simvastatin + ezetimibe
26	LI_Pravi	Num	8	YN.		Pravastatin + aspirin
27	LI_Simc	Num	8	YN.		Simvastatin + niacin
28	LI_OthCom	Num	8	YN.		Other combination medication
29	LI_Gemf	Num	8	YN.		Gemfibrozil
30	LI_GemfDose	Num	8			Gemfibrozil dose (mg/day)
31	LI_Feno	Num	8	YN.		Fenofibrate
32	LI_FenoDose	Num	8			Fenofibrate dose (mg.day)
33	LI_FenoAcid	Num	8	YN.		Fenofibric acid
34	LI_FenoAcidDose	Num	8			Fenofibric acid dose (mg/day)
35	LI_Clof	Num	8	YN.		Clofibrate
36	LI_ClofDose	Num	8			Clofibrate dose (mg/day)

Num	Variable	Type	Len	Format	Informat	Label
37	LI_OthFib	Num	8	YN.		Other fibrate
38	LI_OthFibDose	Num	8			Other fibrate dose (mg/day)
39	LI_Niaspan	Num	8	YN.		Niaspan
40	LI_NiaspanDose	Num	8			Niaspan dose (mg/day)
41	LI_Slonia	Num	8	YN.		Slo-niacin
42	LI_SloniaDose	Num	8			Slo-niacin dose (mg/day)
43	LI_SRNia	Num	8	YN.		Niasin SR
44	LI_SRNiaDose	Num	8			Niasin SR dose (mg/day)
45	LI_IRNia	Num	8	YN.		Niacin IR
46	LI_IRNiaDose	Num	8			Niacin IR dose (mg/day)
47	LI_Cholesty	Num	8	YN.		Cholestyramine
48	LI_CholestyDose	Num	8	YN.		Cholestyramine dose (g/day)
49	LI_Colesti	Num	8	YN.		Colestipol
50	LI_ColestiDose	Num	8			colestipol dose (g/day)
51	LI_Colesev	Num	8	YN.		Colesevelam HCL
52	LI_ColesevDose	Num	8			Colesevelam HCL dose (g/day)
53	LI_OthRes	Num	8	YN.		Other resin
54	LI_OthResDose	Num	8			Other resin dose per day (mg/day)
55	LI_Ezeti	Num	8	YN.		Ezetimibe
56	LI_EzetiDose	Num	8			Ezetimibe dose (mg/day)
57	LI_trial	Num	8	YN.		Participating in a clinical trial of lipid modifying therapy
58	LI_Define	Num	8	YN.		Participating in DEFINE
59	LI_DefineDose	Num	8			Study drug dose (mg/day) in DEFINE
60	LI_Acute	Num	8	YN.		Participating in Dal-ACUTE
61	LI_AcuteDose	Num	8			Study drug dose (mg/day) in Dal-ACUTE
62	LI_OthTrial	Num	8	YN.		Participating in another trial

Data Set Name: pe.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	PatientKey	Num	8	11.	11.	Unique Subject Identifier
2	Visit	Char	200	$200.	$200.	Visit
3	PE_VisDt	Num	8			Date of Visit
4	PE_Ht	Num	8			Height (cm)
5	PE_Wt	Num	8			Weight (kg)
6	PE_Waist	Num	8			Waist circumference (cm)
7	PE_Hip	Num	8			Hip measurement (cm)
8	PE_BPsys	Num	8			Systolic blood pressure
9	PE_BPdia	Num	8			Diastolic blood pressure
10	PE_Met	Num	8	YN.		Does patient have metabolic syndrome
11	PE_AnginaDef	Num	8	ANGINA.		Canadian Cardiovascular Angia classification
12	PE_BMI	Num	8			BMI (derived)

Data Set Name: revasc.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	PatientKey	Num	8	11.	11.	Unique Subject Identifier
2	RV_DisDt	Num	8			Date of discharge
3	RV_Dt	Num	8			Date of revascularization procedure
4	RV_AdminDt	Num	8			Date of admission
5	RV_Type	Num	8	RVTYP.		Type of revascularizaton
6	RV_CardType	Num	8	RVCTYP.		If cardiac, type of procedure
7	RV_Hospital	Num	8	YN.		Was procedure performed as an in-patient procedure?
8	RV_MI	Num	8	YN.		Did an MI occur within 3 days following the procedure?
9	RV_Review	Num	8	YN.		Did AIM-HIGH investigator review materials for this event?
10	RV_Symptom	Num	8	YN.		Was procedure symptom-driven?
11	RV_Records	Num	8	YN.		Basis for determination of symptom driven: Medical records
12	RV_Report	Num	8	YN.		Basis for determination of symptom driven: patient report
13	RV_AHeval	Num	8	YN.		Basis for determination of symptom driven: AIM-HIGH physician evaluation
14	RV_Oteval	Num	8	YN.		Basis for determination of symptom driven: other physician evaluation

Data Set Name: runin.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	PatientKey	Num	8	11.	11.	Unique Subject Identifier
2	RunI_StartDt	Num	8			Date open label Niaspan dispensed
3	RunI_Flush	Num	8	TABFLUSH.		How frequently did patient experience flushing?
4	RunI_Flush2	Num	8	SEV.		On average, how severe were flushing episodes
5	RunI_Prior	Num	8	YN.		Did patient take aspirin prior to taking Niaspan?
6	RunI_MaxDose	Num	8	DOSE.		Maximum dose of Niaspan tolerated
7	RunI_Flush3	Num	8	YN.		Reason not tolerating at least 1500 mg/day was intolerable flushing
8	RunI_Arrhythmia	Num	8	YN.		Reason not tolerating at least 1500 mg/day was abnormal heart rhythm or rate
9	RunI_GlycControl	Num	8	YN.		Reason not tolerating at least 1500 mg/day was glycemic control
10	RunI_Itch	Num	8	YN.		Reason not tolerating at least 1500 mg/day was pruritis
11	RunI_OthIntol	Num	8	YN.		Reason not tolerating at least 1500 mg/day was another reason
12	RunI_NiaspanRtn	Num	8			Number of Niaspan tablets returned
13	RunI_BadWhy	Num	8	BADWHY.		Was adherence poor? If yes, primary reason
14	RunI_Rand	Num	8	YN.		Will patient be randomized?
15	RunI_WhyNot	Num	8	WHYNOT.		If not, why?
16	RunI_Sim_Disp	Num	8	TABDISP.		Bottles of simvastatin dispensed
17	RunI_Niac_Disp	Num	8	TABDISP.		Bottles of Niaspan dispensed during run-in

Data Set Name: ssq.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	PatientKey	Num	8	11.	11.	Unique Subject Identifier
2	Visit	Char	200	$200.	$200.	Visit
3	SSQ_VisitDt	Num	8			Date of contact
4	SSQ_Speak	Num	8	YN.		Has patient had any sudden loss in the ability to speak clearly for no obvious reason?
5	SSQ_Paralysis	Num	8	YN.		Has patient had any sudden paralysis or weakness of an arm, leg or one side of the body?
6	SSQ_Dizzy	Num	8	YN.		Has patient experienced any sudden dizziness, sensation of spinning, loss of balance or sudden veering or lurching to one side while walking?
7	SSQ_Numb	Num	8	YN.		Has patient had any numbness, tingling or a dead feeling of an arm, leg or down one side of the bocy (not due to leaning on or keeping the arm or leg in a certain position)?
8	SSQ_Vision	Num	8	YN.		Has patient had any sudden loss of vision in one or both eyes, loss of the ability to see things to one side or double vision?

Data Set Name: term.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	PatientKey	Num	8	11.	11.	Unique Subject Identifier
2	TERM_Date	Num	8			Date of study termination or end of blinded treatment phase
3	TERM_Reason	Num	8	TERMREAS.		Primary reason for withdrawal from study
4	TERM_Drug	Num	8	YN.		Was patient on blinded study drug at end of trial?
5	TERM_LipidTx	Num	8	YN.		Will patient remain on lipid modifying treatment?
6	TERM_Statin	Num	8	YN.		Will patient remain on statins?
7	TERM_BileAcid	Num	8	YN.		Will patient be placed on bile acid sequentrates?
8	TERM_Nicotin	Num	8	YN.		Will patient remain on nicontinic acid?
9	TERM_Fibric	Num	8	YN.		Will patient be placed on fibric acid derivative?
10	TERM_Absorb	Num	8	YN.		Will patient be placed on cholesterol absorption inhibitors?
11	TERM_OtherDrug	Num	8	YN.		Will patient be placed on other lipid modifying agent?
12	TERM_TLC	Num	8	YN.		Will patient be recommended for therapeutic lifestyle change ONLY?
13	TERM_Duration	Num	8	DURATION.		How long had patient been on statin PRIOR to enrollment in AIM-HIGH
14	TERM_Therapy	Num	8	TABTHER.		Participants best guess of therapy they were assigned
15	TERM_Therapy_RC	Num	8	TABTHER.		Research coordinators best guess of therapy patient was assigned to

Data Set Name: tox.sas7bdat

Num	Variable	Type	Len	Format	Informat	Label
1	PatientKey	Num	8	11.	11.	Unique Subject Identifier
2	Tox_Dt	Num	8			Date evaluated
3	Tox_Lab	Num	8	TOXLAB.		Type of toxicity
4	Tox_CK	Num	8			Most recent CK (mg/dL)
5	Tox_AST	Num	8			Most recent AST (mg/dL)
6	Tox_ALT	Num	8			Most recent ALT (mg/dL)
7	Tox_Fatigue	Num	8	SEV.		Did patient report fatigue?
8	Tox_Maches	Num	8	SEV.		Did patient report musche aches or weakness?
9	Tox_Diarrhea	Num	8	SEV.		Did patient report diarrhea?
10	Tox_Nausea	Num	8	SEV.		Did patient report nausea or vomitting?
11	Tox_Urine	Num	8	SEV.		Did patient report any marked changes in urine?
12	Tox_Jaundice	Num	8	SEV.		Did patient show signs of jaundice?