



ACS EVENT

SITE ID: _____	PATIENT ID: _____
Patient Initials: _____	

INSTRUCTIONS: Fill this form out if the patient is admitted for evaluation/treatment of any possible ACS event (MI, ACS, etc)

Table Name: ACS

BE SURE TO SUBMIT ALL DOCUMENTING MATERIALS TO AXIO RESEARCH AS SOON AS POSSIBLE.

1.	Date of onset of symptoms (mm/dd/yyyy) <small>ACS_OnsetDt</small>	_____/_____/_____ USE (MM/DD/YYYY)
2.	Date of admission (mm/dd/yyyy) <small>ACS_adminDt</small>	_____/_____/_____ USE (MM/DD/YYYY)
3.	Date of discharge (mm/dd/yyyy) <small>ACS_discDt</small>	_____/_____/_____ USE (MM/DD/YYYY)
4.	Which of the following did the patient experience? <small>ACS_event</small>	<input type="checkbox"/> 1 MI <input type="checkbox"/> 2 UNSTABLE ANGINA <input type="checkbox"/> 3 NO DOCUMENTED ISCHEMIA
5.	Did patient experience angina or angina equivalent symptoms within 24 hours prior to event? <small>ACS_angina</small>	<input type="checkbox"/> 0 NO <input type="checkbox"/> 1 YES
6.	If yes, what was the duration of symptoms? <small>ACS_AnginaDuration</small>	<input type="checkbox"/> 1 <1HR BUT > 5 MIN <input type="checkbox"/> 3 24-48 HOURS <input type="checkbox"/> 2 1-24 HOURS <input type="checkbox"/> 4 >48 HOURS
7.	Were cardiac enzyme measurements taken? If yes, add values to the Enzyme log form <small>ACS_enzyme</small>	<input type="checkbox"/> 0 NO <input type="checkbox"/> 1 YES
8.	Were ECGs obtained? If yes, please fill out an ECG form for each <small>ACS_ECG</small>	<input type="checkbox"/> 0 NO <input type="checkbox"/> 1 YES
9.	Did patient undergo PCI within 24 hours or CABG within 72 hours of the onset of symptoms? <small>ACS_RevascPreACS</small>	<input type="checkbox"/> 1 NO <input type="checkbox"/> 2 PCI <input type="checkbox"/> 3 CABG
10.	Was revascularization procedure performed FOLLOWING the event? If yes, please fill out Revascularization form. <small>ACS_RevascPostACS</small>	<input type="checkbox"/> 1 NO <input type="checkbox"/> 2 PCI <input type="checkbox"/> 3 CABG
11.	Did the patient die within 30 days of this event? If yes, please complete Death form. <small>ACS_Fatal</small>	<input type="checkbox"/> 0 NO <input type="checkbox"/> 1 YES

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Instructions: Please complete for any adverse event

Table Name: AE

(Do NOT fill out this page if AE was diagnosed as MI, other coronary event, stroke, or other CNS event please fill out the corresponding Cardiac Event or CNS Event page)

1.	Start Date (mm/dd/yyyy) AE_StDate	____ / ____ / _____ Use (MM/DD/YYYY)
2.	Is the condition continuing? AE_Continu	<input type="checkbox"/> ₀ NO <input type="checkbox"/> ₁ YES
3.	If no, End Date (mm/dd/yyyy) AE_EndDate	____ / ____ / _____ Use (MM/DD/YYYY)
4.	Give a description of the adverse event AE_Text	_____ _____ _____ _____
5.	Was the event/condition serious? AE_Serious	<input type="checkbox"/> ₀ NO <input type="checkbox"/> ₁ YES

An Event is Serious if it meets any of the criteria below

Results in death, is life-threatening, requires in-patient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, is a congenital anomaly/birth defect and/or is a medically important event.

If the event is serious, complete the SAE form within 24 hours of learning of the event.

6.	Severity AE_Severit	<input type="checkbox"/> ₀ NO SYMPTOMS <input type="checkbox"/> ₂ MODERATE <input type="checkbox"/> ₁ MILD <input type="checkbox"/> ₃ SEVERE
7.	Did the event/condition require treatment? AE_Treat	<input type="checkbox"/> ₀ NO TREATMENT REQUIRED <input type="checkbox"/> ₃ BOTH DRUGS AND SURGERY <input type="checkbox"/> ₁ DRUG TREATMENT <input type="checkbox"/> ₄ OTHER <input type="checkbox"/> ₂ SURGICAL TREATMENT
8.	Sequelae AE_Outcome If yes for Death, fill out Death from.	<input type="checkbox"/> ₁ RECOVERED, NO SEQUELAE <input type="checkbox"/> ₃ NOT RECOVERED <input type="checkbox"/> ₂ RECOVERED WITH SEQUELAE <input type="checkbox"/> ₄ DEATH
9.	Was the event/condition related to or caused by the study drug? AE_Cause1	<input type="checkbox"/> ₁ DEFINITELY NOT RELATED <input type="checkbox"/> ₃ POSSIBLY RELATED <input type="checkbox"/> ₂ PROBABLY NOT RELATED <input type="checkbox"/> ₄ RELATED
10.	Did the event/condition result in any changes to the use of the study drug? If yes, fill out Dose Adjustment form. AE_Drug	<input type="checkbox"/> ₀ NO CHANGES MADE <input type="checkbox"/> ₂ STUDY DRUG(S) DOSE DECREASED <input type="checkbox"/> ₁ STUDY DRUG(S) USE INTERRUPTED <input type="checkbox"/> ₃ STUDY DRUG(S) DISCONTINUED



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Amendment 6 Follow-up

Table Name: AFUP

INSTRUCTIONS: Please complete at the Amendment 6 Follow-up visit.

	Visit	<input type="checkbox"/> INTERIM VISIT	<input type="checkbox"/> FINAL VISIT
1.	Type of visit	<input type="checkbox"/> ₁ PHONE CALL <input type="checkbox"/> ₂ IN-OFFICE <input type="checkbox"/> ₃ VISIT NOT DONE AFUP_VisitTp	
2.	Date of visit or phone call (MM/DD/YYYY)	_____ / _____ / _____ AFUP_VisitDt	
3.	If visit was not done, please indicate why:	<input type="checkbox"/> ₁ PARTICIPANT DIED PRIOR TO FOLLOW-UP. (If not already completed, please complete Death CRF and submit documenting materials) <input type="checkbox"/> ₂ PARTICIPANT DECLINED FURTHER PARTICIPATION PRIOR TO THIS VISIT <input type="checkbox"/> ₃ UNABLE TO CONTACT PARTICIPANT AFTER AT LEAST 5 DIFFERENT ATTEMPTS (PLEASE CONTACT COORDINATING CENTER FOR GUIDANCE) AFUP_VisitNtDn	
Query the participants carefully about the following possible events:			
4.	MI: Did the participant have an MI? (If yes, complete ACS Event CRF and submit documenting materials)	<input type="checkbox"/> ₀ NO	<input type="checkbox"/> ₁ YES AFUP_MI
5.	ACS: Was the participant hospitalized for >23 hours for confirmed chest pain/angina/acute coronary syndrome? (If yes, complete ACS Event CRF and submit documenting materials)	<input type="checkbox"/> ₀ NO	<input type="checkbox"/> ₁ YES AFUP_ACS
6.	Cardiac Revascularization: Did the participant have a revascularization of the coronary arteries (CABG or PCI)? (If yes, complete Revascularization CRF and submit documenting materials.)	<input type="checkbox"/> ₀ NO	<input type="checkbox"/> ₁ YES AFUP_CardRevas
7.	Cerebrovascular Revascularization: Did the participant have a revascularization of the carotid arteries (carotid endarterectomy, carotid PTA)? (If yes, complete Revascularization CRF and submit documenting materials)	<input type="checkbox"/> ₀ NO	<input type="checkbox"/> ₁ YES AFUP_CerebRevas
8.	Peripheral Revascularization: Did the participant have a revascularization of peripheral arteries (fem-pop bypass or femoral angioplasty)? (If yes, complete Revascularization CRF and submit documenting materials)	<input type="checkbox"/> ₀ NO	<input type="checkbox"/> ₁ YES AFUP_PeriRevas
9.	Stroke/TIA: Did the participant have a neurological event that fits the definition of a possible TIA or stroke? (If yes, complete CNS Event CRF and submit documenting materials)	<input type="checkbox"/> ₀ NO	<input type="checkbox"/> ₁ YES AFUP_StrokeTIA

SIGNATURE _____ DATE _____



SITE ID: _____ PATIENT ID: _____
 Patient Initials: _____

Table Name: LI

Current Lipid Therapies

INSTRUCTIONS: Please complete this form noting all lipid medications the participant is routinely taking at the time of this visit.

Visit			<input type="checkbox"/> INTERIM VISIT	<input type="checkbox"/> FINAL VISIT
Statins				
1.	Atorvastatin (Lipitor)	LI_Ator	<input type="checkbox"/> _0 NO	<input type="checkbox"/> _1 YES
2.	Dose per day in mg :	LI_AtorDose	_____	
3.	Fluvastatin (Lescol)	LI_Fluv	<input type="checkbox"/> _0 NO	<input type="checkbox"/> _1 YES
4.	Dose per day in mg :	LI_FluvDose	_____	
5.	Lovastatin (Mevacor, Altopre, Altocor)	LI_Lova	<input type="checkbox"/> _0 NO	<input type="checkbox"/> _1 YES
6.	Dose per day in mg :	LI_LovaDose	_____	
7.	Pravastatin (Pravachchol)	LI_Prava	<input type="checkbox"/> _0 NO	<input type="checkbox"/> _1 YES
8.	Dose per day in mg :	LI_PravaDose	_____	
9.	Rosuvastatin (Crestor)	LI_Rosu	<input type="checkbox"/> _0 NO	<input type="checkbox"/> _1 YES
10.	Dose per day in mg :	LI_RosuDose	_____	
11.	Simvastatin (Zocor)	LI_Simv	<input type="checkbox"/> _0 NO	<input type="checkbox"/> _1 YES
12.	Dose per day in mg :	LI_SimvDose	_____	
13.	Other statin	LI_OthSta	<input type="checkbox"/> _0 NO	<input type="checkbox"/> _1 YES
14.	Please specify:	LI_SpcSta	_____	
15.	Dose per day in mg :	LI_OthStaDose	_____	
Combination Medications				
<i>For the combination medication, please enter the dose in this format (xx/xx)</i>				
16.	Lovastatin + niacin (Advicor)	LI_Advi	<input type="checkbox"/> _0 NO	<input type="checkbox"/> _1 YES
17.	Dose per day in mg :	LI_AdviDose	_____	
18.	Atorvastatin + amlodipine (Caduet)	LI_Cadu	<input type="checkbox"/> _0 NO	<input type="checkbox"/> _1 YES
19.	Dose per day in mg :	LI_CaduDose	_____	
20.	Simvastatin +ezetimibe (Vytorin)	LI_Vyto	<input type="checkbox"/> _0 NO	<input type="checkbox"/> _1 YES
21.	Dose per day in mg :	LI_VytoDose	_____	
22.	Pravastatin + aspirin (Pravigard Pac)	LI_Pravi	<input type="checkbox"/> _0 NO	<input type="checkbox"/> _1 YES
23.	Dose per day in mg :	LI_PraviDose	_____	
24.	Simvastatin + niacin (Simcor)	LI_Simc	<input type="checkbox"/> _0 NO	<input type="checkbox"/> _1 YES
25.	Dose per day in mg :	LI_SimcDose	_____	
26.	Other combination medication:	LI_OthCom	<input type="checkbox"/> _0 NO	<input type="checkbox"/> _1 YES

SIGNATURE _____ DATE _____



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27.	Please specify:	LI_SpcCom	
28.	Dose per day in mg :	LI_OthComDose	
Fibrates			
29.	Gemfibrozil (Lopid)	LI_Gemf	<input type="checkbox"/> ₀ NO <input type="checkbox"/> ₁ YES
30.	Dose per day in mg :	LI_GemfDose	
31.	Fenofibrate (Antara, Lofibra, Tricor or Triglide)	LI_Feno	<input type="checkbox"/> ₀ NO <input type="checkbox"/> ₁ YES
32.	Dose per day in mg :	LI_FenoDose	
33.	Fenofibric acid (Trilipix, Fibricor)	LI_FenoAcid	<input type="checkbox"/> ₀ NO <input type="checkbox"/> ₁ YES
34.	Dose per day in mg :	LI_FenoAcidDose	
35.	Clofibrate (Atromid-S)	LI_Clof	<input type="checkbox"/> ₀ NO <input type="checkbox"/> ₁ YES
36.	Dose per day in mg :	LI_ClofDose	
37.	Other fibrate:	LI_OthFib	<input type="checkbox"/> ₀ NO <input type="checkbox"/> ₁ YES
38.	Please specify:	LI_SpcFib	
39.	Dose per day in mg :	LI_OthFibDose	
Niacins			
40.	Niaspan	LI_Niaspan	<input type="checkbox"/> ₀ NO <input type="checkbox"/> ₁ YES
41.	Dose per day in mg :	LI_NiaspanDose	
42.	Slo-Niacin	LI_SloNia	<input type="checkbox"/> ₀ NO <input type="checkbox"/> ₁ YES
43.	Dose per day in mg :	LI_SloNiaDose	
44.	Niacin SR	LI_SRNia	<input type="checkbox"/> ₀ NO <input type="checkbox"/> ₁ YES
45.	Dose per day in mg :	LI_SRNiaDose	
46.	Niacin IR	LI_IRNia	<input type="checkbox"/> ₀ NO <input type="checkbox"/> ₁ YES
47.	Dose per day in mg :	LI_IRNiaDose	
Resins (bile acid sequestrants)			
48.	Cholestyramine (Questran, Questran Light, Prevalite, Locholest, Locholest Light)	LI_Cholesty	<input type="checkbox"/> ₀ NO <input type="checkbox"/> ₁ YES
49.	Dose per day in gram :	LI_CholestyDose	
50.	Colestipol (Cholestid)	LI_Colesti	<input type="checkbox"/> ₀ NO <input type="checkbox"/> ₁ YES
51.	Dose per day in gram :	LI_ColestiDose	
52.	Colesevelam HCL (WelChol)	LI_Colesev	<input type="checkbox"/> ₀ NO <input type="checkbox"/> ₁ YES
53.	Dose per day in mg :	LI_ColesevDose	
54.	Other resins:	LI_OthRes	<input type="checkbox"/> ₀ NO <input type="checkbox"/> ₁ YES
55.	Please specify:	LI_SpcRes	

SIGNATURE _____ DATE _____



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56.	Dose per day in mg : LI_OthResDose	_____
Selective Cholesterol absorption inhibitors		
57.	Ezetimibe (Zetia) LI_Ezeti	<input type="checkbox"/> ₀ NO <input type="checkbox"/> ₁ YES
58.	Dose per day in mg : LI_EzetiDose	_____
Ask the participant if they are participating in another clinical trial involving lipid modifying therapies.		
59.	Are they participating in a clinical trial of lipid modifying therapy? LI_Trial	<input type="checkbox"/> ₀ NO <input type="checkbox"/> ₁ YES
If yes, please indicate the name of the trial, the agent being tested and the total daily dose of the investigational product (realizing that it may be the active drug or placebo).		
60.	Investigational drug: anacetrapib, - Clinical Trial – “DEFINE” LI_Define	<input type="checkbox"/> ₀ NO <input type="checkbox"/> ₁ YES
61.	Dose per day in mg : LI_DefineDose	_____
62.	Investigational drug; dalcetrapib – Clinical Trial – “Dal-ACUTE” LI_Acute	<input type="checkbox"/> ₀ NO <input type="checkbox"/> ₁ YES
63.	Dose per day in mg : LI_AcuteDose	_____
64.	Other lipid modifying therapy trial? LI_OthTrial	<input type="checkbox"/> ₀ NO <input type="checkbox"/> ₁ YES
65.	If so, what is the name of the trial? LI_TrialName	_____
66.	Name of investigational product: LI_TrialProd	_____
67.	Dose per day in mg : LI_TrialDose	_____

SIGNATURE _____ DATE _____



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Table Name: SSQ

Stroke Symptoms Questionnaire

INSTRUCTIONS: Please complete at the Amendment 6 Follow-up visit.

1.	Date of contact (MM/DD/YYYY)	<u> </u> / <u> </u> / <u> </u>	<i>SSQ_VisitDt</i>
2.	Has the patient had any sudden loss in the ability to speak clearly for no obvious reason?	<input type="checkbox"/> _0 NO <input type="checkbox"/> _1 YES	<i>SSQ_Speak</i>
3.	Has the patient had any sudden paralysis or weakness of an arm, leg or one side of the body?	<input type="checkbox"/> _0 NO <input type="checkbox"/> _1 YES	<i>SSQ_Paralysis</i>
4.	Has the patient experienced any sudden dizziness, sensation of spinning, loss of balance or sudden veering or lurching to one side while walking?	<input type="checkbox"/> _0 NO <input type="checkbox"/> _1 YES	<i>SSQ_Dizzy</i>
5.	Has the patient had any numbness, tingling or a dead feeling of an arm, leg or down one side of the body (not due to leaning on or keeping the arm or leg in a certain position)?	<input type="checkbox"/> _0 NO <input type="checkbox"/> _1 YES	<i>SSQ_Numb</i>
6.	Has the 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?	<input type="checkbox"/> _0 NO <input type="checkbox"/> _1 YES	<i>SSQ_Vision</i>

If **YES** to any of the above, please have the patient sign a medical release of information form and request the medical records from the patient's personal physician to determine whether there has been a possible ischemic neurological event (stroke or TIA). Complete the CNS Event form and submit documenting materials to the Elaine Nasco at Axio.

If **YES** to any of the above, but their physician has NOT diagnosed a stroke or TIA, please encourage the patient to discuss these symptoms with their PCP. Notify your PI about the patient's symptoms. Your PI may want to call the patient's PCP to discuss whether a neurological work-up is warranted. The need for a neurological work-up may depend on the nature of the patient's symptoms, concomitant illnesses and medications. It should be explained to the patient that it is their responsibility to pursue further diagnosis and treatment. Call the patient to ascertain they have followed-up with their PCP and request records for event documentation as needed. Complete the CNS Event form and submit documenting materials to Elaine Nasco at Axio.

SIGNATURE _____ DATE _____

SITE ID: _____	PATIENT ID: _____
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INSTRUCTIONS: Please complete at the Baseline visit (the start of the Run-In Phase)

1.	Visit Date (mm/dd/yyyy)	_____ / _____ / _____	BL_VisDt	Use (MM/DD/YYYY)
2.	Date of baseline blood draw (mm/dd/yyyy)	_____ / _____ / _____	BL_BldDate	Use (MM/DD/YYYY)
3.	Was blood drawn in a fasting state?	<input type="checkbox"/> ₀ NO <input type="checkbox"/> ₁ YES	BL_Fasting	
4-5.	Screening LDL	_____	BL_LDL	<input type="checkbox"/> ₁ MG/DL <input type="checkbox"/> ₂ MMOL/L BL_LDLUnit
6-7.	Screening HDL	_____	BL_HDL	<input type="checkbox"/> ₁ MG/DL <input type="checkbox"/> ₂ MMOL/L BL_HDLUnit
8-9.	Screening Triglyceride	_____	BL_Tg	<input type="checkbox"/> ₁ MG/DL <input type="checkbox"/> ₂ MMOL/L BL_TgUnit
10.	Was patient taking statins prior to screening?	<input type="checkbox"/> ₀ NO <input type="checkbox"/> ₁ YES	BL_LipidOnStatin	
11.	Has patient ever taken niacin or Niaspan?	<input type="checkbox"/> ₀ NO <input type="checkbox"/> ₁ YES	BL_PriorNiacin	

Indicate which lipid modifying treatments (if any) the patient has taken within the past month

12.	Statins	<input type="checkbox"/> ₀ NO <input type="checkbox"/> ₁ YES	BL_Statin	
13.	Bile Acid sequestrates	<input type="checkbox"/> ₀ NO <input type="checkbox"/> ₁ YES	BL_BileAcid	
14.	Nicotinic acid other than niacin/niaspan	<input type="checkbox"/> ₀ NO <input type="checkbox"/> ₁ YES	BL_Nicotin	
15.	Fibric acids	<input type="checkbox"/> ₀ NO <input type="checkbox"/> ₁ YES	BL_Fibric	
16.	Cholesterol absorption inhibitors	<input type="checkbox"/> ₀ NO <input type="checkbox"/> ₁ YES	BL_Absorb	
17.	Other lipid modifying agents	<input type="checkbox"/> ₀ NO <input type="checkbox"/> ₁ YES	BL_OtherDr	
18.	Therapeutic lifestyle changes (diet & exercise) ONLY	<input type="checkbox"/> ₀ NO <input type="checkbox"/> ₁ YES	BL_TLC	
19.	Was patient counseled at this visit regarding diet/exercise for lipid control?	<input type="checkbox"/> ₀ NO <input type="checkbox"/> ₁ YES	BL_counsel	



BLOOD DRAW/ LDL FOLLOW-UP

SITE ID: _____	PATIENT ID: _____
Patient Initials: _____	

Table Name: FLab

INSTRUCTIONS: Fill this form at each visit that requires a blood draw.

	Visit <small>INCL_Age</small>	<input type="checkbox"/> 1 MONTH	<input type="checkbox"/> 3 MONTHS	<input type="checkbox"/> 6 MONTHS	
		<input type="checkbox"/> 12 MONTHS	<input type="checkbox"/> 24 MONTHS	<input type="checkbox"/> 36 MONTHS	
		<input type="checkbox"/> 48 MONTHS	<input type="checkbox"/> END OF STUDY	IF OTHER VISIT, _____ MONTH	
1.	Date of lipid & serum chemistry sample collection <small>FLab_LipidDt</small>	____/____/____ Use (MM/DD/YYYY)			
2.	Was blood drawn for lipids and serum chemistries in a fasting state? <small>FLab_Fast</small>	<input type="checkbox"/> _0 NO	<input type="checkbox"/> _1 YES		
3-4.	Reported LDL-C from this draw <small>FLab_IDL</small>	<input type="checkbox"/> _1 MG/DL <small>FLab_IDLUnits</small>	<input type="checkbox"/> _2 MMOL/L		



CARDIAC ENZYMES

SITE ID: _____	PATIENT ID: _____
Patient Initials: _____	

INSTRUCTIONS: Fill out this form each time a cardiac enzyme measurement is taken. Table Name: ENZ

If the enzymes were taken due to a possible ACS event be sure to submit all documenting materials to Axio Research as soon as possible and fill out all the additional forms related to the event.

1.	Date enzymes were drawn	_____ / _____ / _____ ENZ_Date Use (MM/DD/YYYY)
2-3.	Time enzymes were drawn	ENZ_TimeMin ENZ_TimeHH : _____ Use 24 hour clock
4-5.	CK	<div style="display: flex; justify-content: space-between;"> <div style="width: 60%;"> ENZ_CK _____ </div> <div style="width: 35%;"> <input type="checkbox"/> 1 U/L <input type="checkbox"/> 2 MLU/ML ENZ_CKUnit <input type="checkbox"/> 3 UKAT/L </div> </div>
6-7.	The lab's CK upper limit of normal	<div style="display: flex; justify-content: space-between;"> <div style="width: 60%;"> ENZ_CK_ULN _____ </div> <div style="width: 35%;"> <input type="checkbox"/> 1 U/L <input type="checkbox"/> 2 MLU/ML ENZ_CK_ULNUnit <input type="checkbox"/> 3 UKAT/L </div> </div>
8-9.	CK-MB	<div style="display: flex; justify-content: space-between;"> <div style="width: 60%;"> ENZ_CKMB _____ </div> <div style="width: 35%;"> <input type="checkbox"/> 0 NG/ML <input type="checkbox"/> 3 U/L <input type="checkbox"/> 1 UG/L <input type="checkbox"/> 4 MLU/ML <input type="checkbox"/> 2 % <input type="checkbox"/> 5 UKAT/L </div> </div> ENZ_CKMBUnit
10-11.	The lab's CK-MB upper limit of normal	<div style="display: flex; justify-content: space-between;"> <div style="width: 60%;"> ENZ_CKMB_ULN _____ </div> <div style="width: 35%;"> <input type="checkbox"/> 0 NG/ML <input type="checkbox"/> 3 U/L <input type="checkbox"/> 1 UG/L <input type="checkbox"/> 4 MLU/ML <input type="checkbox"/> 2 % <input type="checkbox"/> 5 UKAT/L </div> </div> ENZ_CKMB_ULNUnit
12-13.	Troponin	<div style="display: flex; justify-content: space-between;"> <div style="width: 60%;"> ENZ_Trop _____ </div> <div style="width: 35%;"> <input type="checkbox"/> 1 NG/ML <input type="checkbox"/> 2 UG/L ENZ_TropUnit </div> </div>
14-15.	The lab's Troponin upper limit of normal	<div style="display: flex; justify-content: space-between;"> <div style="width: 60%;"> ENZ_Trop_ULN _____ </div> <div style="width: 35%;"> <input type="checkbox"/> 1 NG/ML <input type="checkbox"/> 2 UG/L ENZ_Trop_ULNUnit </div> </div>



CNS EVENT

SITE ID: _____	PATIENT ID: _____
Patient Initials: _____	

INSTRUCTIONS: Fill this form out if the patient is admitted for evaluation/treatment of any possible CNS Event (Stroke, TIA, etc.)

BE SURE TO SUBMIT ALL DOCUMENTING MATERIALS TO AXIO RESEARCH AS SOON AS POSSIBLE.

Table Name: CNS

1.	Give the start date for event / symptom CNS_symDt	____/____/____ USE (MM/DD/YYYY)
2.	Primary etiology: CNS_Type	<input type="checkbox"/> ₁ ISCHEMIC STROKE <input type="checkbox"/> ₃ TRANSIENT ISCHEMIC ATTACK <input type="checkbox"/> ₂ PRIMARY HEMORRHAGIC STROKE <input type="checkbox"/> ₄ UNABLE TO DETERMINE WHETHER ISCHEMIC OR HEMORRHAGIC
3.	Did the event/condition require hospitalization?	<input type="checkbox"/> ₀ NO CNS_hospital <input type="checkbox"/> ₁ YES
4.	If yes, Date of admission CNS_admDt	____/____/____ USE (MM/DD/YYYY)
5.	If yes, Date of discharge CNS_discDt	____/____/____ USE (MM/DD/YYYY)
6.	Did symptoms persist for more than 24 hrs?	<input type="checkbox"/> ₀ NO CNS_24Hr <input type="checkbox"/> ₁ YES
7.	CT obtained CNS_CT	<input type="checkbox"/> ₀ NO <input type="checkbox"/> ₁ YES
8.	If yes, Date of CT scan CNS_CTDt	____/____/____ USE (MM/DD/YYYY)
9.	MRI obtained CNS_MRI	<input type="checkbox"/> ₀ NO <input type="checkbox"/> ₁ YES
10.	If yes Date of MRI scan CNS_MRIDt	____/____/____ USE (MM/DD/YYYY)
11.	Cardiac Echo obtained CNS_Echo	<input type="checkbox"/> ₀ NO <input type="checkbox"/> ₁ YES
12.	If yes Date of Cardiac echo CNS_EchoDt	____/____/____ USE (MM/DD/YYYY)
13.	Carotid Doppler obtained CNS_Doppler	<input type="checkbox"/> ₀ NO <input type="checkbox"/> ₁ YES
14.	If yes Date of Carotid Doppler exam CNS_DopplerDt	____/____/____ USE (MM/DD/YYYY)
15.	MRA/Angiography obtained CNS_MRA	<input type="checkbox"/> ₀ NO <input type="checkbox"/> ₁ YES
16.	If yes Date of MRA/Angiography CNS_MRADt	____/____/____ USE (MM/DD/YYYY)

Neuroimaging studies demonstrate:

1. No neuroimaging evidence of acute cerebral infarction (or no neuroimaging performed) [noinfarct]
 - 1) Yes
 - 2) No
2. Neuroimaging evidence of acute cerebral infarction on MRI DWI images [Infarct_MRIDWI]
 - 1) Yes
 - 2) No
3. Neuroimaging evidence of acute cerebral infarction on MRI T2/Flair (or MRI sequence not specified) [infarctt2flair]
 - 1) Yes
 - 2) No
4. Neuroimaging evidence of acute cerebral infarction on CT brain [infarctCT]
 - 1) Yes
 - 2) No



CONCOMITANT MEDICATIONS

SITE ID: _____

PATIENT ID: _____

Patient Initials: _____

Table Name: CM

INSTRUCTIONS: Please complete this form noting all medications the patient is routinely taking at the time of this visit. See Manual of Operations for typical drugs in each class.

Visit		<input type="checkbox"/> BASELINE	<input type="checkbox"/> 12 MONTHS	<input type="checkbox"/> 24 MONTHS	<input type="checkbox"/> 36 MONTHS	<input type="checkbox"/> 48 MONTHS
1.	Beta-blockers	CM_Beta	<input type="checkbox"/> _0 NO	<input type="checkbox"/> _1 YES		
2.	ACE inhibitors	CM_Ace	<input type="checkbox"/> _0 NO	<input type="checkbox"/> _1 YES		
3.	Angiotensin II receptor blockers	CM_ATII	<input type="checkbox"/> _0 NO	<input type="checkbox"/> _1 YES		
4.	Calcium channel blockers	CM_CCB	<input type="checkbox"/> _0 NO	<input type="checkbox"/> _1 YES		
5.	Diuretics	CM_Diu	<input type="checkbox"/> _0 NO	<input type="checkbox"/> _1 YES		
6.	Digitalis preparations	CM_Digitalis	<input type="checkbox"/> _0 NO	<input type="checkbox"/> _1 YES		
7.	Nitrates	CM_Nit	<input type="checkbox"/> _0 NO	<input type="checkbox"/> _1 YES		
8.	Warfarin or heparin analog	CM_Warfarin	<input type="checkbox"/> _0 NO	<input type="checkbox"/> _1 YES		
9.	Aspirin (regularly)	CM_Aspirin	<input type="checkbox"/> _0 NO	<input type="checkbox"/> _1 YES		
10.	NSAIDs (regularly)	CM_NSAID	<input type="checkbox"/> _0 NO	<input type="checkbox"/> _1 YES		
11.	Cox-2 inhibitors	CM_Cox2	<input type="checkbox"/> _0 NO	<input type="checkbox"/> _1 YES		
12.	Clopidogrel (Plavix)	CM_Plavix	<input type="checkbox"/> _0 NO	<input type="checkbox"/> _1 YES		
13.	Metformin	CM_Metformin	<input type="checkbox"/> _0 NO	<input type="checkbox"/> _1 YES		
14.	Thiazolidinediones (example: rosiglitazone)	CM_TZD	<input type="checkbox"/> _0 NO	<input type="checkbox"/> _1 YES		
15.	Sulfona Urea	CM_SulU	<input type="checkbox"/> _0 NO	<input type="checkbox"/> _1 YES		
16.	Insulin	CM_Insulin	<input type="checkbox"/> _0 NO	<input type="checkbox"/> _1 YES		
17.	Other Diabetes Treatments	CM_OtDiab	<input type="checkbox"/> _0 NO	<input type="checkbox"/> _1 YES		
18.	Hormone replacement therapy	CM_HRT	<input type="checkbox"/> _0 NO	<input type="checkbox"/> _1 YES		
19.	If yes to HRT, Estrogens	CM_HRTes	<input type="checkbox"/> _0 NO	<input type="checkbox"/> _1 YES		
20.	If yes to HRT, Progestins	CM_HRTpro	<input type="checkbox"/> _0 NO	<input type="checkbox"/> _1 YES		
21.	Corticosteroids (other than topical)	CM_Cort	<input type="checkbox"/> _0 NO	<input type="checkbox"/> _1 YES		
22.	Antibacterial: - erythromycin* (Erythrocin); clarithromycin* (Bioxin)	CM_Antibac	<input type="checkbox"/> _0 NO	<input type="checkbox"/> _1 YES		
23.	Nefazodone* (Serzone)	CM_Serzone	<input type="checkbox"/> _0 NO	<input type="checkbox"/> _1 YES		
24.	Antifungal:- fluconazole* (Diflucan); itraconazole* (Sporonax); ketoconazole* (Nizoral)	CM_Antifun	<input type="checkbox"/> _0 NO	<input type="checkbox"/> _1 YES		
25.	Fibric acid derivative:- gemfibrozil* (Lopid); fenofibrate* (Tricor)	CM_Fibric	<input type="checkbox"/> _0 NO	<input type="checkbox"/> _1 YES		
26.	Cyclosporine* (Sandimmune)	CM_Cyclo	<input type="checkbox"/> _0 NO	<input type="checkbox"/> _1 YES		
27.	High dose vitamins (not multi-vitamin)	CM_HighVit	<input type="checkbox"/> _0 NO	<input type="checkbox"/> _1 YES		
28.	If yes, was the patient taking > 400 IU of vitamin E Or >500mg of vitamin C?	CM_Vit_C_E	<input type="checkbox"/> _0 NO	<input type="checkbox"/> _1 YES		
29.	Was the patient taking niacin or nicotinic acid?	CM_Niacin	<input type="checkbox"/> _0 NO	<input type="checkbox"/> _1 YES		



CONCOMITANT MEDICATIONS

SITE ID: _____

PATIENT ID: _____

Patient Initials: _____

30	If taking niacin, daily dose	CM_NiacDose	<input type="checkbox"/> ₁ 500 MG	<input type="checkbox"/> ₂ 1,000 MG
31	Fish oil or fish oil derivatives or any n-3 fatty acids	CM_FishOil	<input type="checkbox"/> ₀ NO	<input type="checkbox"/> ₁ YES

Drugs listed in questions 22-31 are excluded. Follow up with the patient and his/her physician to see if they can be discontinued.



DEATH

SITE ID: _____	PATIENT ID: _____
Patient Initials: _____	

INSTRUCTIONS: Fill this form out if the patient dies at any time during the study. Table Name: DTH

BE SURE TO SUBMIT ALL DOCUMENTING MATERIALS (if any) TO AXIO RESEARCH AS SOON AS POSSIBLE.

1.	Date of death (mm/dd/yyyy) <i>DTH_Date</i>	_____/_____/_____ USE (MM/DD/YYYY)
2.	What was the presumed cause of death? <i>DTH_Cause</i>	<input type="checkbox"/> 1 CARDIAC <input type="checkbox"/> 3 NON-CARDIOVASCULAR <input type="checkbox"/> 2 VASCULAR, NON-CARDIAC
3.	For Cardiac, please specify <i>DTH_CardiacCause</i>	<input type="checkbox"/> 1 ISCHEMIC <input type="checkbox"/> 4 BRADYARRHYTHMIA /ASYSTOLE <input type="checkbox"/> 2 EMD <input type="checkbox"/> 5 VT/VF <input type="checkbox"/> 3 CHF <input type="checkbox"/> 6 NOT DETERMINED
4.	For vascular, non-cardiac, please specify <i>DTH_VasCause</i>	<input type="checkbox"/> 1 STROKE <input type="checkbox"/> 4 NOT DETERMINED <input type="checkbox"/> 2 NON-CNS HEMORRHAGE <input type="checkbox"/> 5 OTHER <input type="checkbox"/> 3 PULMONARY EMBOLISM
5.	If other, please specify <i>DTH_VasCauseOth</i>	<hr/> <hr/> <hr/> <hr/>
6.	For non-cardiovascular, please specify <i>DTH_NonCause</i>	<input type="checkbox"/> 1 CANCER <input type="checkbox"/> 4 INFECTION/SEPSIS <input type="checkbox"/> 2 PNEUMONIA <input type="checkbox"/> 5 NOT DETERMINED <input type="checkbox"/> 3 OTHER LUNG DISEASE <input type="checkbox"/> 6 OTHER
7.	If other, please specify <i>DTH_NonCauseOth</i>	<hr/> <hr/> <hr/> <hr/>
8.	Was the patient in the emergency room or hospitalized at the time of death?	<input type="checkbox"/> 0 NO <i>DTH_Hospital</i> <input type="checkbox"/> 1 YES
9.	Was an autopsy performed?	<input type="checkbox"/> 0 NO <i>DTH_Autopsy</i> <input type="checkbox"/> 1 YES
10.	Did the death occur within 30 days of undergoing cardiac surgery or a revascularization procedure?	<input type="checkbox"/> 0 NO <i>DTH_Revas</i> <input type="checkbox"/> 1 YES

SITE ID: _____	PATIENT ID: _____
Patient Initials: _____	

INSTRUCTIONS: Please complete at the screening visit. Table Name: Demo

1.	Visit date Demo_VisDt	____ / ____ / _____ Use (MM/DD/YYYY)
2.	Birth date Demo_DOB	____ / ____ / _____ Use (MM/DD/YYYY)
3.	Age Demo_Age	____ (calculated on computer)
4.	Gender Demo_Sex	<input type="checkbox"/> 1 MALE <input type="checkbox"/> 0 FEMALE
5.	Ethnicity Demo_Ethn	<input type="checkbox"/> 1 NOT HISPANIC OR LATINO <input type="checkbox"/> 2 HISPANIC OR LATINO
6.	What does the patient consider his/her predominant race? Demo_Race	<input type="checkbox"/> 1 AMERICAN INDIAN / ALASKA NATIVE / ABORIGINAL CANADIAN <input type="checkbox"/> 2 ASIAN <input type="checkbox"/> 3 BLACK / AFRICAN AMERICAN <input type="checkbox"/> 4 NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER <input type="checkbox"/> 5 WHITE <input type="checkbox"/> 8 MULTI-RACIAL OR OTHER
7.	Tobacco use? Demo_Smoke	<input type="checkbox"/> 1 NEVER USED <input type="checkbox"/> 3 SMOKELESS TOBACCO USER <input type="checkbox"/> 2 CURRENT SMOKER <input type="checkbox"/> 4 FORMER USER (QUIT MORE THAN 1 YEAR AGO)
8.	If tobacco user, estimate the number of pack years of consumptions	Demo_TobNm _____
9.	Does the patient consume alcohol?	<input type="checkbox"/> 0 NO Demo_Alcohol <input type="checkbox"/> 1 YES
10.	If yes, what is the average number of drinks consumed per week? Demo_Alcnm	<input type="checkbox"/> 1 LESS THAN 3 DRINKS <input type="checkbox"/> 2 3-7 DRINKS <input type="checkbox"/> 3 8-15 DRINKS <input type="checkbox"/> 4 MORE THAN 15
11.	What is the patient's current employment status? Demo_Employ	<input type="checkbox"/> 1 FULL TIME <input type="checkbox"/> 5 DISABLED <input type="checkbox"/> 2 PART TIME <input type="checkbox"/> 3 RETIRED <input type="checkbox"/> 6 UNEMPLOYED <input type="checkbox"/> 4 NOT WORKING OUTSIDE THE HOME-BY CHOICE <input type="checkbox"/> 9 NOT PROVIDED
12.	What field best describes the patient's work category? Demo_Job	<input type="checkbox"/> 1 MANAGEMENT <input type="checkbox"/> 7 SKILLED LABOR <input type="checkbox"/> 2 PROFESSIONAL <input type="checkbox"/> 8 GENERAL LABOR <input type="checkbox"/> 3 BUSINESS/FINANCIAL <input type="checkbox"/> 9 FARMER <input type="checkbox"/> 4 IT SPECIALIST <input type="checkbox"/> 10 SELF-EMPLOYED BUSINESS <input type="checkbox"/> 5 SALES <input type="checkbox"/> 11 POLICE/MILITARY <input type="checkbox"/> 6 CLERICAL <input type="checkbox"/> 12 NOT PROVIDED
13.	Education Level Demo_Edu	<input type="checkbox"/> 1 LESS THAN HIGH SCHOOL <input type="checkbox"/> 2 HIGH SCHOOL GRAD (OR GED) <input type="checkbox"/> 3 SOME COLLEGE/UNIVERSITY <input type="checkbox"/> 4 COLLEGE/UNIVERSITY GRADUATE <input type="checkbox"/> 5 POST COLLEGE/UNIVERSITY DEGREE <input type="checkbox"/> 9 NOT PROVIDED



DRUG DOSE ADJUSTMENT

SITE ID: _____	PATIENT ID: _____
	Patient Initials: _____

Table Name: DAdj

INSTRUCTIONS: Fill this form for any visit where the dose levels for the patient need to be adjusted.

1.	Date of dose adjustment <i>DAdj_VisDt</i>	____/____/____ Use (MM/DD/YYYY)	
2.	Was the dose of niaspan/placebo adjusted or drug discontinued? <i>DAdj_DoseAdj</i>	<input type="checkbox"/> 0 NO	<input type="checkbox"/> 2 YES, LOWERED
		<input type="checkbox"/> 1 DISCONTINUED	<input type="checkbox"/> 3 YES, RAISED
3.	What is new dose level? <i>DAdj_NiaspanDoseNewLevel</i>	<input type="checkbox"/> 1 500 MG/DAY	<input type="checkbox"/> 3 1,500 MG/DAY
		<input type="checkbox"/> 2 1,000 MG/DAY	<input type="checkbox"/> 4 2,000 MG/DAY
4.	If niaspan dose adjusted or discontinued, what was the primary reason? Note change in reason choices – coated product! <i>DAdj_NiaspanDoseAdjReason</i>	<input type="checkbox"/> 1 FLUSHING, ITCHING	<input type="checkbox"/> 6 OTHER CLINICAL REASON TO LOWER DOSE
		<input type="checkbox"/> 2 LIVER FUNCTION TEST ABNORMALITY	<input type="checkbox"/> 7 INCREASED GLUCOSE
		<input type="checkbox"/> 3 RESUME HIGHER DOSE	<input type="checkbox"/> 8 GI SYMPTOMS
		<input type="checkbox"/> 4 PATIENT REQUEST	<input type="checkbox"/> 9 COATED PRODUCT
		<input type="checkbox"/> 5 NON-STUDY PHYSICIAN REQUEST	
5.	If other reason, please specify <i>DAdj_DoseAdjSpcReason</i>		
6.	Was the dose of Zocor (simvastatin) adjusted or discontinued? <i>DAdj_StatinDoseAdj</i>	<input type="checkbox"/> 0 NO	<input type="checkbox"/> 2 YES, LOWERED
		<input type="checkbox"/> 1 DISCONTINUED	<input type="checkbox"/> 3 YES, RAISED
7.	What is new dose level? <i>DAdj_StatinDoseNewLevel</i>	<input type="checkbox"/> 5 5 MG/DAY	<input type="checkbox"/> 3 40 MG/DAY
		<input type="checkbox"/> 1 10 MG/DAY	<input type="checkbox"/> 6 60 MG/DAY
		<input checked="" type="checkbox"/> 2 20 MG/DAY	<input checked="" type="checkbox"/> 4 80 MG/DAY
8.	If yes, what was the primary reason? <i>DAdj_StatinDoseAdjReason</i>	<input type="checkbox"/> 1 LOWER DOSE FOR ADVERSE CLINICAL SYMPTOMS	<input type="checkbox"/> 4 NON-STUDY PHYSICIAN REQUEST
		<input type="checkbox"/> 2 RAISE DUE TO HIGH LDL	<input type="checkbox"/> 5 OTHER REASON FOR DOSE ADJUSTMENT
		<input type="checkbox"/> 3 PATIENT REQUEST	<input type="checkbox"/> 6 LOWER DUE TO LOW LDL
9.	If other reason, please specify <i>DAdj_StatinDoseAdjSpcReason</i>		
10.	If not on Zocor, is patient taking another statin? <i>DAdj_AnotherStatin</i>	<input type="checkbox"/> 0 NO	<input type="checkbox"/> 1 YES
11.	If yes, which? <i>DAdj_StatinType</i>	<input type="checkbox"/> 1 Atorvastatin (Lipitor®)	<input type="checkbox"/> 4 Pravastatin (Pravacol®)
		<input type="checkbox"/> 2 Fluvastatin (Lescol®)	<input type="checkbox"/> 5 Rosuvastatin (Crestor®)
		<input type="checkbox"/> 3 Lovastatin (Altacor® or Mevacor®)	<input type="checkbox"/> 7 Other



DRUG DOSE

ADJUSTMENT

SITE ID: _____	PATIENT ID: _____
	Patient Initials: _____

12.	If other, please specify <div style="text-align: center; color: blue;">DAdj_StatinOth</div>	
13.	What dose level of statin (in mgs) is the patient taking? <div style="text-align: center; color: blue;">DAdj_StatinDose</div>	_____ MGS/DAY
14.	What is current ezetimibe use? <div style="text-align: center; color: blue;">DAdj_EzDoseAdj</div>	<input type="checkbox"/> 1 NOT USED AT THIS TIME <input type="checkbox"/> 3 CONTINUING USE <input type="checkbox"/> 2 ADDED AT THIS VISIT <input type="checkbox"/> 4 DISCONTINUED THIS VISIT
15.	If discontinued, what was the primary reason? <div style="text-align: center; color: blue;">DAdj_EzDoseAdjReason</div>	<input type="checkbox"/> 1 PATIENT REQUEST <input type="checkbox"/> 3 OTHER REASON FOR DOSE ADJUSTMENT <input type="checkbox"/> 2 NON-STUDY PHYSICIAN REQUEST <input type="checkbox"/> 4 LIVER FUNCTION TEST ABNORMALITY
16.	If other reason, please specify <div style="text-align: center; color: blue;">DAdj_EzDoseAdjSpcReason</div>	_____ _____ _____



SITE ID: _____	PATIENT ID: _____
	Patient Initials: _____

DRUG ADHERENCE

INSTRUCTIONS: Fill this form at every in-office visit starting at the 3 Month visit.

Table Name: DAdh

1.	Visit Date (mm/dd/yyyy) DAdh_VisDt	____ / ____ / _____ USE (MM/DD/YYYY)
2.	What was the kit number for the drug returned? DAdh_KitNum	_____
3.	Was another kit returned? If so, please list the kit number here. DAdh_KitNum2	_____
4.	What date did the patient start taking the drugs in this kit? DAdh_KitNumDt	____ / ____ / _____ USE (MM/DD/YYYY)
5.	Question removed per Amendment 3. DAdh_NiaspanDose	
6.	Question removed per Amendment 3. DAdh_StatinDose	
7.	Approximate number of Niaspan/Placebo tablets returned or otherwise not taken (e.g. lost)? DAdh_Niaspan_Return	_____
Returned Niaspan/Placebo should be destroyed – See Manual of Operations		
8.	Approximate number of Zocor (simvastatin) tablets returned or otherwise not taken (e.g. lost)? DAdh_Statin_Return	_____
9.	Was ezetimibe prescribed? DAdh_Ezt	<input type="checkbox"/> 0 NO <input type="checkbox"/> 1 YES
10.	If on ezetimibe, approximate number of ezetimibe tablets returned or otherwise not taken (e.g. lost)? DAdh_Ezt_Return	_____
11.	Did patient report taking drugs as prescribed? DAdh_Adhere	<input type="checkbox"/> 0 NO <input type="checkbox"/> 1 YES
12.	If no, was it the Niaspan/Placebo? DAdh_NoAdhereNia	<input type="checkbox"/> 0 NO <input type="checkbox"/> 1 YES
13.	If no, was it the Zocor (simvastatin)? DAdh_NoAdhereZocor	<input type="checkbox"/> 0 NO <input type="checkbox"/> 1 YES
14.	If no, was it the ezetimibe? DAdh_NoAdhereEze	<input type="checkbox"/> 0 NO <input type="checkbox"/> 1 YES
15.	If medications were not taken as prescribed or if adherence is suspected to be poor (less than 75%), what was the primary reason for poor adherence? DAdh_BadWhy	<input type="checkbox"/> 0 N/A, GOOD ADHERENCE <input type="checkbox"/> 4 PATIENT DECISION <input type="checkbox"/> 1 ADVERSE CLINICAL SYMPTOMS <input type="checkbox"/> 5 SUPPLY RAN OUT <input type="checkbox"/> 2 PATIENT FORGETFUL <input type="checkbox"/> 6 UNKNOWN <input type="checkbox"/> 3 NON-STUDY PHYSICIAN RECOMMENDED DIFFERENT DOSE <input type="checkbox"/> 7 OTHER



DRUG ADHERENCE

SITE ID: _____	PATIENT ID: _____
	Patient Initials: _____

16.	If other reason for poor adherence, please describe DAdh_BadSpWhy	<hr/> <hr/> <hr/> <hr/>
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SITE ID: _____	PATIENT ID: _____
	Patient Initials: _____

INSTRUCTIONS: Complete this form at randomization and all in-clinic visits after randomization or whenever Blinded Study Drug Kits, Zocor (simvastatin) or Ezetimibe bottles are dispensed. Table Name: Disp

	Visit	<input type="checkbox"/> RANDOMIZATION <input type="checkbox"/> 3 MONTHS <input type="checkbox"/> 6 MONTHS <input type="checkbox"/> 9 MONTHS <input type="checkbox"/> 12 MONTHS <input type="checkbox"/> 15 MONTHS <input type="checkbox"/> 18 MONTHS <input type="checkbox"/> 21 MONTHS <input type="checkbox"/> 24 MONTHS <input type="checkbox"/> 27 MONTHS <input type="checkbox"/> 30 MONTHS <input type="checkbox"/> 33 MONTHS <input type="checkbox"/> 36 MONTHS <input type="checkbox"/> 39 MONTHS <input type="checkbox"/> 42 MONTHS <input type="checkbox"/> 45 MONTHS <input type="checkbox"/> 48 MONTHS <input type="checkbox"/> 51 MONTHS <input type="checkbox"/> 54 MONTHS <input type="checkbox"/> 57 MONTHS <input type="checkbox"/> _____
1	Visit Date (mm/dd/yyyy)	Disp_VstDt ____ / ____ / ____ Use (MM/DD/YYYY)
2	What daily dose of Niaspan/Placebo will be dispensed? Disp_Dose	<input type="checkbox"/> 0 NONE DISPENSED <input type="checkbox"/> 3 1,500 MG/DAY <input type="checkbox"/> 1 500 MG/DAY <input type="checkbox"/> 4 2,000 MG/DAY <input type="checkbox"/> 2 1,000 MG/DAY
3	Study drug kit number dispensed:	Disp_Kit ____
4	If the next study kit was also provided at this visit, give the kit number:	Disp_Kit2 ____
5	What daily dose of Zocor (simvastatin) will be dispensed? Disp_StatinDose	<input type="checkbox"/> 0 NONE DISPENSED <input type="checkbox"/> 7 30 MG <input type="checkbox"/> 5 5 MG <input type="checkbox"/> 3 40 MG <input type="checkbox"/> 1 10 MG <input type="checkbox"/> 6 60 MG <input type="checkbox"/> 2 20 MG <input type="checkbox"/> 4 80 MG
NUMBER OF BOTTLES OF ZOCOR (SIMVASTATIN) DISPENSED.		
6	Number of 10 mg Zocor (simvastatin) bottles dispensed	Disp_StatinBottles_10 _____
7	Number of 20 mg Zocor (simvastatin) bottles dispensed	Disp_StatinBottles_20 _____
8	Number of 40 mg Zocor (simvastatin) bottles dispensed	Disp_StatinBottles_40 _____
9	Number of ezetimibe bottles dispensed	Disp_Ezetimibe _____



ECG

SITE ID: _____	PATIENT ID: _____
	Patient Initials: _____

INSTRUCTIONS: Fill this form at the Baseline (start of Run-In) visit, 12, 24, 36, 48, and 60-month visit. Also, fill this form out EVERY time the patient has an ECG done for any reason.

PLEASE REMEMBER TO SEND THE ORIGINAL ECG TRACES TO THE CORE ECG LAB AS SOON AS POSSIBLE.

Table Name: ECG

1.	What was the reason the ECG was taken? <div style="text-align: right; color: blue; font-size: small;">ECG_reason</div>	<input type="checkbox"/> 1 BASELINE HISTORY <input type="checkbox"/> 3 CARDIAC EVENT <input type="checkbox"/> 2 SCHEDULED FOLLOW-UP <input type="checkbox"/> 4 OTHER UNSCHEDULED EVENT
2.	Date of ECG (<i>mm/dd/yyyy</i>) <div style="text-align: right; color: blue; font-size: small;">ECG_date</div>	____/____/____ USE (MM/DD/YYYY)
3.	Time of ECG- hour (use 24 hour clock) <div style="text-align: right; color: blue; font-size: small;">ECG_timeHr ECG_TimeMin</div>	____ : ____ (USE 24 HOUR CLOCK)



END OF BLINDED

TREATMENT PHASE

SITE ID: _____	PATIENT ID: _____
Patient Initials: _____	

Table Name: Term

INSTRUCTIONS: Fill this form out at the end of blinded treatment phase for all randomized patients.

1.	Visit Date (mm/dd/yyyy)	<u> </u> / <u> </u> / <u> </u> Term_Date Use (MM / DD / YYYY)	
2.	What was the primary reason for withdrawal from the study? <input type="checkbox"/> If death, complete Death Event form and submit documenting materials. If lost, contact the Coordinating Center for instructions.	<input type="checkbox"/> ₁ END OF STUDY <input type="checkbox"/> ₄ NON-STUDY PHYSICIAN REQUEST <input type="checkbox"/> ₂ PROTOCOL VIOLATION <input type="checkbox"/> ₅ DEATH <input type="checkbox"/> ₃ PATIENT REQUEST <input type="checkbox"/> ₆ LOST TO FOLLOW-UP	Term_Reason
3.	Was the patient on blinded study drug (Niacin/Placebo) at the end of the trial (May 24 th , 2011)?	<input type="checkbox"/> ₀ NO <input type="checkbox"/> ₁ YES	Term_Drug
4.	Will patient remain on lipid lowering/modifying treatments? If yes, which one(s)?	<input type="checkbox"/> ₀ NO <input type="checkbox"/> ₁ YES	Term_LipidTx
5.	Statins	<input type="checkbox"/> ₀ NO <input type="checkbox"/> ₁ YES	Term_Statin
6.	Bile Acid sequestrates	<input type="checkbox"/> ₀ NO <input type="checkbox"/> ₁ YES	Term_BileAcid
7.	Nicotinic acid (e.g. extended release niacin (Niaspan), combination statin with extended release niacin(Advicor))	<input type="checkbox"/> ₀ NO <input type="checkbox"/> ₁ YES	Term_Nicotin
8.	Fibric acid derivative (e.g. gemfibrozil (Lopid); fenofibrate (Tricor))	<input type="checkbox"/> ₀ NO <input type="checkbox"/> ₁ YES	Term_Fibric
9.	Cholesterol absorption inhibitors	<input type="checkbox"/> ₀ NO <input type="checkbox"/> ₁ YES	Term_Absorb
10.	Other lipid modifying agents	<input type="checkbox"/> ₀ NO <input type="checkbox"/> ₁ YES	Term_OtherDrug
11.	Therapeutic lifestyle changes (diet & exercise) ONLY	<input type="checkbox"/> ₀ NO <input type="checkbox"/> ₁ YES	Term_TLC
12.	Thinking back to when the participant was enrolled, how long had they been taking a statin PRIOR to enrollment in AIM-HIGH?	<input type="checkbox"/> ₀ NOT ON A STATIN AT ENTRY <input type="checkbox"/> ₁ < 1 YEAR PRIOR TO ENROLLMENT <input type="checkbox"/> ₂ 1 – 5 YEARS PRIOR TO ENROLLMENT <input type="checkbox"/> ₃ > 5 YEARS PRIOR TO ENROLLMENT	Term_Duration
13.	Please ask the participant to make their best guess regarding which therapy they were assigned:	<input type="checkbox"/> ₁ ACTIVE NIASPAN <input type="checkbox"/> ₂ PLACEBO <input type="checkbox"/> ₃ NO IDEA	Term_Therapy
14.	What is <i>your</i> (Research Coordinator) best guess regarding which therapy the participant was assigned:	<input type="checkbox"/> ₁ ACTIVE NIASPAN <input type="checkbox"/> ₂ PLACEBO <input type="checkbox"/> ₃ NO IDEA	Term_TherapyRC



EVENT NOTIFICATION

SITE ID: _____	PATIENT ID: _____
	Patient Initials: _____

INSTRUCTIONS: Fill this form out as soon as you learn that a patient has experienced any study event.

This is not to be filled out if the patient experiences an Adverse Event (see the Adverse Event form). Only use this form for the specific events listed below in Question #2.

Please complete and enter all relevant supplemental forms, as indicated below.

BE SURE TO SUBMIT ALL DOCUMENTING MATERIALS TO AXIO RESEARCH AS SOON AS POSSIBLE.

1.	Date of event (mm/dd/yyyy) <i>EvtNot_EvtDt</i>	____/____/____ Use (MM/DD/YYYY)
2.	Event type <i>EvtNot_Type</i>	<input type="checkbox"/> 1 ACS <input type="checkbox"/> 5 RULED NOT AN EVENT <input type="checkbox"/> 2 CNS <input type="checkbox"/> 3 REVASCULARIZATION <input type="checkbox"/> 4 DEATH
3.	If ACS Event, which of the following? (If applicable, complete ACS Event, ECG and Cardiac Enzyme forms and submit documenting materials) <i>EvtNot_ACS</i>	<input type="checkbox"/> 1 MI <input type="checkbox"/> 2 UNSTABLE ANGINA <input type="checkbox"/> 3 NO DOCUMENTED ISCHEMIA
4.	If CNS Event, which of the following? (If yes, complete CNS Event form and submit documenting materials) <i>EvtNot_CNS</i>	<input type="checkbox"/> 1 ISCHEMIC STROKE <input type="checkbox"/> 3 TRANSIENT ISCHEMIC ATTACK <input type="checkbox"/> 2 PRIMARY HEMORRHAGIC STROKE <input type="checkbox"/> 4 UNABLE TO DETERMINE WHETHER ISCHEMIC OR HEMORRHAGIC
5.	If Revascularization, which of the following? <i>EvtNot_Revasc</i> (If yes, complete Revascularization form and submit documenting materials)	<input type="checkbox"/> 1 CARDIAC <input type="checkbox"/> 2 CEREBROVASCULAR <input type="checkbox"/> 3 PERIPHERAL

EXCLUSION CRITERIA

 Table Name: **Exc**

INSTRUCTIONS: Please complete at the Screening Visit. If you select YES for any of the questions below, the patient is NOT eligible for the study.

Exc_ACS	1.	Has the patient been hospitalized for acute coronary syndrome with discharge within 4 weeks prior to planned enrollment?	<input type="checkbox"/> ₀ NO	<input type="checkbox"/> ₁ YES
Exc_CAB	2.	Has the patient had CABG surgery within the past 5 years without recent ACS? (recent \leq 1 year)	<input type="checkbox"/> ₀ NO	<input type="checkbox"/> ₁ YES
Exc_PCI	3.	Has the patient had a PCI within the past 4 weeks?	<input type="checkbox"/> ₀ NO	<input type="checkbox"/> ₁ YES
Exc_stroke8wk	4.	Has the patient had a stroke or TIA within the past 8 weeks?	<input type="checkbox"/> ₀ NO	<input type="checkbox"/> ₁ YES
Exc_Glucometer	5.	Is the patient diabetic and unable to or refuses to use a glucometer for home monitoring of glucose?	<input type="checkbox"/> ₀ NO	<input type="checkbox"/> ₁ YES
Exc_PostMIvas	6.	Is the need/likelihood of urgent revascularization is high?	<input type="checkbox"/> ₀ NO	<input type="checkbox"/> ₁ YES
Exc_LfCAD	7.	Does the patient have left main coronary disease \geq 50% and no prior CABG?	<input type="checkbox"/> ₀ NO	<input type="checkbox"/> ₁ YES
Exc_Ejc	8.	Is the patient's ejection fraction $<$ 30%?	<input type="checkbox"/> ₀ NO	<input type="checkbox"/> ₁ YES
Exc_Unresp	9.	Does the patient have cardiogenic shock, pulmonary edema, angina, or CHF unresponsive to standard medical therapy? (CCS class IV)	<input type="checkbox"/> ₀ NO	<input type="checkbox"/> ₁ YES
Exc_CVD	10.	Does the patient have concomitant valvular heart disease likely to require surgery or affect prognosis during follow-up period?	<input type="checkbox"/> ₀ NO	<input type="checkbox"/> ₁ YES
Exc_CardMy	11.	Does the patient have congenital or primary cardiomyopathy likely to affect prognosis during follow-up period?	<input type="checkbox"/> ₀ NO	<input type="checkbox"/> ₁ YES
Exc_ICD	12.	Has the patient experienced resuscitated out-of-hospital sudden death or symptomatic sustained or non-sustained ventricular tachycardia and does not now have an implantable cardioverter-defibrillator (ICD)?	<input type="checkbox"/> ₀ NO	<input type="checkbox"/> ₁ YES
Exc_Hyper	13.	Does the patient have significant systemic hypertension (BP $>$ 200/100 mm Hg) unresponsive to medical therapy?	<input type="checkbox"/> ₀ NO	<input type="checkbox"/> ₁ YES
Exc_Peptic	14.	Does the patient have active peptic ulcer disease?	<input type="checkbox"/> ₀ NO	<input type="checkbox"/> ₁ YES
Exc_Meds	15.	Must the patient continue with any of the excluded medications?	<input type="checkbox"/> ₀ NO	<input type="checkbox"/> ₁ YES
Exc_preg	16.	If the patient is female , is she pregnant or likely to become pregnant (i.e. premenopausal and not using birth control)?	<input type="checkbox"/> ₀ NO	<input type="checkbox"/> ₁ YES
			<input type="checkbox"/> ₃ N/A (MALE)	

 Continue 2nd


SITE ID: _____	PATIENT ID: _____
Patient Initials: _____	

Exc_comorb	17.	Does the patient have any significant co-morbidity likely to cause death in the 3-5 year follow-up period?	<input type="checkbox"/> ₀ NO	<input type="checkbox"/> ₁ YES
Exc_HIV	18.	Does the patient have AIDS or active HIV infection?	<input type="checkbox"/> ₀ NO	<input type="checkbox"/> ₁ YES
Exc_abuse	19.	Does the patient have a significant active history of substance abuse within the previous 5 years?	<input type="checkbox"/> ₀ NO	<input type="checkbox"/> ₁ YES
Exc_Clintrial	20.	Is the patient currently participating in another long-term clinical trial?	<input type="checkbox"/> ₀ NO	<input type="checkbox"/> ₁ YES
Exc_patient	21.	Is the patient unwilling to participate?	<input type="checkbox"/> ₀ NO	<input type="checkbox"/> ₁ YES
Exc_Physician	22.	Is the physician or other non-study physicians unwilling to allow patient to participate?	<input type="checkbox"/> ₀ NO	<input type="checkbox"/> ₁ YES
LAB value Exclusions				
Exc_Glu	23.	Is the patient's fasting glucose >180 mg/dL or hemoglobin A ₁ C >9.0%?	<input type="checkbox"/> ₀ NO	<input type="checkbox"/> ₁ YES
Exc_Liver	24.	Does the patient have AST or ALT > 2 times upper limit of normal or active liver disease?	<input type="checkbox"/> ₀ NO	<input type="checkbox"/> ₁ YES
Exc_Gout	25.	Does the patient have a recent history of acute gout or uric acid > 7.0 mg/dL despite therapy with allopurinol?	<input type="checkbox"/> ₀ NO	<input type="checkbox"/> ₁ YES
Exc_creat	26.	Does the patient have chronic renal insufficiency with creatinine ≥ 2.5 mg/dl?	<input type="checkbox"/> ₀ NO	<input type="checkbox"/> ₁ YES



FOLLOW-UP

SITE ID: _____	PATIENT ID: _____
Patient Initials: _____	

Table Name: FoL

INSTRUCTIONS: Please complete at each Follow-up visit or Follow-up phone call.

Visit	<input type="checkbox"/> 2 WEEK RUN IN	<input type="checkbox"/> 9 MONTHS	<input type="checkbox"/> 27 MONTHS	<input type="checkbox"/> 45 MONTHS
	<input type="checkbox"/> 2 WEEK	<input type="checkbox"/> 12 MONTHS	<input type="checkbox"/> 30 MONTHS	<input type="checkbox"/> 48 MONTHS
	<input type="checkbox"/> 1 MONTH	<input type="checkbox"/> 15 MONTHS	<input type="checkbox"/> 33 MONTHS	<input type="checkbox"/> 52 MONTHS
	<input type="checkbox"/> 2 MONTHS	<input type="checkbox"/> 18 MONTHS	<input type="checkbox"/> 34 MONTHS	<input type="checkbox"/> 54 MONTHS
	<input type="checkbox"/> 3 MONTHS	<input type="checkbox"/> 21 MONTHS	<input type="checkbox"/> 39 Months	<input type="checkbox"/> 57 MONTHS
	<input type="checkbox"/> 6 MONTHS	<input type="checkbox"/> 24 MONTHS	<input type="checkbox"/> 42 Months	<input type="checkbox"/> 60 MONTHS

1.	Date of visit or phone call Fol_Date	____ / ____ / ____ USE (MM/DD/YYYY)
2.	In-office Visit or Phone call? Fol_VisitType	<input type="checkbox"/> ₁ IN-OFFICE <input type="checkbox"/> ₂ PHONE CALL
3.	Reason for follow-up Fol_Reason	<input type="checkbox"/> ₁ SCHEDULED <input type="checkbox"/> ₂ UNSCHEDULED FOR SIDE EFFECT <input type="checkbox"/> ₃ UNSCHEDULED FOR DOSE ADJUSTMENT
4.	Was study drug dose adjusted or discontinued? (If yes, please complete Dose Adjustment form) Fol_DrugDC	<input type="checkbox"/> ₀ NO <input type="checkbox"/> ₁ YES

Screen Patient for Possible Efficacy Endpoints:

5.	MI: (If yes, complete ACS Event form and submit documenting materials) Fol_MI	<input type="checkbox"/> ₀ NO <input type="checkbox"/> ₁ YES
6.	Stroke: (If yes or possible, complete CNS Event form and submit documenting materials) Fol_Stroke	<input type="checkbox"/> ₀ NO <input type="checkbox"/> ₁ YES – WITH DOCUMENTATION <input type="checkbox"/> ₂ POSSIBLE – YES TO STROKE SYMPTOM QUESTION(S)
7.	Hospitalization for evaluation of acute coronary syndrome (ACS): (If yes, complete ACS Event form and submit documenting materials) Fol_ACS	<input type="checkbox"/> ₀ NO <input type="checkbox"/> ₁ YES
8.	Cardiac revascularization (CABG or PCI): (If yes, complete Revascularization form.) Fol_CardRevasc	<input type="checkbox"/> ₀ NO <input type="checkbox"/> ₁ YES
9.	Cerbrovascular revascularization (carotid endarterectomy, carotid PTA): (If yes, complete Revascularization form) Fol_CerebRevasc	<input type="checkbox"/> ₀ NO <input type="checkbox"/> ₁ YES
10.	Peripheral revascularization: Fol_PeriphRevasc (If yes, complete Revascularization form)	<input type="checkbox"/> ₀ NO <input type="checkbox"/> ₁ YES

Continue 2nd page

SITE ID: _____	PATIENT ID: _____
Patient Initials: _____	

<i>Screen Patient for Possible Adverse Events or Symptoms:</i>				
<i>Follow-up as needed</i>				
11.	<p>How frequently did the patient experience flushing?</p> <p style="text-align: center;"><i>Fol_Flush</i></p> <table style="width: 100%;"> <tr> <td style="width: 50%; vertical-align: top;"> <input type="checkbox"/> 1 NO FLUSHING REPORTED <input type="checkbox"/> 2 INFREQUENTLY (ONLY A FEW TIMES DURING THIS PERIOD) </td> <td style="width: 50%; vertical-align: top;"> <input type="checkbox"/> 3 MODERATELY FREQUENTLY MANY DAYS, BUT NOT EVERY DAY <input type="checkbox"/> 4 DAILY (ALMOST EVERY DAY, USUALLY FOLLOWING THE DOSE) </td> </tr> </table>	<input type="checkbox"/> 1 NO FLUSHING REPORTED <input type="checkbox"/> 2 INFREQUENTLY (ONLY A FEW TIMES DURING THIS PERIOD)	<input type="checkbox"/> 3 MODERATELY FREQUENTLY MANY DAYS, BUT NOT EVERY DAY <input type="checkbox"/> 4 DAILY (ALMOST EVERY DAY, USUALLY FOLLOWING THE DOSE)	
<input type="checkbox"/> 1 NO FLUSHING REPORTED <input type="checkbox"/> 2 INFREQUENTLY (ONLY A FEW TIMES DURING THIS PERIOD)	<input type="checkbox"/> 3 MODERATELY FREQUENTLY MANY DAYS, BUT NOT EVERY DAY <input type="checkbox"/> 4 DAILY (ALMOST EVERY DAY, USUALLY FOLLOWING THE DOSE)			
12.	<p>On average, how severe (annoying) were the flushing episodes?</p> <p style="text-align: center;"><i>Fol_Flush2</i></p> <table style="width: 100%;"> <tr> <td style="width: 50%; vertical-align: top;"> <input type="checkbox"/> 1 NO SYMPTOMS <input type="checkbox"/> 2 MILD </td> <td style="width: 50%; vertical-align: top;"> <input type="checkbox"/> 3 MODERATE <input type="checkbox"/> 4 SEVERE </td> </tr> </table>	<input type="checkbox"/> 1 NO SYMPTOMS <input type="checkbox"/> 2 MILD	<input type="checkbox"/> 3 MODERATE <input type="checkbox"/> 4 SEVERE	
<input type="checkbox"/> 1 NO SYMPTOMS <input type="checkbox"/> 2 MILD	<input type="checkbox"/> 3 MODERATE <input type="checkbox"/> 4 SEVERE			
13.	<p>Did the patient take aspirin or other analgesic prior to taking the Niaspan or Placebo?</p> <table style="width: 100%;"> <tr> <td style="width: 50%;"> <input type="checkbox"/> 0 NO <i>Fol_Prior</i> </td> <td style="width: 50%;"> <input type="checkbox"/> 1 YES </td> </tr> </table>	<input type="checkbox"/> 0 NO <i>Fol_Prior</i>	<input type="checkbox"/> 1 YES	
<input type="checkbox"/> 0 NO <i>Fol_Prior</i>	<input type="checkbox"/> 1 YES			
14.	<p>Was it generally effective in preventing or reducing the incidence or severity of flushing?</p> <table style="width: 100%;"> <tr> <td style="width: 50%;"> <input type="checkbox"/> 0 NO <i>Fol_Prior2</i> </td> <td style="width: 50%;"> <input type="checkbox"/> 1 YES </td> </tr> </table>	<input type="checkbox"/> 0 NO <i>Fol_Prior2</i>	<input type="checkbox"/> 1 YES	
<input type="checkbox"/> 0 NO <i>Fol_Prior2</i>	<input type="checkbox"/> 1 YES			
15.	<p>Did the patient report any itching? (if yes, note severity)</p> <p style="text-align: center;"><i>Fol_Itch</i></p> <table style="width: 100%;"> <tr> <td style="width: 50%; vertical-align: top;"> <input type="checkbox"/> 0 NO SYMPTOMS <input type="checkbox"/> 1 MILD </td> <td style="width: 50%; vertical-align: top;"> <input type="checkbox"/> 2 MODERATE <input type="checkbox"/> 3 SEVERE </td> </tr> </table>	<input type="checkbox"/> 0 NO SYMPTOMS <input type="checkbox"/> 1 MILD	<input type="checkbox"/> 2 MODERATE <input type="checkbox"/> 3 SEVERE	
<input type="checkbox"/> 0 NO SYMPTOMS <input type="checkbox"/> 1 MILD	<input type="checkbox"/> 2 MODERATE <input type="checkbox"/> 3 SEVERE			
16.	<p>Did the patient report any nausea? (if yes, note severity)</p> <p style="text-align: center;"><i>Fol_Nausea</i></p> <table style="width: 100%;"> <tr> <td style="width: 50%; vertical-align: top;"> <input type="checkbox"/> 0 NO SYMPTOMS <input type="checkbox"/> 1 MILD </td> <td style="width: 50%; vertical-align: top;"> <input type="checkbox"/> 2 MODERATE <input type="checkbox"/> 3 SEVERE </td> </tr> </table>	<input type="checkbox"/> 0 NO SYMPTOMS <input type="checkbox"/> 1 MILD	<input type="checkbox"/> 2 MODERATE <input type="checkbox"/> 3 SEVERE	
<input type="checkbox"/> 0 NO SYMPTOMS <input type="checkbox"/> 1 MILD	<input type="checkbox"/> 2 MODERATE <input type="checkbox"/> 3 SEVERE			
17.	<p>Did the patient report other gastro-intestinal symptoms (heartburn, gas) associated with the study drugs? (if yes, note severity)</p> <p style="text-align: center;"><i>Fol_HeartBurn</i></p> <table style="width: 100%;"> <tr> <td style="width: 50%; vertical-align: top;"> <input type="checkbox"/> 0 NO SYMPTOMS <input type="checkbox"/> 1 MILD </td> <td style="width: 50%; vertical-align: top;"> <input type="checkbox"/> 2 MODERATE <input type="checkbox"/> 3 SEVERE </td> </tr> </table>	<input type="checkbox"/> 0 NO SYMPTOMS <input type="checkbox"/> 1 MILD	<input type="checkbox"/> 2 MODERATE <input type="checkbox"/> 3 SEVERE	
<input type="checkbox"/> 0 NO SYMPTOMS <input type="checkbox"/> 1 MILD	<input type="checkbox"/> 2 MODERATE <input type="checkbox"/> 3 SEVERE			
18.	<p>Did patient report muscle aches or weakness? (if yes, note severity)</p> <p style="text-align: center;"><i>Fol_Muscle</i></p> <table style="width: 100%;"> <tr> <td style="width: 50%; vertical-align: top;"> <input type="checkbox"/> 0 NO SYMPTOMS <input type="checkbox"/> 1 MILD </td> <td style="width: 50%; vertical-align: top;"> <input type="checkbox"/> 2 MODERATE <input type="checkbox"/> 3 SEVERE </td> </tr> </table>	<input type="checkbox"/> 0 NO SYMPTOMS <input type="checkbox"/> 1 MILD	<input type="checkbox"/> 2 MODERATE <input type="checkbox"/> 3 SEVERE	
<input type="checkbox"/> 0 NO SYMPTOMS <input type="checkbox"/> 1 MILD	<input type="checkbox"/> 2 MODERATE <input type="checkbox"/> 3 SEVERE			
19.	<p>Did the patient experience fatigue? (if yes, note severity)</p> <p style="text-align: center;"><i>Fol_Fatigue</i></p> <table style="width: 100%;"> <tr> <td style="width: 50%; vertical-align: top;"> <input type="checkbox"/> 0 NO SYMPTOMS <input type="checkbox"/> 1 MILD </td> <td style="width: 50%; vertical-align: top;"> <input type="checkbox"/> 2 MODERATE <input type="checkbox"/> 3 SEVERE </td> </tr> </table>	<input type="checkbox"/> 0 NO SYMPTOMS <input type="checkbox"/> 1 MILD	<input type="checkbox"/> 2 MODERATE <input type="checkbox"/> 3 SEVERE	
<input type="checkbox"/> 0 NO SYMPTOMS <input type="checkbox"/> 1 MILD	<input type="checkbox"/> 2 MODERATE <input type="checkbox"/> 3 SEVERE			
20.	<p>Did the patient report any marked changes in eyesight? (if yes, note severity)</p> <p style="text-align: center;"><i>Fol_Vision</i></p> <table style="width: 100%;"> <tr> <td style="width: 50%; vertical-align: top;"> <input type="checkbox"/> 0 NO SYMPTOMS <input type="checkbox"/> 1 MILD </td> <td style="width: 50%; vertical-align: top;"> <input type="checkbox"/> 2 MODERATE <input type="checkbox"/> 3 SEVERE </td> </tr> </table>	<input type="checkbox"/> 0 NO SYMPTOMS <input type="checkbox"/> 1 MILD	<input type="checkbox"/> 2 MODERATE <input type="checkbox"/> 3 SEVERE	
<input type="checkbox"/> 0 NO SYMPTOMS <input type="checkbox"/> 1 MILD	<input type="checkbox"/> 2 MODERATE <input type="checkbox"/> 3 SEVERE			
21.	<p>Did the patient report development of gout or severe symptoms of arthritis? (if yes, note severity)</p> <p style="text-align: center;"><i>Fol_Gout</i></p> <table style="width: 100%;"> <tr> <td style="width: 50%; vertical-align: top;"> <input type="checkbox"/> 0 NO SYMPTOMS <input type="checkbox"/> 1 MILD </td> <td style="width: 50%; vertical-align: top;"> <input type="checkbox"/> 2 MODERATE <input type="checkbox"/> 3 SEVERE </td> </tr> </table>	<input type="checkbox"/> 0 NO SYMPTOMS <input type="checkbox"/> 1 MILD	<input type="checkbox"/> 2 MODERATE <input type="checkbox"/> 3 SEVERE	
<input type="checkbox"/> 0 NO SYMPTOMS <input type="checkbox"/> 1 MILD	<input type="checkbox"/> 2 MODERATE <input type="checkbox"/> 3 SEVERE			
22.	<p>For diabetic patients, did they use a glucometer? <i>Fol_Diabetic</i></p> <table style="width: 100%;"> <tr> <td style="width: 33%;"> <input type="checkbox"/> 0 NOT DIABETIC </td> <td style="width: 33%;"> <input type="checkbox"/> 1 NO </td> <td style="width: 33%;"> <input type="checkbox"/> 2 YES </td> </tr> </table>	<input type="checkbox"/> 0 NOT DIABETIC	<input type="checkbox"/> 1 NO	<input type="checkbox"/> 2 YES
<input type="checkbox"/> 0 NOT DIABETIC	<input type="checkbox"/> 1 NO	<input type="checkbox"/> 2 YES		
23.	<p>Did fasting glucometer measurements rise by more than 15 mg/dl (0.75 mmol/l)?</p> <table style="width: 100%;"> <tr> <td style="width: 50%;"> <input type="checkbox"/> 0 NO <i>Fol_Glucose</i> </td> <td style="width: 50%;"> <input type="checkbox"/> 1 YES </td> </tr> </table>	<input type="checkbox"/> 0 NO <i>Fol_Glucose</i>	<input type="checkbox"/> 1 YES	
<input type="checkbox"/> 0 NO <i>Fol_Glucose</i>	<input type="checkbox"/> 1 YES			
<i>If the answer to questions 19-21, or 23 was yes and these were considered to be possibly or probably related to the study drug, complete the suspected toxicity and Adverse Event forms.</i>				
24.	<p>Any other adverse events: (f yes, add events on "Averse Events" page)</p> <p style="text-align: center;"><i>Fol_AEs</i></p> <table style="width: 100%;"> <tr> <td style="width: 50%;"> <input type="checkbox"/> 0 NO </td> <td style="width: 50%;"> <input type="checkbox"/> 1 YES </td> </tr> </table>	<input type="checkbox"/> 0 NO	<input type="checkbox"/> 1 YES	
<input type="checkbox"/> 0 NO	<input type="checkbox"/> 1 YES			



HEALTH CARE UTILIZATION

SITE ID: _____	PATIENT ID: _____
	Patient Initials: _____

Table Name: HU

INSTRUCTIONS: Please fill out this form at in-office visits at month 6, 12, 18, 24, 30, 36, 42, 48 and 60 month.

1.	Visit Date (mm/dd/yyyy)	HU_Date ____/____/____ USE (MM/DD/YYYY)
2.	Number of outpatient doctor visits to cardiologist, peripheral vascular surgeon or physician, neurologist or family physician/internist for cardiovascular problems since last follow-up contact	HU_Outpatient ____
3.	Number of home health care days of assistance since last follow-up	HU_HomeHealth ____
4.	Number of days in nursing or rehab facility since last follow-up	HU_Rehab ____
5.	What is the patient's current work status? HU_WorkStatus	<input type="checkbox"/> 1 FULL TIME <input type="checkbox"/> 5 DISABLED <input type="checkbox"/> 2 PART TIME <input type="checkbox"/> 6 UNEMPLOYED <input type="checkbox"/> 3 RETIRED <input type="checkbox"/> 9 NOT PROVIDED <input type="checkbox"/> 4 NOT WORKING OUTSIDE THE HOME-BY CHOICE
6.	Has the patient changed work status since the last follow-up due to health issues?	<input type="checkbox"/> 0 NO HU_WorkChg <input type="checkbox"/> 2 QUIT WORKING <input type="checkbox"/> 1 REDUCED WORK HOURS <input type="checkbox"/> 3 INCREASED WORK HOURS
7.	If still working, what number of days was the patient unable to work because of health issues:	HU_WorkLost ____
Mark all (if any) cardiac outpatient procedures done since the last follow-up:		
8.	Cardiac catheterization HU_Cath	<input type="checkbox"/> 0 NO <input type="checkbox"/> 1 YES
9.	Cardioversion HU_Cardiov	<input type="checkbox"/> 0 NO <input type="checkbox"/> 1 YES
10.	Pacemaker implant HU_Pacemaker	<input type="checkbox"/> 0 NO <input type="checkbox"/> 1 YES
11.	Electrophysiology study HU_EP	<input type="checkbox"/> 0 NO <input type="checkbox"/> 1 YES
12.	Transthoracic cardiac echo HU_echo	<input type="checkbox"/> 0 NO <input type="checkbox"/> 1 YES
13.	Transesophageal cardiac echo HU_TEE	<input type="checkbox"/> 0 NO <input type="checkbox"/> 1 YES
14.	Radionuclide scan HU_NucScan	<input type="checkbox"/> 0 NO <input type="checkbox"/> 1 YES
15.	CT scan (cardiac or other) HU_CT	<input type="checkbox"/> 0 NO <input type="checkbox"/> 1 YES
16.	MRI scan (cardiac or other) HU_MRI	<input type="checkbox"/> 0 NO <input type="checkbox"/> 1 YES

SITE ID: _____	PATIENT ID: _____
	Patient Initials: _____

INSTRUCTIONS: Please fill out this form any time the patient is hospitalized for any reason.

Table Name: HOSP

1.	Date of admission (mm/dd/yyyy) <i>Hosp_Admt</i>	____/____/____ USE (MM/DD/YYYY)
2.	Date of discharge (mm/dd/yyyy) <i>Hosp_DischDt</i>	____/____/____ USE (MM/DD/YYYY)
3.	Type of admission: <i>Hosp_ED</i>	<input type="checkbox"/> ₁ HOSPITAL <input type="checkbox"/> ₂ EMERGENCY DEPARTMENT ONLY
4.	Number of days in ICU	_____ <i>Hosp_ICU</i>
5.	Admission diagnosis (ICD code)	_____ <i>Hosp_AdmtDx</i>
6.	Primary discharge diagnosis (ICD code)	_____ <i>Hosp_DischDx</i>
7.	Did the patient die during this admission? If yes, complete death form.	<input type="checkbox"/> ₀ NO <input type="checkbox"/> ₁ YES <i>Hosp_Death</i>
8.	Did patient undergo revascularization during this hospitalization? If yes, complete Revascularization form.	<input type="checkbox"/> ₀ NO <input type="checkbox"/> ₁ YES <i>Hosp_Revasc</i>
9.	Did patient suffer an MI during this admission? If yes, complete ACS Event form.	<input type="checkbox"/> ₀ NO <input type="checkbox"/> ₁ YES <i>Hosp_MI</i>

Check if any of the procedures below were performed during this hospital/ER visit.

10.	Cardiac catheterization	____ ₀ NO ____ ₁ YES <i>Hosp_Cath</i>
11.	Cardioversion	____ ₀ NO ____ ₁ YES <i>Hosp_Cardiov</i>
12.	Pacemaker implant	____ ₀ NO ____ ₁ YES <i>Hosp_Pace</i>
13.	ICD implant	____ ₀ NO ____ ₁ YES <i>Hosp_ICD</i>
14.	Aneurysm resection	____ ₀ NO ____ ₁ YES <i>Hosp_Aneur</i>
15.	Valve repair or replacement	____ ₀ NO ____ ₁ YES <i>Hosp_Valve</i>
16.	Electrophysiology study	____ ₀ NO ____ ₁ YES <i>Hosp_EP</i>
17.	Transthoracic cardiac echo	____ ₀ NO ____ ₁ YES <i>Hosp_echo</i>
18.	Transesophageal cardiac echo	____ ₀ NO ____ ₁ YES <i>Hosp_TEE</i>
19.	Radionuclide scan	____ ₀ NO ____ ₁ YES <i>Hosp_NucScan</i>
20.	CT scan (cardiac or other)	____ ₀ NO ____ ₁ YES <i>Hosp_CT</i>
21.	MRI scan (cardiac or other)	____ ₀ NO ____ ₁ YES <i>Hosp_MRI</i>



MEDICAL HISTORY

SITE ID: _____	PATIENT ID: _____
Patient Initials: _____	

INSTRUCTIONS: Fill this form at the Baseline visit.
 Based on all available medical records, please record the history for each condition. Answer "yes" only if probable or certain.

Table Name: Hx

Cardiovascular Medical History		
1.	Angina HX_Angina	<input type="checkbox"/> _0 NO <input type="checkbox"/> _1 YES
2.	Acute coronary syndrome (ACS) HX_ACS	<input type="checkbox"/> _0 NO <input type="checkbox"/> _1 YES
3.	Date of most recent hospitalization for ACS - month HX_ACSdateMM	____
4.	Date of most recent hospitalization for ACS - year HX_ACSdateYY	____
5.	Myocardial infarction (MI) Hx_MI	<input type="checkbox"/> _0 NO <input type="checkbox"/> _1 YES
6.	Date of most recent MI - month HX_MIdateMM	____
7.	Date of most recent MI - year HX_MIdateYY	____
8.	Ventricular arrhythmia Hx_VenArr	<input type="checkbox"/> _0 NO <input type="checkbox"/> _1 YES
9.	Atrial fibrillation Hx_Afib	<input type="checkbox"/> _0 NO <input type="checkbox"/> _1 YES
10.	Congestive heart failure (CHF) Hx_CHF	<input type="checkbox"/> _0 NO <input type="checkbox"/> _1 YES
11.	Is a recent Ejection Fraction measurement available? HX_EF	<input type="checkbox"/> _0 NO <input type="checkbox"/> _1 YES
12.	If yes, Ejection Fraction (in percent, most recent) HX_EF%	____ %
13.	Or, if qualitative: HX_EFqual	<input type="checkbox"/> _1 30 – 50% <input type="checkbox"/> _2 > 50%
14.	Date of most recent EF - month HX_EFdateMM	____
15.	Date of most recent EF - year HX_EFdateYY	____
16.	Pulmonary embolism Hx_PE	<input type="checkbox"/> _0 NO <input type="checkbox"/> _1 YES
17.	Deep vein thrombosis (DVT) requiring anti-coagulant Hx_DVT	<input type="checkbox"/> _0 NO <input type="checkbox"/> _1 YES
18.	Ischemic dilated cardiomyopathy Hx_IDC	<input type="checkbox"/> _0 NO <input type="checkbox"/> _1 YES
19.	Moderate to severe mitral or aortic stenosis Hx_aorsten	<input type="checkbox"/> _0 NO <input type="checkbox"/> _1 YES
20.	Moderate to severe mitral regurgitation Hx_mitregurg	<input type="checkbox"/> _0 NO <input type="checkbox"/> _1 YES
21.	Hypertension (Blood pressure \geq 140/90 or taking anti-hypertension meds) Hx_Hyper	<input type="checkbox"/> _0 NO <input type="checkbox"/> _1 YES
22.	Transient ischemic attack (TIA) Hx_TIA	<input type="checkbox"/> _0 NO <input type="checkbox"/> _1 YES
23.	Stroke Hx_Stroke	<input type="checkbox"/> _0 NO <input type="checkbox"/> _1 YES
24.	Date of most recent Stroke/TIA - month HX_StrokeMM	____
25.	Date of most recent Stroke/TIA - year HX_StrokeYY	____
26.	What was the etiology of the stroke? HX_StrokeDef	<input type="checkbox"/> _1 ISCHEMIC <input type="checkbox"/> _2 PRIMARY HEMORRHAGIC
27.	Abdominal aortic aneurysm Hx_AAA	<input type="checkbox"/> _0 NO <input type="checkbox"/> _1 YES

SITE ID: _____	PATIENT ID: _____
	Patient Initials: _____

28.	Peripheral vascular disease	Hx_PVD	<input type="checkbox"/> _0 NO	<input type="checkbox"/> _1 YES
29.	Carotid Artery Disease	Hx_Carotid	<input type="checkbox"/> _0 NO	<input type="checkbox"/> _1 YES
30.	Family history of premature cardiovascular disease	Hx_famCVD	<input type="checkbox"/> _0 NO	<input type="checkbox"/> _1 YES
<i>Family history of premature cardiovascular disease is prior to 55 years for male or 65 years of age for female 1st degree relative</i>				
Cardiovascular Interventions				
31.	Coronary artery bypass graft (CABG)	Hx_CABG	<input type="checkbox"/> _0 NO	<input type="checkbox"/> _1 YES
32.	Date of most recent CABG - month	HX_CABGdateMM	_____	
33.	Date of most recent CABG - year	HX_CABGdat	_____	
34.	Percutaneous coronary revascularization (PCI), angioplasty	Hx_PCI	<input type="checkbox"/> _0 NO	<input checked="" type="checkbox"/> _1 YES
35.	Date of most recent - month	HX_PCIdateMM	_____	
36.	Date of most recent - year	HX_PCIdateYY	_____	
37.	Was a stent placed?	HX_PCISTent	<input type="checkbox"/> _0 NO	<input type="checkbox"/> _1 YES
38.	Valve repair/replacement	Hx_valve	<input type="checkbox"/> _0 NO	<input type="checkbox"/> _1 YES
39.	Abdominal aortic aneurysm repair	Hx_AAArepair	<input type="checkbox"/> _0 NO	<input type="checkbox"/> _1 YES
40.	Carotid endarterectomy	Hx_edart	<input type="checkbox"/> _0 NO	<input type="checkbox"/> _1 YES
41.	Carotid Stent	Hx_CarotidStent	<input type="checkbox"/> _0 NO	<input type="checkbox"/> _1 YES
42.	Peripheral revascularization	Hx_PeriRevas	<input type="checkbox"/> _0 NO	<input type="checkbox"/> _1 YES
43.	ICD implant	Hx_ICD	<input type="checkbox"/> _0 NO	<input type="checkbox"/> _1 YES
44.	Pacemaker implant	Hx_Pace	<input type="checkbox"/> _0 NO	<input type="checkbox"/> _1 YES
Other Medical History				
45.	Chronic pulmonary disease	Hx_CPD	<input type="checkbox"/> _0 NO	<input type="checkbox"/> _1 YES
46.	Hepatic disease	Hx_Hep	<input type="checkbox"/> _0 NO	<input type="checkbox"/> _1 YES
47.	Renal disease	Hx_Renal	<input type="checkbox"/> _0 NO	<input type="checkbox"/> _1 YES
48.	Diabetes mellitus	Hx_Diabetes	<input type="checkbox"/> _0 NO	<input type="checkbox"/> _1 YES
49.	Year of onset	Hx_DiabetesYear	_____	
50.	Type	Hx_Dtype	<input type="checkbox"/> _1 TYPE I	<input type="checkbox"/> _2 TYPE II
51.	Does the current treatment ONLY dietary counseling?	Hx_DtreatDiet	<input type="checkbox"/> _0 NO	<input type="checkbox"/> _1 YES
52.	Does the current treatment include use of Oral Hypoglycemic?	Hx_DtreatOral	<input type="checkbox"/> _0 NO	<input type="checkbox"/> _1 YES
53.	Does the current treatment include use of insulin?	Hx_DtreatInsulin	<input type="checkbox"/> _0 NO	<input type="checkbox"/> _1 YES
54.	Is patient currently using a glucometer?	HX_Glucom	<input type="checkbox"/> _0 NO	<input type="checkbox"/> _1 YES



PHYSICAL EXAM

SITE ID: _____	PATIENT ID: _____
Patient Initials: _____	

INSTRUCTIONS: Please complete at Baseline, annually and at end of study. Table Name: PE

	Visit	<input type="checkbox"/> BASELINE <input type="checkbox"/> 12 MONTH <input type="checkbox"/> 24 MONTH <input type="checkbox"/> 36 MONTH <input type="checkbox"/> 48 MONTH <input type="checkbox"/> END OF STUDY	
1.	Visit Date (mm/dd/yyyy)	_____ / _____ / _____ PE_VisDt Use (MM/DD/YYYY)	
2-3.	Height (round to nearest in/cm)	PE_Ht _____ <input type="checkbox"/> ₁ INCHES <input type="checkbox"/> ₂ CENTIMETERS	
3.1	Standard height (derived value)	PE_HtStd _____ PE_Htunits	
4-5.	Weight (round to nearest lb/kg)	PE_Wt _____ <input type="checkbox"/> ₁ POUNDS <input type="checkbox"/> ₂ KILOGRAMS	
5.1	Standard weight (derived value)	PE_WtStd _____ PE_WtUnits	
5.2	BMI (derived value)	PE_BMI _____	
6-7.	Waist circumference (round to nearest in/cm)	PE_waist _____ <input type="checkbox"/> ₁ INCHES <input type="checkbox"/> ₂ CENTIMETERS	
7.1	Standard waist circumference (derived value)	PE_WaistStd _____ PE_WaistUnit	
8-9.	Hip circumference (round to nearest inch/centimeter)	PE_Hip _____ <input type="checkbox"/> ₁ INCHES <input type="checkbox"/> ₂ CENTIMETERS	
9.1	Standard hip circumference (derived value)	PE_HipStd _____ PE_HipUnits	
10-11.	Sitting Blood Pressure	PE_BPsys _____ / PE_BPdia _____ mmHg	
Metabolic syndrome (NCEP) Confirm metabolic syndrome if there are <u>three</u> or more of the following: <ul style="list-style-type: none"> ✓ A waistline of 40 inches or more for men and 35 inches or more for women ✓ A blood pressure of 130/85 mm Hg or higher ✓ A triglyceride level above 150 mg/dl ✓ A fasting blood glucose (sugar) level greater than 110 mg/dl ✓ A high density lipoprotein level (HDL) less than 40 mg/dl (men) or under 50 mg/dl (women) 			
12.	Does the patient have Metabolic Syndrome (NCEP) PE_Met	<input type="checkbox"/> ₀ NO <input type="checkbox"/> ₁ YES	
Canadian Cardiovascular Class: I. Ordinary physical activity, such as walking and climbing stairs, does not cause angina. Angina with strenuous or rapid or prolonged exertion at work or recreation. II. Slight limitations of ordinary activity. Walking or climbing stairs rapidly, walking uphill, walking or stair climbing after meals, or in cold, or in wind, or under emotional stress, or only during the few hours after awakening. Walking more than two blocks on the level and climbing more than one flight of ordinary stairs at a normal pace and in normal conditions. III. Marked limitation of ordinary physical activity. Walking one to two blocks on the level and climbing more than one flight of stairs in normal conditions and at normal pace. IV. Inability to carry on any physical activity without discomfort - angina syndrome may be present at rest.			
13.	What is the patient's CCS classification at this visit? PE_AnginaDef	<input type="checkbox"/> ₀ NO ANGINAL SYMPTOMS <input type="checkbox"/> ₂ II <input type="checkbox"/> ₁ I <input type="checkbox"/> ₃ III <input type="checkbox"/> ₄ IV	



REVASCULARIZATION

SITE ID: _____	PATIENT ID: _____
Patient Initials: _____	

INSTRUCTIONS: Fill this form out if the patient has any revascularization procedure.

AIM-HIGH Physician Investigator must review materials to determine whether revascularization was “symptom-driven” or not. See reverse side for definitions.

BE SURE TO SUBMIT ALL DOCUMENTING MATERIALS TO AXIO RESEARCH AS SOON AS POSSIBLE.

Table Name: RV

1.	Date of revascularization procedure <i>RV_Date</i>	_____/_____/_____ USE (MM/DD/YYYY)
2.	Type of revascularization <i>RV_Type</i>	<input type="checkbox"/> 1 CARDIAC <input type="checkbox"/> 2 CERBROVASCULAR <input type="checkbox"/> 3 PERIPHERAL
3.	What type of cardiac procedure? <i>RV_CardType</i>	<input type="checkbox"/> 1 ANGIOPLASTY WITHOUT STENT <input type="checkbox"/> 2 STENT <input type="checkbox"/> 3 OTHER PCI (E.G. ATHERECTOMY, ROTATIONAL ABLATION LASER) <input type="checkbox"/> 4 CABG
4.	Was the procedure performed as an in-patient procedure? <i>RV_hospital</i>	<input type="checkbox"/> 0 NO <input type="checkbox"/> 1 YES
5.	Date of admission (mm/dd/yyyy) <i>RV_adminDt</i>	_____/_____/_____ USE (MM/DD/YYYY)
6.	Date of discharge (mm/dd/yyyy) <i>RV_disDt</i>	_____/_____/_____ USE (MM/DD/YYYY)
7.	Did an MI occur within 3 days following the procedure? <i>RV_MI</i>	<input type="checkbox"/> 0 NO <input type="checkbox"/> 1 YES
8.	Did AIM-HIGH investigator review materials for this event? <i>RV_Review</i>	<input type="checkbox"/> 0 NO <input type="checkbox"/> 1 YES
9.	Was the procedure “symptom driven”? <i>RV_Symptom</i>	<input type="checkbox"/> 0 NO <input type="checkbox"/> 1 YES <input type="checkbox"/> 9 UNABLE TO DETERMINE

Please indicate below what was the basis for determination of “symptom driven”.

10.	Medical records (e.g., admission or discharge notes, operative reports, etc. Include in documentation and send to Coordinating Center)	<input type="checkbox"/> 0 NO <input type="checkbox"/> 1 YES <i>RV_Records</i>
11.	Patient report <i>RV_Report</i>	<input type="checkbox"/> 0 NO <input type="checkbox"/> 1 YES
12.	AIM-HIGH Physician evaluation (summarize in signed narrative and send to Coordinating Center) <i>RV_AHeval</i>	<input type="checkbox"/> 0 NO <input type="checkbox"/> 1 YES
13.	Other physician evaluation (obtain letter or other written documentation from physician to send to Coordinating Center)	<input type="checkbox"/> 0 NO <input type="checkbox"/> 1 YES <i>RV_Oteval</i>

Revascularization is defined as any of the following procedures:

- Coronary revascularization: PCI (includes percutaneous transluminal coronary angioplasty [PTCA], coronary stenting, and others such as brachytherapy, atherectomy, laser, and rotational ablation) or CABG.
- Cerebrovascular revascularization: carotid endarterectomy, carotid percutaneous transluminal angioplasty (with or without stent).
- Peripheral revascularization: peripheral arterial bypass surgery, or any therapeutic intervention for critical leg ischemia (including thrombolysis)
- Renovascular surgery

Symptom driven is defined as:

- Symptoms lead to revascularization regardless of whether or not the procedure itself is successful
- Worsening symptoms after randomization associated with ischemia demonstrated on non-invasive testing or coronary disease progression at angiography followed by PCI or CABG at least 30 days after randomization
- Worsening symptoms after randomization associated with revascularization of the cerebrovascular or peripheral vascular system at least 30 days after randomization
- Persistent stable symptoms after randomization associated with ischemia demonstrated on non-invasive testing or coronary disease progression at angiography followed by PCI or CABG 6 or more months after randomization

Revascularization, not symptom driven is defined as:

- Revascularization procedures for restenosis, early or late stent thrombosis
- Elective coronary revascularization procedures in non-symptom driven patients even if non-invasive testing is abnormal since it cannot be determined if this represents disease that was present before randomization (for example, as part of a non-cardiac preoperative work-up, a non-invasive test reveals ischemia leading to angiography and coronary revascularization)



RUN-IN

SITE ID: _____	PATIENT ID: _____
Patient Initials: _____	

Table Name: RunI

INSTRUCTIONS: Fill this form out at completion of run-in, whether or not the patient is to be randomized.

1.	Date Niacin Extended-Release was dispensed.	<u>RunI_StartDt</u> ____ / ____ / ____ USE (MM/DD/YYYY)	
2.	How frequently did the patient experience flushing? RunI_Flush	<input type="checkbox"/> ₁ NO FLUSHING REPORTED <input type="checkbox"/> ₂ INFREQUENTLY (ONLY A FEW TIMES DURING THIS PERIOD)	<input type="checkbox"/> ₃ MODERATELY FREQUENTLY MANY DAYS, BUT NOT EVERY DAY) <input type="checkbox"/> ₄ DAILY (ALMOST EVERY DAY, USUALLY FOLLOWING THE DOSE)
3.	On average, how severe (annoying) were the flushing episodes?	<input type="checkbox"/> ₀ NO SYMPTOMS <input type="checkbox"/> ₁ MILD	<input type="checkbox"/> ₂ MODERATE <input type="checkbox"/> ₃ SEVERE RunI_Flush2
4.	Did the patient take aspirin or other analgesic prior to taking the Niacin Extended-Release?	<input type="checkbox"/> ₀ NO <input type="checkbox"/> ₁ YES	RunI_Prior
5.	Maximum niacin dose tolerated.	<input type="checkbox"/> ₀ NONE TOLERATED <input type="checkbox"/> ₁ 500 MG/DAY <input type="checkbox"/> ₂ 1000 MG/DAY	<input type="checkbox"/> ₃ 1500 MG/DAY <input type="checkbox"/> ₄ 2000 MG/DAY RunI_MaxDose
<i>If patient tolerated less than 1,500 mg/day, select the reasons why below.</i>			
6.	Intolerable flushing despite aspirin/NSAID co-therapy	<input type="checkbox"/> ₀ NO <input type="checkbox"/> ₁ YES	RunI_Flush_ASA
7.	Abnormal heart rhythm or heart rate	<input type="checkbox"/> ₀ NO <input type="checkbox"/> ₁ YES	RunI_Arrhythmia
8.	Glycemic control in diabetics	<input type="checkbox"/> ₀ NO <input type="checkbox"/> ₁ YES	RunI_GlycControl
9.	Pruritis (itching)	<input type="checkbox"/> ₀ NO <input type="checkbox"/> ₁ YES	RunI_Itch
10.	Other	<input type="checkbox"/> ₀ NO <input type="checkbox"/> ₁ YES	RunI_OthIntol
11.	Describe other symptoms that made Niacin Extended-Release intolerable.	_____ RunI_Spc_othIntol _____ _____	
12.	How many bottles of Zocor (simvastatin) were dispensed during Run-In?	<input type="checkbox"/> ₀ NONE RunI_Sim_Disb	<input type="checkbox"/> ₁ ONE <input type="checkbox"/> ₂ TWO

Continue 2nd page



RUN-IN

SITE ID: _____	PATIENT ID: _____
Patient Initials: _____	

13.	How many bottles of Niacin Extended-Release were dispensed during Run-In?	<input type="checkbox"/> ₁ ONE RunI_Niac_Dis	<input type="checkbox"/> ₂ TWO
14.	Number of Niacin Extended-Release tablets returned.	_____ RunI_NiaspanRtn	
15.	Was adherence poor (or suspected as poor)? If yes, select the primary reason. RunI_BadWhy	<input type="checkbox"/> ₀ GOOD COMPLIANCE <input type="checkbox"/> ₄ PATIENT DECISION <input type="checkbox"/> ₁ ADVERSE CLINICAL SYMPTOMS <input type="checkbox"/> ₅ SUPPLY RAN OUT <input type="checkbox"/> ₂ PATIENT FORGETFUL <input type="checkbox"/> ₆ UNKNOWN <input type="checkbox"/> ₃ NON-STUDY PHYSICIAN RECOMMENDED DIFFERENT DOSE <input type="checkbox"/> ₇ OTHER	
16.	If other reason for poor adherence, please describe. RunI_BadSpWhy	_____ _____ _____	
<p>Confirm whether the patient can be randomized to the study. If the patient CANNOT be randomized to the study, please give the reason why and mark the patient as DISCONTINUED.</p> <p>If the patient will be randomized, complete and RANDOMIZE using the Web system.</p>			
17.	Will patient be randomized to double-blind phase? RunI_Rand	<input type="checkbox"/> ₀ NO <input type="checkbox"/> ₁ YES	
18.	If not, why? RunI_WhyNot	<input type="checkbox"/> ₁ DID NOT TOLERATE AT LEAST 1,500 MG/DAY OF NIACIN EXTENDED-RELEASE <input type="checkbox"/> ₄ PATIENT DIED <input type="checkbox"/> ₂ PATIENT REFUSAL <input type="checkbox"/> ₅ EXCLUSION CRITERIA <input type="checkbox"/> ₃ REFERRING PHYSICIAN REFUSAL <input type="checkbox"/> ₆ POOR ADHERENCE <input type="checkbox"/> ₇ OTHER INTERVENING EVENT	
19.	If other intervening event, please specify RunI_SpcWhyNot	_____ _____ _____	



SCREENING & ELIGIBILITY

SITE ID: _____	PATIENT ID: _____
Patient Initials: _____	

Table Name: INCL

INSTRUCTIONS: Please complete at the Screening Visit.

INCL_Age	1.	Is the patient at least 45 years old?	<input type="checkbox"/> _0 NO	<input type="checkbox"/> _1 YES
Risk Factors: At least one risk factor (question 2-6) must be documented.				
INCL_CAD	2.	Does the patient have documented multi-vessel CAD (with one or more $\geq 50\%$ stenosis in two major epicardial coronary arteries)?	<input type="checkbox"/> _0 NO	<input type="checkbox"/> _1 YES
INCL_MI	3.	Has the patient experienced a documented myocardial infarction?	<input type="checkbox"/> _0 NO	<input type="checkbox"/> _1 YES
INCL_ACS	4.	Has the patient been hospitalized for acute coronary syndrome (ACS) with objective evidence of ischemia?	<input type="checkbox"/> _0 NO	<input type="checkbox"/> _1 YES
INCL_CVD	5.	Does the patient have documented cerebrovascular or carotid disease?	<input type="checkbox"/> _0 NO	<input type="checkbox"/> _1 YES
INCL_PAD	6.	Does the patient have documented symptomatic peripheral artery disease (PAD)?	<input type="checkbox"/> _0 NO	<input type="checkbox"/> _1 YES

If the patient meets inclusion criteria 1-6, has signed the screening consent, and has no obvious clinical exclusions, then enter this patient into the eDC system.

Assign an AIM-HIGH ID and obtain screening blood sample.

7.	Was the patient taking a <i>statin</i> drug at the time of screening? INCL_OnStatin	<input type="checkbox"/> _0 NO	<input type="checkbox"/> _1 YES
8.	If yes, which? INCL_StatinType	<input type="checkbox"/> _1 Atorvastatin (Lipitor®)	<input type="checkbox"/> _4 Pravastatin (Pravaco®)
		<input type="checkbox"/> _2 Fluvastatin (Lescol®)	<input type="checkbox"/> _5 Rosuvastatin (Crestor®)
		<input type="checkbox"/> _3 Lovastatin (Altacor® or Mevacor®)	<input type="checkbox"/> _6 Simvastatin (Zocor®)
		<input type="checkbox"/> _7 Other	
9.	If other, please specify INCL_StatinOth	_____	
10.	What dose level of statin (in mgs) is the patient taking? INCL_StatinDose	_____ MGS/DAY	
11.	Is LDL-C in the protocol specified range? INCL_LDL	<input type="checkbox"/> _0 NO	<input type="checkbox"/> _1 YES
12.	Is HDL-C in the protocol specified range? INCL_HDL	<input type="checkbox"/> _0 NO	<input type="checkbox"/> _1 YES
13.	Are the triglycerides in the protocol specified range? INCL_TG	<input type="checkbox"/> _0 NO	<input type="checkbox"/> _1 YES

LDL Level	10 mg		20 mg		40 mg		80 mg	
	mg/dL	mmol/L	mg/dL	mmol/L	mg/dL	mmol/L	mg/dL	mmol/L
None	≤ 160	≤ 4.0	≤ 160	≤ 4.0	≤ 160	≤ 4.0	≤ 160	≤ 4.0
Atorvastatin	≤ 100	≤ 2.6	≤ 90	≤ 2.3	≤ 82	≤ 2.1	≤ 77	≤ 2.0
Pravastatin*	≤ 125	≤ 3.2	≤ 115	≤ 3.0	≤ 104	≤ 2.7	≤ 98	≤ 2.5
Simvastatin	≤ 115	≤ 3.0	≤ 104	≤ 2.7	≤ 98	≤ 2.5	≤ 86	≤ 2.2
Fluvastatin	--	--	≤ 125	≤ 3.2	≤ 120	≤ 3.1	≤ 102	≤ 2.6

HDL-C \leq (men)	40 mg/dl (1.0 mmol)	HDL-C \leq (men)	42 mg/dl (1.1 mmol)
HDL-C \leq (women)	50 mg/dl (1.3 mmol)	HDL-C \leq (women)	53 mg/dl (1.4 mmol)
TG between	150 - 400 mg/dl (1.7-4.5 mmol)	TG between	125 - 400 mg/dl (1.4-4.5 mmol)

*or Lovastatin **for Rosuvastatin 5 mg use 100 mg/dL (2.6 mmol/L)

No or Off Statin Therapy	On Statin Therapy
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SERUM CHEMISTRY

SITE ID: _____	PATIENT ID: _____
Patient Initials: _____	

INSTRUCTIONS: Review the Serum Chemistry data from the Central Lab and fill out the form below. Describe if the value for each was clinically significant. If yes, please have the **AIM-HIGH** physician provide a diagnostic comment. If measurement for an analyte was **NOT** done, please skip the question(s).

Table Name: Scm

	Visit	<input type="checkbox"/> BASELINE <input type="checkbox"/> 1 MONTHS <input type="checkbox"/> 3 MONTHS <input type="checkbox"/> 6 MONTHS	<input type="checkbox"/> 12 MONTHS <input type="checkbox"/> 18 MONTHS <input type="checkbox"/> 24 MONTHS <input type="checkbox"/> 30 MONTHS	<input type="checkbox"/> 36 MONTHS <input type="checkbox"/> 42 MONTHS <input type="checkbox"/> 48 MONTHS <input type="checkbox"/> 54 MONTHS	<input type="checkbox"/> 60 MONTHS If other visit, _____ Month
1.	Date the blood draw was taken <i>mm/dd/yyyy</i>)	_____ / _____ / Scm_Date USE (MM/DD/YYYY)			
2.	Had the patient fasted prior to the blood draw?	<input type="checkbox"/> ₀ NO Scm_Fast <input type="checkbox"/> ₁ YES			
3.	Creatinine Kinase (CK) Scm_CK	<input type="checkbox"/> ₀ NORMAL <input type="checkbox"/> ₃ LOW, AT CLINICAL WARNING LEVEL <input type="checkbox"/> ₁ ABNORMAL, BUT NOT SIGNIFICANT <input type="checkbox"/> ₄ HIGH, AT CONCERN LEVEL <input type="checkbox"/> ₂ LOW, AT CONCERN LEVEL <input type="checkbox"/> ₅ HIGH, AT CLINICAL WARNING LEVEL			
4.	If levels are clinically significant, provide comment.	Scm_CK_Cm			
5.	Uric Acid Scm_UA	<input type="checkbox"/> ₀ NORMAL <input type="checkbox"/> ₃ LOW, AT CLINICAL WARNING LEVEL <input type="checkbox"/> ₁ ABNORMAL, BUT NOT SIGNIFICANT <input type="checkbox"/> ₄ HIGH, AT CONCERN LEVEL <input type="checkbox"/> ₂ LOW, AT CONCERN LEVEL <input type="checkbox"/> ₅ HIGH, AT CLINICAL WARNING LEVEL			
6.	If levels are of clinically significant, please provide comments.	Scm_UA_Cm			
7.	HGBA1c Scm_HGBA	<input type="checkbox"/> ₀ NORMAL <input type="checkbox"/> ₃ LOW, AT CLINICAL WARNING LEVEL <input type="checkbox"/> ₁ ABNORMAL, BUT NOT SIGNIFICANT <input type="checkbox"/> ₄ HIGH, AT CONCERN LEVEL <input type="checkbox"/> ₂ LOW, AT CONCERN LEVEL <input type="checkbox"/> ₅ HIGH, AT CLINICAL WARNING LEVEL			
8.	If levels are of clinically significant, please provide comments.	Scm_HGBA_Cm			
9.	Glucose Scm_Glu	<input type="checkbox"/> ₀ NORMAL <input type="checkbox"/> ₃ LOW, AT CLINICAL WARNING LEVEL <input type="checkbox"/> ₁ ABNORMAL, BUT NOT SIGNIFICANT <input type="checkbox"/> ₄ HIGH, AT CONCERN LEVEL <input type="checkbox"/> ₂ LOW, AT CONCERN LEVEL <input type="checkbox"/> ₅ HIGH, AT CLINICAL WARNING LEVEL			
10.	If levels are of clinically significant, please provide comments.	Scm_Glu_Cm			
11.	Aspartate Transaminase (AST) Scm_AST	<input type="checkbox"/> ₀ NORMAL <input type="checkbox"/> ₃ LOW, AT CLINICAL WARNING LEVEL <input type="checkbox"/> ₁ ABNORMAL, BUT NOT SIGNIFICANT <input type="checkbox"/> ₄ HIGH, AT CONCERN LEVEL <input type="checkbox"/> ₂ LOW, AT CONCERN LEVEL <input type="checkbox"/> ₅ HIGH, AT CLINICAL WARNING LEVEL			
12.	If levels are of clinically significant, please provide comments.	Scm_AST_Cm			

Continue 2nd page



SERUM CHEMISTRY

SITE ID: _____	PATIENT ID: _____
	Patient Initials: _____

13.	Creatinine <i>Scm_Cre</i>	<input type="checkbox"/> 0 NORMAL <input type="checkbox"/> 1 ABNORMAL, BUT NOT SIGNIFICANT <input type="checkbox"/> 2 LOW, AT CONCERN LEVEL	<input type="checkbox"/> 3 LOW, AT CLINICAL WARNING LEVEL <input type="checkbox"/> 4 HIGH, AT CONCERN LEVEL <input type="checkbox"/> 5 HIGH, AT CLINICAL WARNING LEVEL
14.	If levels are of clinically significant, please provide comments.	<i>Scm_Cre_Cm</i> _____	
15.	Creatinine Clearance <i>Scm_CC</i>	<input type="checkbox"/> 0 NORMAL <input type="checkbox"/> 1 ABNORMAL, BUT NOT SIGNIFICANT <input type="checkbox"/> 2 LOW, AT CONCERN LEVEL	<input type="checkbox"/> 3 LOW, AT CLINICAL WARNING LEVEL <input type="checkbox"/> 4 HIGH, AT CONCERN LEVEL <input type="checkbox"/> 5 HIGH, AT CLINICAL WARNING LEVEL
16.	If levels are of clinically significant, please provide comments.	<i>Scm_CC_Cm</i> _____	



STUDY TERMINATION

SITE ID: _____	PATIENT ID: _____
Patient Initials: _____	

INSTRUCTIONS: Fill this form out at the last study visit for all patients (including early termination)

		Table Name: Term	
1.	Last Patient Contact Date (mm/dd/yyyy)	<div style="display: flex; justify-content: space-between;"> Term_Date Use (MM/DD/YYYY) </div> _____ / _____ / _____	
2.	What was the primary reason for withdrawal from the study? If death, complete Death Event form and submit documenting materials.	<input type="checkbox"/> ₁ END OF STUDY <input type="checkbox"/> ₂ PROTOCOL VIOLATION <input type="checkbox"/> ₃ PATIENT REQUEST	<input type="checkbox"/> ₄ NON-STUDY PHYSICIAN REQUEST <input type="checkbox"/> ₅ DEATH <input type="checkbox"/> ₆ LOST TO FOLLOW-UP Term_Reason
3.	Did the patient remain on study drug throughout the trial? If no, make sure that a Drug Dose Adjustment/Discontinuation page documents when study drug was discontinued.	<input type="checkbox"/> ₀ NO <input type="checkbox"/> ₁ YES	Term_Drug
4.	If still alive and withdrawn prior to end of study, did patient agree to allow follow-up through medical records for study endpoints? If yes, obtain consent to request medical records.	<input type="checkbox"/> ₀ NO <input type="checkbox"/> ₁ YES	Term_MedRecs
5.	Will patient remain on lipid lowering/modifying treatments? If yes, which one(s)?	<input type="checkbox"/> ₀ NO <input type="checkbox"/> ₁ YES	Term_LipidTx
6.	Statins	<input type="checkbox"/> ₀ NO <input type="checkbox"/> ₁ YES	Term_Statin
7.	Bile Acid sequestrates	<input type="checkbox"/> ₀ NO <input type="checkbox"/> ₁ YES	Term_BileAcid
8.	Nicotinic acid	<input type="checkbox"/> ₀ NO <input type="checkbox"/> ₁ YES	Term_Nicotin
9.	Fibric acids	<input type="checkbox"/> ₀ NO <input type="checkbox"/> ₁ YES	Term_Fibric
10.	Cholesterol absorption inhibitors	<input type="checkbox"/> ₀ NO <input type="checkbox"/> ₁ YES	Term_Absorb
11.	Other lipid modifying agents	<input type="checkbox"/> ₀ NO <input type="checkbox"/> ₁ YES	Term_OtherDr
12.	Therapeutic lifestyle changes (diet & exercise) ONLY	<input type="checkbox"/> ₀ NO <input type="checkbox"/> ₁ YES	Term_TLC

SITE ID: _____

PATIENT ID: _____

Patient Initials: _____

SUSPECTED TOXICITY

Table Name: TOX

INSTRUCTIONS: Add a row to the form each time drug toxicity is suspected.

1.	Date evaluated (mm/dd/yyyy) <i>Tox_Dt</i>	____ / ____ / _____ Use (MM / DD / YYYY)
2.	What is the reason for completion? <i>Tox_Lab</i>	<input type="checkbox"/> ₁ HEPATOTOXICITY <input type="checkbox"/> ₂ MYOPATHY <input type="checkbox"/> ₃ LOW LDL <input type="checkbox"/>
3.	Most recent CK level (in U/L) <i>Tox_CK</i>	____
4.	Most recent AST level (in U/L) <i>Tox_AST</i>	____
5.	Most recent ALT level (in U/L) <i>Tox_ALT</i>	____
6.	Did the patient experience fatigue? (If yes, note severity) <i>Tox_Fatigue</i>	<input type="checkbox"/> ₀ NO SYMPTOMS <input type="checkbox"/> ₂ MODERATE <input type="checkbox"/> ₁ MILD <input type="checkbox"/> ₃ SEVERE
7.	Did patient report muscle aches or weakness? (If yes, note severity) <i>Tox_Aches</i>	<input type="checkbox"/> ₀ NO SYMPTOMS <input type="checkbox"/> ₂ MODERATE <input type="checkbox"/> ₁ MILD <input type="checkbox"/> ₃ SEVERE
8.	Did patient report diarrhea? (If yes, note severity) <i>Tox_Diarrhea</i>	<input type="checkbox"/> ₀ NO SYMPTOMS <input type="checkbox"/> ₂ MODERATE <input type="checkbox"/> ₁ MILD <input type="checkbox"/> ₃ SEVERE
9.	Did the patient experience nausea or vomiting? (If yes, note severity) <i>Tox_Nausea</i>	<input type="checkbox"/> ₀ NO SYMPTOMS <input type="checkbox"/> ₂ MODERATE <input type="checkbox"/> ₁ MILD <input type="checkbox"/> ₃ SEVERE
10.	Did the patient report any marked changes in urine? (If yes, note severity) <i>Tox_Urine</i>	<input type="checkbox"/> ₀ NO SYMPTOMS <input type="checkbox"/> ₂ MODERATE <input type="checkbox"/> ₁ MILD <input type="checkbox"/> ₃ SEVERE
11.	Did the patient show signs of jaundice? (If yes, note severity) <i>Tox_jaundice</i>	<input type="checkbox"/> ₀ NO SYMPTOMS <input type="checkbox"/> ₂ MODERATE <input type="checkbox"/> ₁ MILD <input type="checkbox"/> ₃ SEVERE