Time & Events Schedule

		[S]	[S]	[S]	[D,R]	[S]	[D]	[S]	[S]
Visit Calculator Enabled? *	Yes / No								
If Visit Calculator is enabled, specify Visit Start Hours for Scheduled Visits:									
	Visit Name	**Baseline Visit**	**Day 60 Visit**	**Diagnostic Testing**	**Follow-up Visit**	**Imaging**	**Cross Active Study**	**Insig CAD**	**FU Blood Draw**
	Visit Mnemonic	**BASE**	**60D**	**DIAGTST**	**FU**	**QC**	**CAS**	**INSIGCAD**	**FUBD**
SUBJECT CONTACT INFORMATION	SCI	1							
VISIT STATUS	VISIT	2	1						
VISIT FOLLOW-UP	DOV				1				
FOLLOW-UP ASSESSMENTS	FU		2		2				
FOLLOW-UP	FU2		3DF		3DF				
END OF STUDY	TERM		16						
INCLUSION/EXCLUSION	ELIG	3							
DEMOGRAPHICS	DEM	4							
PREGNANCY TEST	PREG	5 DF							
VITALS	VITALS	6							
CARDIAC RISK FACTORS	CRDRSK	7							
PROVIDERS ASSESSMENT OF PATIENT RISK	PAPR	8							
PRESENTING SYMPTOMS 1	PS1	9 RF							
PRESENTING SYMPTOMS 2	PS2	10							
OFFICE ECG	ECG	11							
DIAGNOSTIC LABORATORY TESTING	DXLAB	12							
STATUS	STATUS	13							
CONCOMITANT MEDICATIONS	CONMED	14 RF/ DF	4 RF/DF		4 RF/DF				
BIOMARKER/GENETICS COLLECTION	BMKGEN	15DF							
RANDOMIZATION	RAND	16							
RANDOMIZATION 1	RAND1			1					
PATIENT SATISFACTION QUESTIONNAIRE	PSQ		5						
MEDICAL THERAPY/LIFESTYLE COUNSELLING	MTLC		6						
INVESTIGATOR SIGNATURE	SIG		17						
EXERCISE ECG STRESS TEST	EEST			2 RF/DF					
DOBUTAMINE STRESS TEST DIAGNOSTIC TESTING	DBST			3 RF/DF					
VASODILATOR PHARMACOLOGIC STRESS TEST DIAGNOSTIC TESTING	VPST			4 RF/DF					
STRESS ECHO 1	ECHO1			6 RF/DF					
STRESS ECHO 2	ECHO2			7 RF/DF					
STRESS NUCLEAR 1	NUC1			8 RF/DF					
STRESS NUCLEAR 2	NUC2			9 RF/DF					
CTA TEST PHYSICIAN READING	CTA			10 RF/DF					
CTA 2	CTA2			11 RF/DF					
CTA SAFETY EVENTS	CTASF			12 RF/DF					
EXERCISE ECG SAFETY EVENTS	EETSF			13 RF/DF					
STRESS ECHO SAFETY EVENTS	ECHOSF			14 RF/DF					

PROMISE CRF ANNO.xls

Item	Code							
STRESS NUCLEAR SAFETY EVENTS	NUCSF					15 RF/DF		
CARDIAC CATHERIZATION	CC	7 RF/DF						
REVASCULARIZATION	REVASC	8 DF						
REVASCULARIZATION1	REVASC1	8 RF/DF						
HOSPITALIZATION/EMERGENCY DEPT VISIT	HOSPER	9 RF/DF		5 RF/DF				
DEATH EVENT	DEATH				1			
STROKE/TIA EVENT	STROKE	11 RF/DF		7 RF/DF				
MI/UNSTABLE ANGINA EVENT	MI	12 RF/DF		8 RF/DF				
BLEEDING EVENT	BLEED	13 RF/DF		9 RF/DF				
RENAL FAILURE EVENT	RENAL	14 RF/DF		10 RF/DF				
UNSTABLE ANGINA HOSPITALIZATION	ANGINA	15RF/DF		11 RF/DF				
ANAPHYLAXIS	ANAPHY	16RF/DF		12 RF/DF				
IMAGE QUALITY CONTROL STATUS	QCSTAT					1RF		
QC EXERCISE ECG - TECHNICAL QUALITY ASSESSMENT	ECGQC					2 RF/DF		
QC STRESS ECHO - TECHNICAL QUALITY ASSESSMENT	ECHOQC					3 RF/DF		
QC STRESS NUCLEAR - TECHNICAL QUALITY ASSESSMENT	NUCQC					4 RF/DF		
QC CTA - TECHNICAL QUALITY ASSESSMENT	CTAQC					9 RF/DF		
QC CARDIAC CATH - TECHNICAL QUALITY ASSESSMENT	CCQC					11 RF/DF		
CORE LAB OVERREAD	CLRD					5		
EXERCISE ECG STRESS TEST - CORE LAB	EEST_CL					6 RF/DF		
STRESS ECHO - CORE LAB	ECHO_CL					7 RF/DF		
STRESS NUCLEAR - CORE LAB	NUC_CL					8 RF/DF		
CTA - CORE LAB	CTA_CL					10 RF/DF		
CARDIAC CATH - CORE LAB	CC_CL					12 RF/DF		
ACRIN Z5	ACRIN_Q					13 RF		
PATIENT STATUS	PTSTATUS		13					
INSIGNIFICANT CAD	INCAD						1	
CEC Cardiac Catheterization Adjudication Form	CECINCAD						2 DF	
QCA1	QCA						3 RF/DF	
FOLLOW UP BLOOD DRAW CONSENT	FUBDC							1
FOLLOW UP BLOOD DRAW SAMPLE	FUBDS							2

PROMISE CRF ANNO.xls

NR   **FORM: VISIT STATUS (VISIT)**

			Code	Attributes	Range	Comments	SAS Name	SAS Label
1	Date of Visit	____/____/____		DATE	2010 - 2020		VISITDT	VISIT DATE

Enterable only by CRA, View by CDM

				Code	Attributes	Range	Comments	SAS Name	SAS Label
NR	**2**	SDV Status	⭕ Complete 100% SDV performed	1	I:3			SDVSTAT	SDV STATUS
			⭕ Not Completed	2					

Day 60 DOV is not 60 days (+?-) from screening DOV

NR **FORM: DATE OF VISIT (DOV)**

		Code	Attributes	Range	Comments	SAS Name	SAS Label
1	Date of Contact ____/____/____		DATE	2010 - 2020		VSDT	VISIT DATE
2	Contact Timepoint		I:3			VSTMPT	VISIT TIMEPOINT
	○ Month 6	1					
	○ Month 12	2					
	○ Month 18	3					
	○ Month 24	4					
	○ Month 30	5					
	○ Month 36	6					
	○ Month 42	7					
	○ Month 48	8					
	○ Month 54	9					
	○ Month 60	10					
	○ Month 66	11					
	○ Month 72	12					
	○ Month 78	13					
	○ Month 84	14					

This is a DOV form for repeating visit - forced DOV

Instructions for FU entry into this form

DOV is in chronological order

FORM: FOLLOW-UP ASSESSMENTS [FU]

			Code	Attributes	Range	Comments	SAS Name	SAS Label
1	Was visit performed?	O Yes, indicate type of visit	1	I:3			VSTPERF	VISIT PERFORMED
		O Mail	1	I:3			VSTTYPE	VISIT TYPE
		O Phone	2					
		O Office/Clinic (60 day visit only)	3					
		No, indicate reason not O performed	0					
		O Death (Complete Death Event Form)	1	I:3			REASPERF	REASON NOT PERFORMED
		O Subject refused	2					
		O Unable to contact	3					
		O Consent withdrawn	4					
2	Who answered the follow-up questions?	O Subject	1	I:3			RESP	RESPONDENT
		O Proxy/subject representative	2					
		O Not done	97					
3	Was the Follow-up Assessment (FU2) performed? (If any known events have occurred, answer YES, regardless of whether or not visit was completed.)	O Yes	1	I:3			ASSPERF	ASSESSMENT PERFORMED
		O No	0					

Enterable only by CRA, View by CDM

			Code	Attributes	Range	Comments	SAS Name	SAS Label
NR 4	SDV Status	O Complete 100% SDV performed	1	I:3			SDVSTA2	SDV STATUS
		O Not Completed	2					

No edit checks
Dynamic -- Question 3 - if YES,
INTEVT appears

FORM: FOLLOW-UP (FU2) [DF]

			Code	Attributes	Range	Comments	SAS Name	SAS Label
Is the subject still experiencing the same type of chest discomfort or other symptoms that led the subjects doctor to order a stress test or heart CT scan when the subject first entered the PROMISE trial?	O **Yes, but symptoms are improved**		2	I:3			SMCHTPN	EXPERIENCING SAME CHEST PN
	O **Yes, symptoms are similar/unchanged**		3					
	O **Yes, symptoms are worse**		4					
	O **No, symptoms are completely resolved**		1					
	O **Unknown/unable to answer.**		99					
Has the subject smoked tobacco in the past two weeks?	O **Yes**		1	I:3			PTSMOK2	PATIENT SMOKED
	O **No**		0					
Is the subject following a specific diet to promote heart health?	O **Yes**		1	I:3			PTDIET2	PATIENT DIET
	O **No**		0					
During the past month, did the subject participate in any physical activities or exercise regularly (1 or more times per week)? Examples include: running, aerobics, golf, gardening or walking, etc.	O **Yes**		1	I:3			PTEXER2	PATIENT EXERCISE
	O **No**		0					
Weight	_____			F:9	70-150 where WTUN = 2 ??-330 where WTUN= 1	Precision 0 Range for DVC checks	WT2	WEIGHT
Weight unit	O **lbs**		1	I:3			WTUN2	WEIGHT UNIT
	O **kg**		2					
Since the last contact, did the subject have any hospitalizations/emergency department visits for any reason?	O **Yes, complete HOSPER form**		1	I:3			HOSPER	HOSPITAL OR ER VISIT
	O **No**		0					
Did the subject have chest pain, unstable angina (acute coronary syndrome or 'ACS')?	O **Yes, complete Unstable Angina event form**		1	I:3			HVANG2	SUBJECT HAVE UNSTABLE ANGINA
	O **No**		0					
	O **Unknown/Don't know**		99					

NR (row label for Weight)

Question	Answer options			Code	Type	Range	Note	Variable	Label	
Did the subject have a heart attack (myocardial infarction/MI)?	O Yes, complete MI event form			1	I:3			HVMI2	SUBJECT HAVE MI	
	O No			0						
	O Unknown/Don't know			99						
Did the subject have shortness of breath or congestive heart failure?	Yes, complete Unstable O Angina event form			1	I:3			HVSOB2	SUBJECT HAVE SOB	
	O No			0						
	O Unknown/Don't know			99						
Did the subject have a stroke or cerebrovascular accident (CVA)?	Yes, complete Stroke event O form			1	I:3			HVSTRK2	SUBJECT HAVE STROKE	
	O No			0						
	O Unknown/Don't know			99						
Did the subject die?	O Yes, complete DEATH form			1	I:3			SUBDTH	SUBJECT DIE	
	O No			0						

For Day 60 visit - Indicate any tests other than the test(s) indicated at DIAGTST visit for question 7.

Question	Answer options			Code	Type	Range	Note	Variable	Label	
Since the last contact, did the subject undergo additional heart test(s)/procedures as an inpatient or outpatient?	Yes, Enter each test below O in add entry			1	I:3			HRTTSTPR	HEART TEST PROCEDURES	
	O No			0						
ADD ENTRY:										
Cardiac Diagnostic Test	O See Drop down list 1				I:3			HRTTST	HEART IMAGING TEST	see update to codelist wording below
Date of Test	_ _ /_ _/_ _ _ _				DATE	2010-2020	allow unk for day/month	TSTDT	TEST DATE	

For Day 60: Indicate any complications due to randomized test or any reported procedures or tests under the Cardiac Diagnostic Test section above. If any of these complications occurred, complete a hospitalization form.

Question	Answer options			Code	Type	Range	Note	Variable	Label
Severe bleeding (for example, requiring a transfusion)?	Yes , indicate date and O complete BLEED form			1	I:3			BLDEVT	BLEEDING EVENT
		_ _ /_ _/_ _ _ _			DATE	2010-2020	allow unk for day/month	BLDDT	BLEED EVENT DATE
	O No			0					
	O Unknown			99					
Shock (anaphylaxis) requiring emergency treatment	Yes , indicate date and O complete ANAPHY form			1	I:3			ANAPEVT	ANAPHYLAXIS EVENT
		_ _ /_ _/_ _ _ _			DATE	2010-2020	allow unk for day/month	ANAPDT	ANAPHYLAXIS EVENT DATE
	O No			0					
	O Unknown			99					
Renal (kidney) failure	Yes , indicate date and O complete RENAL form			1	I:3			RENEVT	RENAL EVENT
		_ _ /_ _/_ _ _ _			DATE	2010-2020	allow unk for day/month	RENDT	RENALEVENT DATE
	O No			0					
	O Unknown			99					

	Is the subject currently taking any medications (including vitamins and/or herbal supplements) on an ongoing basis?	O	Yes (complete ConMed form)			1	I:3			MEDTKN	**ANY MEDICATIONS TAKEN**
		O	No			0					
	Question 17 and 18 viewable and editable by site										
NR SV	**Was the subject told about any abnormalities outside of their heart that were seen on the initial [CTA or stress] test?**	O	No			0	I:3			TSTABN2	**TEST ABNORMALITIES**
		O	Yes			1					
NR SV	**If Q 18 is yes, has the subject had or is the subject scheduled to have any test or procedure to further investigate or treat that finding?**	O	No			0	I:3			TSTDONE2	**TEST PROCEDURES PERFORMED**
		O	Yes, indicate the following:			1					
			Type of test	See Drop Down List 2			I:3			IFTEST2	**INCIDENTAL FINDINGS TEST**
			Date of test _ _/_ _/_ _ _ _				DATE	2010-2020	allow unk for day/month	IFTSTDT2	**INC FINDINGS TEST DATE**
			Facility Name				S:200			IFFACNM2	**FACILITY NAME**
	Question 19 - viewable and editable by FU group- DELETE										
NR SV	**Since your last follow-up, have you had any test or procedure of the lung?**	O	No			0	I:3			TSTDONE3	**TEST PROCEDURES PERFORMED**
		O	Yes, indicate the following:			1					
			Type of test	See Drop Down List 2			I:3			IFTEST3	**INCIDENTAL FINDINGS TEST**
			Date of test _ _/_ _/_ _ _ _				DATE	2010-2020	allow unk for day/month	IFTSTDT3	**INC FINDINGS TEST DATE**
			Facility Name				S:200			IFFACNM3	**FACILITY NAME**
	Viewed and enterable only by CEC personnel										
NR	**Indicate any new event identified during adjudication**	❑	Death			1	I:3			CEC1	**ENDPOINT 1**
		❑	Myocardial Infarction			1	I:3			CEC2	**ENDPOINT 2**
		❑	Hospitalization for Unstable Angina			1	I:3			CEC3	**ENDPOINT 3**
		❑	Hospitalization for other acute CV problem			1	I:3			CEC4	**ENDPOINT 4**
		❑	Bleeding - Periprocedural Event			1	I:3			CEC5	**ENDPOINT 5**
		❑	Stroke or TIA - Periprocedural Event			1	I:3			CEC6	**ENDPOINT 6**

	Renal Failure - ☐ Periprocedural Event				1	I:3			CEC7	ENDPOINT 7
	Anaphylaxis (reaction to contrast dye or any sort of medication at testing) - ☐ Periprocedural Event				1	I:3			CEC8	ENDPOINT 8

Enterable only by CRA, View by CDM

NR	SDV Status	Complete 100% SDV ○ performed			1	I:3			SDVSTA3	SDV STATUS
		○ Not Completed			2					

Weight range

Drop Down List 1
Cardiac catheterization (heart cath, invasive angiogram) WITHOUT balloon angioplasty or stent
Cardiac catheterization (heart cath, invasive angiogram) WITH balloon angioplasty or stent
Stress echocardiogram (ECHO)
Cardiac (heart) CT - WITH contrast material given through an IV (known as CT Angiogram or CTA)
Cardiac (heart) CT - WITH NO contrast material given through an IV (known as CT Angiogram or CTA)
Exercise treadmill stress test
Nuclear stress test - SPECT scan
Nuclear stress test - PET scan

Drop Down List 2
PET scan
Chest X-ray
Chest CT scan
Chest MRI
Chest or lung biopsy
Chest or lung surgery
Bronchoscopy
Pulmonary function testing
Other

NR   **FORM: EARLY WITHDRAWAL/STUDY COMPLETION (TERM)**

Section 1: Day 60 Early Withdrawal/Study Completion - Complete this form based on the subject status at Day 60

	Question	Response				Code	Attributes	Range	Comments	SAS Name	SAS Label
1	Did the subject complete the study through Day 60?	O Yes				1	I:3			STUDYCOM	STUDY COMPLETED
		O No, indicate primary reason				0					
			O Consent withdrawn			1	I:3			REASON	REASON NOT COMPLETED
			O Unable to contact			2					
				Last known date alive: _ _ /_ _/_ _ _ _			DATE	2010-2020	ALLOW UNK FOR MONTH/DAY	ALIVEDT	DATE LAST KNOWN ALIVE
			O Physician decision			3					
			O Death, complete DEATH event form			4					
*			O Other, Specify			98	S:200			REASONSP	REASON SPECIFY
2	Has subject continued to the follow-up phase of the study?	O Yes				1	I:3			SUBCONT	SUBJECT CONTINUED TO FU
		O No, reason not continuing				0					
			O Consent withdrawn			1	I:3			RSNOCONT	REASON NOT CONTINUING
			O Death			2					

Enterable by CRA, Viewed by CDM

		Question	Response				Code	Attributes	Range	Comments	SAS Name	SAS Label
NR	3	SDV Required	☐ Yes				1	I:3			SDVREQ	SDV REQUIRED
NR	4	SDV Status	O Complete 100% SDV performed				1	I:3			SDVSTA4	SDV STATUS
			O Not Completed				2					

End of study date is before day 60 date of visit
date last know alive is after the end of study
date

_____

_____

FORM: Patient Status (PTSTATUS)

			Code	Attributes	Range	Comments	SAS Name	SAS Label
*	1	Date of Status _ _ /_ _/_ _ _ _		DATE	2010-2020		PSTATDT	PATIENT STATUS DATE
*	2	Current Patient Status						
		○ Active	1	I:3			CURSTATA	CURRENT STATUS ACTIVE
		Date of Last Contact : _ _ /_ _/_ _ _ _		DATE	2010-2020		CNTACTDT	PATIENT LAST CONTACT DATE
		❑ Annual follow-up		I:3			CURANNU	CURRENT STAT ANNUAL FU
		❑ Phone follow-up		I:3			CURAPHO	CURRENT STAT PHONE FU
		❑ Mail follow-up		I:3			CURAMAIL	CURRENT STAT MAIL FU
		❑ Email follow-up		I:3			CURAEMAI	CURRENT STAT EMAIL FU
		❑ Follow-up via family		I:3			CURAFAMI	CURRENT STAT FAMILY FU
		❑ Follow-up via healthcare provider		I:3			CURAHEAL	CURRENT STAT HEALTHCARE FU
		❑ Follow-up via medical records		I:3			CURAMEDR	CURRENT STAT MED REC FU
		❑ Currently unable to contact	1	I:3			CURAUNAB	CURRENT UNABLE TO CONTACT
		○ Dead	2					CURRENT STATUS DEAD
		Date of Death: _ _ /_ _/_ _ _ _		DATE	2010-2020		PSTATDDT	PATIENT STATUS DEATH DATE
		○ Consent Withdrawn	3					CURRENT STATUS WITHDRAWN
		Date of Withdrawl: _ _ /_ _/_ _ _ _		DATE	2010-2020		PSTATWDT	PATIENT STAT WITHDRAW DATE

			Code	Attributes	Range	Comments	SAS Name	SAS Label
1 Did subject meet all eligibility criteria?	O Yes		1	I:3			ELIG	ELIGIBILITY CRITERIA MET
	O No, indicate all criteria not met		0					
	❑	Inclusion Criteria not met	1	I:3			INCCRT	INCLUSION CRITERIA NOT MET
		Specify Number(s) _____		S:50			INCCRTNO	INCLUSION CRITERIA NUMBERS
	❑	Exclusion Criteria met	1	I:3			EXCCRT	EXCLUSION CRITERIA NOT MET
		Specify Number(s) _____		S:50			EXCCRTNO	EXCLUSION CRITERIA NUMBERS

Enterable only by CRA, View by CDM

			Code	Attributes	Range	Comments	SAS Name	SAS Label
NR 2 SDV Status	O Complete 100% SDV performed		1	I:3			SDVSTA5	SDV STATUS
	O Not Completed		2					

NR   FORM: DEMOGRAPHICS (DEM)

			Code	Attributes	Range	Comments	SAS Name	SAS Label
1	Date of birth	____/____/____		Date	1900-1980	Mapped from SCR.SCRDOBDT - editable by site	DOBDT	BIRTHDATE
2	Subject Age			F:9		Calculated by InForm	SUBAGE	SUBJECT AGE
3	Sex	O Male	1	I:3		Mapped from SCR.SCRSEX - editable by site	SEX	SEX
		O Female, is subject able to bear children?	2					
		O Yes	1	I:3			CHBPOT	CHILD BEARING POTENTIAL
		O No	0					
4	Ethnicity	O Hispanic or Latino	1	I:3			ETHNIC	ETHNICITY
		O Not Hispanic or Latino	2					
5	Race (check all that apply)	❑ White	1	I:3			WHITE	WHITE
		❑ Black or African American	1	I:3			BLACK	BLACK
		❑ Asian	1	I:3			ASIAN	ASIAN
		❑ American Indian or Alaska Native	1	I:3			INDIAN	INDIAN
		❑ Native Hawaiian or Other Pacific Islander	1	I:3			HAWAIIAN	NATIVE HAWAIIAN OR ISLANDER

Enterable only by CRA, View by CDM

			Code	Attributes	Range	Comments	SAS Name	SAS Label
NR 7	SDV Status	O Complete 100% SDV performed	1	I:3			SDVSTA6	SDV STATUS
		O Not Completed	2					

DOB range is not between __ and __
subject age not > 45 if male
subject age not > 50 if female

NR   FORM: PREGNANCY TEST (PREG) [DF]

						Code	Attributes	Range	Comments	SAS Name	SAS Label
1	Was pregnancy test performed?	O	Yes, indicate most recent test			97	I:3			PRGTST	PREG TEST
			Pregnancy test date		____/____/____	1	DATE	2010-2020	allow unk for day	PRGTSTDT	PREG TEST DATE
			Pregnancy test result	O	Negative	0	I:3			PRGRSLT	PREG TEST RESULT
				O	Positive	1					
		O	Not done			97					

Enterable only by CRA, View by CDM

						Code	Attributes	Range	Comments	SAS Name	SAS Label
NR	2	SDV Status	O	Complete 100% SDV performed		1	I:3			SDVSTA7	SDV STATUS
			O	Not Completed		2					

Need DVC for CTA and ECHO that pregnancy test result is present

Pregnancy test date is more than 30 days before the Screening DOV
Pregnancy test date is after scheduled date for testing

FORM: VITAL SIGNS (VITALS)

			Code	Attributes	Range	Comments	SAS Name	SAS Label
1	Date of vital signs	___/___/___		DATE	2010-2020	All Required	VTLDT	VITALS DATE
2	Weight			F:9	70-150 where WTUN = 2 ??-330 where WTUN= 1		WT1	WEIGHT
	Weight unit	O lbs	1	I:3			WTUN1	WEIGHT UNIT
		O kg	2					
3	Height			F:9	35-200 where HTUN = 2 ??-84 where HTUN = 1		HT	HEIGHT
	Height unit	O in	1	I:3			HTUN	HEIGHT UNIT
		O cm	2					
4	Pulse (bpm)	_____ bpm		I:3	40-220		PULSE	PULSE
5	Systolic blood pressure (arm)	_____ mmHg		I:3	40-250		BPSYS	SYSTOLIC BP
6	Diastolic blood pressure (arm)	_____ mmHg		I:3	40-200		BPDIA	DIASTOLIC BP
7	Was ankle BP performed?	O Yes, indicate systolic pressure	1	I:3			ANKBP	ANKLE BP
		_____ mmHg		I:3			ANKSYS	SYSTOLIC ANKLE BP
		O No	0					

Enterable only by CRA, View by CDM

			Code	Attributes	Range	Comments	SAS Name	SAS Label
NR 8	SDV Status	O Complete 100% SDV performed	1	I:3			SDVSTA8	SDV STATUS
		O Not Completed	2					

BMI and ABI will be calculated by Stats

ABI calculation: Ankle BP systolic/Arm BP Systolic

Date of Vitals is before screening DOV
Date of Vitals is a future date
Systolic BP Range
Diastolic BP Range
Height Range - If units are cm height is
not between 35-200. Height - if units
are in - height is not between 55 and
84
Weight Range - If unit is kg weight is
not between 70-150, Height - if units
is lbs, weight is not between 85-300

Pulse Range - not between 45 and 90
ANKLE BP Range

FORM: CARDIAC RISK FACTORS (CRDRSK)

				Code	Attributes	Range	Comments	SAS Name	SAS Label
1	Hypertension	○ Yes		1	I:3			HTN	HYPERTENSION
		○ No		0					
2	Diabetes	○ Yes		1	I:3			DIAB	DIABETES
			❑ Diet control	1	I:3			DIET1	DIET
			❑ Oral agent	1	I:3			ORAL1	ORAL
			❑ Insulin	1	I:3			INS1	INSULIN
		○ No		0					
3	Dyslipidemia	○ No		0	I:3			DYSLIP	DYSLIPIDEMIA
		○ Yes		1					
4	Cerebrovascular disease	○ Yes, check all that apply		1	I:3			CVD	CV DISEASE
			❑ History of TIA	1				HSTIA	HISTORY TIA
			❑ History of stroke	1	I:3			HSSTR	HISTORY STROKE
			❑ Carotid artery stenosis > or = 50% documented by invasive or noninvasive test: ultrasound, MR, CT, invasive angiography, etc.	1	I:3			HSCAS	HIST CAROTID ART STEN
			❑ History of carotid revascularization (endarterectomy, PTCA, stent, bypass)	1	I:3			HSRVS	HISTORY CAROTID REVAS
			❑ Unknown	1	I:3			CVUNK	CV DISEASE UNKNOWN
		○ No		0					
5	Peripheral artery disease	○ Yes, check all that apply		1	I:3			PAD	PERIPHERAL ARTERY DISEASE
			❑ Intermittent claudication	1	I:3			INTCLAU	INT CLAUDICATION
			❑ ABI < 0.9	1	I:3			ABI	ABI

#						Code				Var	Label
			☐ Peripheral artery (i.e. renal, subclavian, femoral, iliac) stenosis > or = 50% documented by invasive or noninvasive test: ultrasound, MR, CT, invasive angiography, etc.	1	I:3					PHARTST	PERIPHERAL ARTERY STENOSIS
			☐ History of peripheral revascularization (PTCA, stent, bypass) or amputation	1	I:3					HSPHREV	HISTORY PERIPHERAL REVAS
			☐ Non-traumatic amputation	1	I:3					NTRAMP	NON TRAUMATIC AMPUTATION
			☐ Documented aortic aneurysm with or without repair	1	I:3					AORANEU	AORTIC ANEURYSM
			☐ Unknown	1	I:3					PADUNK	PAD UNKNOWN
		○ No		0							
6	History of heart failure	○ Yes, indicate current NYHA Class		1	I:3					HRTFAIL	HEART FAILURE
			○ NYHA Class I	1	I:3					NYHACLS	NYHA CLASS
			○ NYHA Class II	2							
			○ NYHA Class III	3							
			○ NYHA Class IV	4							
			○ Unknown	99							
		○ No		0							
7	Tobacco smoking	○ Current smoker (within past 2 weeks)		2	I:3					SMOKE	SMOKING
		○ Former smoker		3							
		○ Never		1							
8	Family History of premature (<55 years) coronary artery disease (CAD)	○ Yes		1	I:3					FMHXCAD	FAMILY HISTORY CAD
		○ No		0							
9	History of depression	○ Yes		1	I:3					DEPRESS	DEPRESSION
		○ No		0							

10	During the past month, did the subject regularly (1 or more times per week) participate in any physical activities such as running, calisthenics, golf, gardening or walking for exercise ?	O Yes		1	I:3			PHYSACT	PHYSICAL ACTIVITY
		O No		0					

Enterable only by CRA, View by CDM

NR	11	SDV Status	O Complete 100% SDV performed		1	I:3			SDVSTA9	SDV STATUS
			O Not Completed		2					

FORM: PROVIDERS ASSESSMENT OF PATIENT RISK (PAPR)

Complete the following question prior to the randomized diagnostic test

			Code	Attributes	Range	Comments	SAS Name	SAS Label
1 Provider Credentials	○	MD/DO - Cardiologist	1	I:3			PROVCRED	PROVIDER CREDENTIALS
	○	MD/DO - Internal Medicine	2					
	○	MD/DO - Family Practice	3					
	○	MD/DO - Other	5					
	○	PA/NP	4					
	○	Other	98					
2 Based on your clinical judgment, what do you think the chances are that the subject has significant (> or = 70%) epicardial coronary stenois OR (> or = 50%) left main stenosis?	○	Very low (< 10%)	1	I:3			CLINJDG	CLINICAL JUDGEMENT OF RISK
	○	Low (10 - 30%)	2					
	○	Intermediate (31 - 70%)	3					
	○	High (71% - 90%)	4					
	○	Very high (> 90%)	5					
3 Would you characterize this patient's chest pain/discomfort (or other symptoms suggesting cardiac ischemia) as:	○	Typical (definite angina)	1	I:3			ANGSYMP	ANGINA SYMPTOMS
	○	Atypical (Probable angina)	2					
	○	Non-cardiac	3					

Enterable only by CRA, View by CDM

			Code	Attributes	Range	Comments	SAS Name	SAS Label
NR 11 SDV Status	○	Complete 100% SDV performed	1	I:3			SDVSTA10	SDV STATUS
	○	Not Completed	2					

FORM: PRESENTING SYMPTOMS 1 (PS1) [RF]

Section 1: Presenting Symptoms - Indicate all symptoms leading to referral
for testing choose only one of the symptoms as the primary symptom
NOTE: Enter primary symptom first

				Code	Attributes	Range	Comments	SAS Name	SAS Label
1	Symptom present	O		1	I:3			SYMPRSRB	SYMPTOM PRESENT CHECKED
			DROPDOWN List 1					SYMPRS	SYMPTOM PRESENT
		O	Other symptom, specify	98					
			_____		S:100			SYMSPEC	SYMPTOM SPECIFY
2	Primary symptom (mark only one symptom as Yes)	O	Yes	1	I:3			PRIMRY	PRIMARY SYMPTOM
		O	No	0					

NOTE: If CHEST PAIN/PRESSURE was not selected, confirm the subject had no Chest Pain or Pressure

Enterable only by CRA, View by CDM

				Code	Attributes	Range	Comments	SAS Name	SAS Label
NR	3 SDV Status	O	Complete 100% SDV performed	1	I:3			SDVSTA11	SDV STATUS
		O	Not Completed	2					

DROPDOWN List 1

1	Arm or shoulder pain
2	Back pain
3	Chest pain/pressure - substernal or left anterior
4	Chest pain/pressure - other
5	Diaphoresis/sweating
6	Dizziness/lightheaded
7	Epigastric pain/abdominal pain
8	Fatigue/weakness
9	Nausea/vomiting
10	Neck or jaw pain
11	Palpitations
12	Shortness of breath/dyspnea
13	Syncope

Symptom present is Other and Specify is not answered

Specify is answered but symptom present is not other

Primary Symptom = YES is present for more than one symptom

Primary symptom - Yes is not answered for one symptom

FORM: PRESENTING SYMPTOMS 2   (PS2)

			Code	Attributes	Range	Comments	SAS Name	SAS Label
1	**Is the primary symptom related to physical exertion or mental stress?**	O **Yes, occurs with mild exertion/mild stress**	2	I:3			**PSRLPE**	**PRIM SYM REL TO EXERTION**
		O **Yes, occurs with moderate exertion/moderate stress**	3					
		O **Yes, occurs with strenuous exertion/severe stress**	4					
		O **No, unrelated to exertion or stress**	1					
		O **Unknown**	99					
2	**Is the primary symptom relieved by rest or nitroglycerin within 10 minutes?**	O **Always**	1	I:3			**PAINRL**	**PAIN RELIEVED**
		O **Usually**	2					
		O **Rarely**	3					
		O **Never**	4					
		O **Unknown**	99					
	If Symptom of Chest Pain/Pressure was indicated, answer question 3							
NR 3	**Description of pain (check all that apply)**	❑ **Aching/dull**	1	I:3			**ACHDULL**	**ACHING PAIN**
		❑ **Burning/pins and needles**	1	I:3			**BURN**	**BURNING PAIN**
		❑ **Crushing/pressure/squeezing/tightness**	1	I:3			**CRUSH**	**CRUSHING PAIN**
		❑ **Sharp/stabbing**	1	I:3			**SHARP**	**SHARP PAIN**
		❑ **Tearing**	1	I:3			**TEAR**	**TEARING PAIN**
		❑ **Other pain**	1	I:3			**OTHPAIN**	**OTHER PAIN**
	Enterable only by CRA, View by CDM							
NR 4	**SDV Status**	O **Complete 100% SDV performed**	1	I:3			**SDVSTA12**	**SDV STATUS**
		O **Not Completed**	2					

If symptom present on PS1 is = 3 or 4, Questions 3 is not answered.
Question 3 is answered and symptom present on PS1 is not 3 or 4

Canadian angina class - something for instructions

FORM: ECG ASSESSMENT (ECG)

			Code	Attributes	Range	Comments	SAS Name	SAS Label
1	Date and time of ECG (most recent prior to randomization)	____/____/____ ____ : ____		Date	2010-2020	allow unk for day, time	ECGDTM	ECG DATE/TIME
2	Heart rate	_____bpm		I:3			HR	ECG HEART RATE
3	Rhythm at time of recording			I:3			ECGRHYM1	ECG RHYTHM
		O Sinus	1					
		O Atrial fibrillation/flutter	2					
		O SVT	3					
		O 2nd or 3rd degree AV block	4					
		O Bigeminy/trigeminy	5					
		O Ventricular tachycardia	6					
		O Ventricular pacing	7					
		O Undetermined/unknown	8					
		O Other	98					
4	Did the ECG interpretation indicate Q waves (prior infarct)?	O No	0	I:3			QWAVE1	Q WAVES PRESENT
		O Yes	1					
5	Are there ECG findings that could interfere with exercise stress test interpretation?	Yes, indicate all findings O that were present	1	I:3			ECGINFR1	ECG INTERFERE WITH STRESS
		❏ LBBB	1	I:3			LBBB1	LBBB
		❏ ST depression	1	I:3			STDEP1	ST DEPRESSION
		❏ LVH with repolarization	1	I:3			LVHREP1	LVH WITH REPOLARIZATION
		❏ Other	1	I:3			OTHER1	OTHER
		O No	0					

Enterable only by CRA, View by CDM

			Code	Attributes	Range	Comments	SAS Name	SAS Label
NR 6	SDV Status	O Complete 100% SDV performed	1	I:3			SDVSTA13	SDV STATUS
		O Not Completed	2					

date of ECG is more than 60 days before screening DOV

Date of ECG is after the randomization date

NEW Enrollment only

FORM DIAGNOSTIC LABORATORY TESTING (DXLAB)

Section 1: Creatinine

						Code	Attributes	Range	Comments	SAS Name	SAS Label	
* 1	Creatinine (Within 90 days prior to randomization)	Creatinine Date	___/___/___				DATE	2010-2020	allow unk for day and month	DLAB01DT	LAB 1 DATE	
		Creatinine Time	__ : __				TIME		allow for unknown	DLAB01TM	LAB DATE 1 TIME	NEW
		Creatinine Result	_____				F9			DX01RSLT	LAB 1 RESULT	
				O	mg/dL	1				DX01UNIT	LAB 1 UNIT	
				O	umol/L	2						
		ULN	_____							DX01ULN	LAB 1 ULN	

Section 2: Diagnostic Labs - If any of the following tests were performed within the past year, enter the most recent results below

						Code	Attributes	Range	Comments	SAS Name	SAS Label	
* 2	BNP or pro-BNP	BNP Date	___/___/___				DATE	2009-2020	allow unk for day and month	DLAB02DT	LAB 2 DATE	
		BNP Result	_____				F9			DX02RSLT	LAB 2 RESULT	
		Unit		O	pg/ml OR ng/L	1	I:3			DX02UNIT	LAB 2 UNIT	
		ULN	_____				F9			DX02ULN	LAB 2 ULN	
		Not Done					I:3			DX02ND	Lab 2 NOT DONE	NEW
* 3	High Sensitivity C-Reactive Protein (hs-CRP) (Most recent)	hs-CRP Date	___/___/___				DATE	2009-2020	allow unk for day and month	DLAB03DT	LAB 3 DATE	
		hs-CRP Result	_____				F9			DX03RSLT	LAB 3 RESULT	
		Unit		O	mg/dl	1	I:3			DX03UNIT	LAB 3 UNIT	
				O	mg/L	2						
		ULN	_____				F9			DX03ULN	LAB 3 ULN	
	O	Not Done					I:3			DX03ND	LAB 3 NOT DONE	NEW
* 4	Total Cholesterol (Most recent)	Cholesterol Date	___/___/___				DATE	2009-2020	allow unk for day and month	DLAB04DT	LAB 4 DATE	
		Cholesterol Result	_____				F9			DX04RSLT	LAB 4 RESULT	
		Unit		O	mg/dL	1	I:3			DX04UNIT	LAB 4 UNIT	
				O	mmol/L	2						
	O	Not Done					I:3			DX04ND	LAB 4 NOT DONE	NEW
* 5	Triglyceride (Most recent)	Triglyceride Date	___/___/___				DATE	2009-2020	allow unk for day and month	DLAB05DT	LAB 5 DATE	
		Triglyceride Result	_____				F9			DX05RSLT	LAB 5 RESULT	
		Unit		O	mg/dL	1	I:3			DX05UNIT	LAB 5 UNIT	
				O	mmol/L	2						
	O	Not Done								DX05ND	LAB 5 NOT DONE	NEW
* 6	HDL (Most recent)	HDL Date	___/___/___				DATE	2009-2020	allow unk for day and month	DLAB06DT	LAB 6 DATE	
		HDL Result	_____				F9			DX06RSLT	LAB 6 RESULT	
		Unit		O	mg/dL	1	I:3			DX06UNIT	LAB 6 UNIT	
				O	mmol/L	2						
	O	Not Done					I:3			DX06NDX	LAB 6 NOT DONE	NEW
* 7	LDL (Most recent)	LDL Date	___/___/___				DATE	2009-2020	allow unk for day and month	DLAB07DT	LAB 7 DATE	
		LDL Result	_____				F9			DX07RSLT	LAB 7 RESULT	
		Unit		O	mg/dL	1	I:3			DX07UNIT	LAB 7 UNIT	
				O	mmol/L	2						

		○ Not Done				I:3			DX07ND	LAB 7 NOT DONE	NEW
* 8	Hemoglobin (Most recent)	Hemoglobin Date ____/____/____			DATE	2009-2020	allow unk for day and month	DLAB08DT	LAB 8 DATE
		Hemoglobin Result _____			F9			DX08RSLT	LAB 8 RESULT
		Unit ○ g/dl	1		I:3			DX08UNIT	LAB 8 UNIT
		○ mmol/L	2						
		○ g/L	3						
		○ Not Done			I:3			DX08ND	LAB 8 NOT DONE	NEW
* 9	Hematocrit (Most recent)	Hematocrit Date ____/____/____			DATE	2009-2020	allow unk for day and month	DLAB09DT	LAB 9 DATE
		Hematocrit Result _____			F9			DX09RSLT	LAB 9 RESULT
		Unit ○ %	1		I:3			DX09UNIT	LAB 9 UNIT
		○ Not Done			I:3			DX09ND	LAB 9 NOT DONE	NEW

Enterable only by CRA, View by CDM

NR 10	SDV Status	○ Complete 100% SDV performed			1	I:3			SDVSTA14	SDV STATUS
		○ Not Completed			2				

CREA date is more than 90 days after randomization

other dates? Do we need a date timepoint? - within one year

crea range - or value greater than ULN?

Form: STATUS (STATUS)

				Code	Attributes	Range	Comments	SAS Name	SAS Label
1	At the Screening Visit, was the subject taking any concomitant medications (including vitamins and/or herbal supplements)?	O Yes, complete the CONMED Form		1	I:3			MEDTKEN	MEDICATIONS TAKEN
		O No		0					
		O Unknown/not provided		99					
2	Did subject consent to provide biomarker samples?	Yes, indicate date of consent and complete O BMKGEN form		1	I:3			BMKRCNS	BIOMARKER CONSENT
			_ _ /_ /_ _ _ _		DATE	2010-2020	all required	BMKRDT	DATE OF BIOMARKER CONSENT
		O No		0					
3	Did subject consent to provide genetics samples?	Yes, indicate date of consent and complete the O BMKGEN form		1	I:3			GENOCNS	GENOMICS CONSENT
			_ _ /_ /_ _ _ _		DATE	2010-2020	all required	GENODT	DATE OF GENOMIC CONSENT
		O No		0					

Enterable only by CRA, View by CDM

				Code	Attributes	Range	Comments	SAS Name	SAS Label
NR 4	SDV Status	O Complete 100% SDV performed		1	I:3			SDVSTA15	SDV STATUS
		O Not Completed		2					

If Question1 = Yes, ConMed form will appear
If Question 2 or Question 3 = YES, BMKGEN
form will appear

Changes to NEW enrollment only

FORM: CONCOMITANT MEDICATIONS (CONMED) [RF] [DF]

		Code	Attributes	Range	Comments	SAS Name	SAS Label	
Section 1:Medications								
1	**Concomitant Medication (Please enter Brand or Generic name only. Do not enter dosage, route, etc.)**		S:50			CMEDTX	CONCOMITANT MEDICATION TEXT	modify wording

Enterable only by CRA, View by CDM

				Code	Attributes	Range	Comments	SAS Name	SAS Label
NR	2	SDV Status	O Complete 100% SDV performed	1	I:3			SDVSTA18	SDV STATUS
			O Not Completed	2					

Need coding

Changes to OLD and NEW enrollment
FORM: BIOMARKER/GENETICS COLLECTION (BMKGEN) [DF]

Section 1: Biomarker

#	Question		Code	Attributes	Range	Comments	SAS Name	SAS Label	
1	Was subject fasting?	O Yes	1	I:3			SUBFST	SUBJECT FASTING	
		O No	0						
2	Accession Number	_____		I:9			ACCNUM	ACCESSION NUMBER	
3	Number of serum cryovials	_____		I:1			NOSER	NUMBER SERUM VIALS	
4	Number of plasma cryovials	_____		I:1			NOPLAS	NUMBER PLASMA VIALS	
5	Number of whole blood EDTA tubes	_____		I:1			NOEDTA	NUMBER EDTA TUBES	
6	Number of whole blood Pax-Gene tubes	_____		I:1			NOGENE	NUMBER PAX GENE TUBES	
7	Number of Red Blood Cell Pellet EDTA tubes	_____		I:1			NORBC	NUMBER RBC EDTA TUBES	NEW question
	ADD ENTRY: Complete a separate row for biomarker and genetic sample collection.								NEW wording
8	Sample Type	O Biomarker	1	I:3			SAMPTYP	SAMPLE TYPE	
		O Genetics	2						
9	Date sample collected	_ _ /_ /_ _ _ _		DATE	2010-2020		SMPDT	BIOMARKER SAMPLE DATE	
10	Date sent to reference lab	_ _ /_ /_ _ _ _		DATE	2010-2020		SNTDT	DATE BIOMARKER SENT	
NR 11	Did subject withdraw consent for sample testing before sample was sent to reference lab?	O Yes, indicate date consent withdrawn	1	I:3			BMKRWD	BIOMARKER CONSENT WITHDRAWN	
		_ _ /_ /_ _ _ _		DATE	2010-2020		BMKRWDDT	BMKR CONSENT WITHDRAWN DATE	

Enterable only by CRA, View by CDM

#	Question		Code	Attributes	Range	Comments	SAS Name	SAS Label
NR 12	SDV Status	O Complete 100% SDV performed	1	I:3			SDVSTA19	SDV STATUS

		○ Not Completed		2					

Genetics is indicated on Status, but SAMPTYP = 2 is
not present
Biomarkers is indicated on Status, but SAMPTYP = 1
is not present
Date sample collected is before screen DOV and after
Day 45 DOV
Date sent to reference lab is before date sample
collected
Listing for tubes sent to look for outliers
Sample type - 1 (Biomarker) but Question 2 on Status
is not YES
Sample type - 2 (Geneticsr) but Question 3 on Status
is not YES

FORM: RANDOMIZATION (RAND)

Section 1: Pre- Randomization

			Code	Attributes	Range	Comments	SAS Name	SAS Label
1	**What clinical non-invasive cardiovascular functional test was the enrolling provider planning on performing first, if the subject is randomized to a functional test?**	O **Exercise ECG**	1	I:3		**MAPPED from ALMAC- not editable by sites**	**PLNTST**	**PLANNED FUNC TEST**
		O **Stress ECHO**	2					
		O **Stress Nuclear**	3					

Section 2: Randomization

			Code	Attributes	Range	Comments	SAS Name	SAS Label
2	**Date of Randomization**	_ _ /_ /_ _ _ _		**DATE**	2010-2020	**MAPPED from ALMAC not editable by sites**	**RANDDT**	**DATE OF RANDOMIZATION**
3	**Randomization Arm**	O **Selected Functional Test**	1	I:3		**MAPPED from ALMAC not editable by sites**	**RANDARM**	**RANDOMIZED ARM FUNCTIONAL TEST**
		O **Exercise ECG**	1	I:3			**FUNCTST1**	
		O **Stress ECHO**	2					
		O **Stress Nuclear**	3					
		O **Coronary CTA**	2					
4	**Scheduled date of randomized test**	_ _ /_ /_ _ _ _		**DATE**	2010-2020		**SCHDT**	**SCHEDULED DATE**

Enterable only by CRA, View by CDM

			Code	Attributes	Range	Comments	SAS Name	SAS Label
NR 5	**SDV Status**	O **Complete 100% SDV performed**	1	I:3			**SDVSTA20**	**SDV STATUS**
		O **Not Completed**	2					

Randomization date is before screening DOV

Scheduled date is before randomization date
Scheduled date is more than 30 days after randomization date

Changes to OLD and NEW enrollment
FORM: RANDOMIZATION 1 (RAND1)

#	Question		Option	Code	Attributes	Range	Comments	SAS Name	SAS Label
1	Randomization arm with selected test	○	Functional test - Exercise ECG	1	I:3		MAPPED from RAND.FUNCTST = 1 not editable by sites	RANDTST	RANDOMIZED TEST
		○	Functional test - Stress ECHO, indicate Stress agent (check all that apply)	2			MAPPED from RAND.FUNCTST = 2 not editable by sites		
		❑	Exercise	1	I:3			STSEXER1	EXERCISE STRESS
		❑	Dobutamine	1	I:3			STRSDOB1	DOBUTAMINE STRESS
		❑	Not Done	1	i:3			STRAGTND	STRESS AGT NOT DONE
		○	Functional test - Stress Nuclear, indicate Stress agent (check all that apply)	3			MAPPED from RAND.FUNCTST = 3 not editable by sites		
		❑	Exercise	1	I:3			STSEXER2	EXERCISE STRESS
		❑	Dobutamine	1	I:3			STRSDOB2	DOBUTAMINE STRESS
		❑	Vasodilator Pharmacologic	1	I:3			STRSVASO	VASODILATOR STRESS
		❑	Not Done	1	i:3			STRAGND	STRESS AGT NOT DONE
		○	Coronary CTA	4			MAPPED from RAND.RANDARM = 2 not editable by sites		
2	Was the diagnostic test to which the subject was randomized ~~completed~~ performed?	○	Yes, within 30 days of randomization	2	I:3			RNDTSPER	RANDOMIZED TEST PERFORMED
		○	Yes, more than 30 days after randomization, indicate reason	1					
		○	Unable to schedule within 30 days	1				TSTAFTER	TEST PERFORMED AFTER 30 DAYS
		○	Technical problem/ equipment failure	2					
		○	Subject missed appointment	3					
		○	No, indicate primary reason the randomized diagnostic test was not performed	0					
			Test not performed					TSTPERF	TEST NOT PERFORMED

		O Pull down list		1				RNDNPER	**REASON TEST NOT PERFORMED**
		Unable to schedule within 30 days		1					
		Technical problem/ equipment failure		2					
		Contraindication to test		3					
		Subject missed appointment		4					
		Subject withdrew consent		5					
		Subject death		6					
		Subject underwent catheterization prior to diagnostic test		7					
		Unstable angina requiring hospitalization prior to testing		8					
		Myocardial infarction prior to testing		9					
		Anaphylaxis related to contrast or medications at time of testing		10					
		Other side effect or complication at time of testing		11					
		Subject unable to complete test due to claustrophobia or other reason		12					
		Physician elected to perform another test		13					
		Unknown		99					
		O Other, specify,		98					
		_____			S:50			RDTSSPC1	**SPECIFY**
3	**Was a diagnostic test other than the assigned/randomized test performed instead of or prior to the randomized test?**	O Yes, indicate test		1	I:3			OTHDGTST	**OTHER DIAGNOSTIC TEST**
		O Exercise ECG		1	I:3			FUNCTST2	**FUNCTIONAL TEST**

		○	Stress ECHO, indicate Stress agent (check all that apply)			2			
				☐ Exercise		1	I:3		STSEXER3	EXERCISE STRESS
				☐ Dobutamine		1	I:3		STRSDOB3	DOBUTAMINE STRESS
		○	Stress Nuclear, indicate Stress agent (check all that apply)			3			
				☐ Exercise		1	I:3		STSEXER4	EXERCISE STRESS
				☐ Dobutamine		1	I:3		STRSDOB4	DOBUTAMINE STRESS
				☐ Vasodilator Pharmacologic		1	I:3		STRSVAS4	VASODILATOR STRESS
		○	Coronary CTA			4			
		○	Invasive catheterization			5			
		○	Other, Specify:			98			
				_____			S:50		SPEC2	SPECIFY
	○	No				0			

Enterable only by CRA, View by CDM

NR	4	SDV Status	○	Complete 100% SDV performed			1	I:3		SDVSTA21	SDV STATUS
			○	Not Completed			2			

Dynamics: If Question 2 = YES, then test in
Q1 will appear
Question 5 =- test is indicated will appear

FORM: PATIENT SATISFACTION QUESTIONNAIRE (PSQ)

Thinking about the heart tests that you had since you enrolled in the trial

			Code	Attributes	Range	Comments	SAS Name	SAS Label
1	How satisfied are you that everything possible has been done to find the cause of your symptoms?	O Strongly satisfied	1	I:3			PSQ1	SATISFIED CAUSE OF SYMPTOMS
		O Satisfied	2					
		O Neither satisfied nor dissatisfied	3					
		O Dissatisfied	4					
		O Strongly dissatisfied	5					
2	How satisfied are you that these tests allowed your doctors to choose the best treatments for your heart symptoms?	O Strongly satisfied	1	I:3			PSQ2	SATISFIED CHOSEN TREATMENTS
		O Satisfied	2					
		O Neither satisfied nor dissatisfied	3					
		O Dissatisfied	4					
		O Strongly dissatisfied	5					
3	How likely would you be to agree to have these same tests done again?	O Not at all likely	1	I:3			PSQ3	PERFORM THESE TESTS AGAIN
		O A little likely	2					
		O Moderately likely	3					
		O Very likely	4					
		O Extremely likely	5					

Enterable only by CRA, View by CDM

			Code	Attributes	Range	Comments	SAS Name	SAS Label
NR 4	SDV Status	O Complete 100% SDV performed	1	I:3			SDVSTA22	SDV STATUS
		O Not Completed	2					

FORM: MEDICAL THERAPY AND LIFESTYLE COUNSELING (MTLC)

				Code	Attributes	Range	Comments	SAS Name	SAS Label
1	Since the index diagnostic test, has the subject been counseled by a health provider regarding any of the following:	○ Yes , check all that apply		1	I:3			PTCOUN	PATIENT COUNSELING
		❑ Exercise		1	I:3			EXER	EXERCISE
		❑ Diet		1	I:3			DIET2	DIET
		❑ Ideal body weight		1	I:3			BDWT	BODY WEIGHT
		Diabetes control (if applicable)						DIABC	DIABETES CONTROL
		❑ Smoking (if applicable)		1	I:3			SMOK	SMOKING
		❑ Cholesterol/lipid goals (if applicable)		1	I:3			CHOL	CHOLESTEROL
		❑ Blood pressure control (if applicable)		1	I:3			BP	BLOOD PRESSURE
		❑ Sodium intake		1	I:3			SODIUM	SODIUM
		○ No		0					

Enterable only by CRA, View by CDM

				Code	Attributes	Range	Comments	SAS Name	SAS Label
NR 2	SDV Status	○ Complete 100% SDV performed		1	I:3			SDVSTA23	SDV STATUS
		○ Not Completed		2					

FORM: EXERCISE ECG STRESS TEST DIAGNOSTIC TESTING (EEST) [RF] [DF]

	Section 1: Exercise ECG Date				Code	Attributes	Range	Comments	SAS Name	SAS Label
1	Date and time of exercise ECG stress test	_ _/_ _/_ _ _ _ _ _:_ _				DATE	2010-2020	unk for time	EEST1DTM	EXERCISE ECG DATE TIME
	Section 2: Exercise Protocol									
2	Type of exercise protocol	○ Treadmill			1	I:3			EESTTYP	EXERCISE PROTOCOL
			○ Bruce		1	I:3			TRDPROT	TREADMILL PROCOTOL
			○ Modified Bruce		2					
			○ Naughton		3					
			○ Other		98					
		○ Bicycle			2					
			○ Supine		1	I:3			BICPROT	BICYCLE PROTOCOL
			○ Upright		2					
	Section 3: Functional Capacity									
3	Resting heart rate	_____ bpm				I:3			RESTHR1	RESTING HEART RATE
4	Resting systolic blood pressure	_____ mmHg				I:3			RESTSYS1	RESTING SYSTOLIC PRESSURE
5	Resting diastolic blood pressure	_____ mmHg				I:3			RESTDIA1	RESTING DIASTOLIC PRESSURE
6	Maximum heart rate	_____ bpm				I:3			MAXHR1	MAXIMUM HEART RATE
7	Systolic blood pressure at peak stress	_____ mmHg				I:3			PEAKSYS1	PEAK SYSTOLIC PRESSURE
8	Diastolic blood pressure at peak stress	_____ mmHg				I:3			PEAKDIA1	PEAK DIASTOLIC PRESSURE
9	Duration of exercise	____ min	____ sec			I:3			DURMIN	EXERCISE DURATION IN MIN
						I:3			DURSEC	EXERCISE DURATION IN SEC
10	Metabolic Equivalents (METS)	_____				F:5			METS	METS
	Section 4: ECG Results									
11	ECG result - Changes meet criteria for ischemia?	○ Negative, no evidence of ischemia			1	I:3			ECGRSLT1	ECG RESULT
		○ Borderline or indeterminate			2					
		○ Positive			3					
		○ Noninterpretable , indicate all that apply			4					
			☐ LBBB		1	I:3			LBBB2	LBBB
			☐ RBBB		1	I:3			RBBB1	RBBB
			☐ Resting ST-T W abnormalities		1	I:3			WABM1	RESTING ST ABNORMALITIES

HIDE THIS QUESTION

#	Question		Option		Value				Variable	Label	Notes
		☐	Poor technical quality/non-diagnostic		1	I:3			PTQ1	POOR TECHNICAL QUALITY	
		☐	Other		1	I:3			OTHER2	OTHER	
11	ECG result - Changes meet criteria for ischemia?	O	Negative, no evidence of ischemia		1	I:3			ECGRSL3	ECG RESULT	NEW…..replaces the former Q11 (see above)
		O	Borderline or indeterminate		2						
		O	Positive		3						
12	Overall Study Quality										
		O	Diagnostic		1	I:3			EESTDIA	EEST OVERALL IMAGE QUALITY	NEW
		O	Non- Diagnostic		2						
		☐	LBBB		1	I:3			LBBB2A	LBBB A	
		☐	RBBB		1	I:3			RBBB1A	RBBB A	
		☐	Resting ST-T W abnormalities		1	I:3			WABM1A	RESTING ST ABNORMALITIES A	
		☐	Poor technical quality/non-diagnostic		1	I:3			PTQ1A	POOR TECHNICAL QUALITY A	
		☐	Other		1	I:3			OTHER2A	OTHER	
13	If ECG result is positive, borderline or indeterminate, check all changes that apply	☐	ST depression		1	I:3			STDEP2	ST DEPRESSION	
		☐	ST elevation		1	I:3			STELE1	ST ELEVATION	
		☐	Other, specify		1	I:3			OTH1	OTHER	
			_____			S:50			SPEC1	OTHER SPECIFY	
	Section 5: Symptoms and Reason for Stopping										
14	Did the stress test reproduce the subject's presenting symptoms?	O	Yes		1	I:3			PRDSYMP1	PRODUCT USUAL SYMPTOMS	
		O	No		0						
15	Primary reason for stopping	O	Finished protocol or target HR achieved		1	I:3			STPREAS1	PRIMARY REASON FOR STOPPING	
		O	Chest pain, SOB or other ischemic symptoms reproduced		2						
		O	Fatigue, leg or joint pain, subject request		3						
		O	Hypotension		4						
		O	Ventricular arrhythmia		5						
		O	Supraventricular arrhythmia (e.g. atrial fib)		6						
		O	Other, specify		98						
			_____			S:50			REASSPC1	SPECIFY REASON	

NR

Enterable only by CRA, View by CDM

NR	16	Was exercise stress test report received by DCRI?	☐ Yes		1				EESTREC	EXERCISE STRESS REPORT RECD
NR	17	SDV Status	O Complete 100% SDV performed		1	I:3			SDVSTA24	SDV STATUS
			O Not Completed		2					

SV Changes to OLD and NEW enrollment

FORM: DOBUTAMINE STRESS TEST DIAGNOSTIC TESTING (DBST) [RF] [DF]

Section 1: Dobutamine			Code	Attributes	Range	Comments	SAS Name	SAS Label
Date of Dobutamine Stress Test	__ _ _/_ _/_ _ _ _			DATE		2010-2020	DOBUDT	DOBUTAMINE TEST DATE
1 Maximum Dobutamine dose given	_____ mcg/kg/min			F:5			DOBUDS	DOSE DOBUTAMINE
2 Atropine given?	O	Yes, indicate total dose given	1	I:3			ATRPGVN	ATROPINE GIVEN
		_____		F:5			ATRPDS	ATROPINE DOSE
	O	No	0					
3 Handgrip used?	O	Yes	1	I:3			HNDGRP	HANDGRIP USED
	O	No	0					
Section 2: Physiologic Monitoring								
4 Resting heart rate	_____ bpm			I:3			RESTHR2	RESTING HEART RATE
5 Resting systolic blood pressure	_____ mmHg			I:3			RESTSYS2	RESTING SYSTOLIC PRESSURE
6 Resting diastolic blood pressure	_____ mmHg			I:3			RESTDIA2	RESTING DIASTOLIC PRESSURE
7 Maximum heart rate	_____ bpm			I:3			MAXHR2	MASIMUM HEART RATE
8 Systolic blood pressure at peak stress	_____ mmHg			I:3			PEAKSYS2	PEAK SYSTOLIC PRESSURE
9 Diastolic blood pressure at peak stress	_____ mmHg			I:3			PEAKDIA2	PEAK DIASTOLIC PRESSURE
Section 3: ECG Results								
NR SV 10 ECG result - Changes meet criteria for ischemia?	O	Negative, no evidence of ischemia	1	I:3			ECGRSLT2	ECG RESULT
	O	Borderline or indeterminate	2					
	O	Positive	3					
	O	Noninterpretable , indicate all that apply	4					
	❑	LBBB	1	I:3			LBBB3	LBBB
	❑	RBBB	1	I:3			RBBB2	RBBB

HIDE

		☐ Resting ST-T W abnormalities	1	I:3			WABM2	RESTING ST ABNORMALITIES
		☐ Poor technical quality/non-diagnostic	1	I:3			PTQ2	POOR TECHNICAL QUALITY
		☐ Other	1	I:3			OTHER3	OTHER
10	ECG result - Changes meet criteria for ischemia?	○ Negative, no evidence of ischemia	1	I:3			ECGRST3	ECG RESULT	NEW…..replaces the former Q10 (see above)
		○ Borderline or indeterminate	2					
		○ Positive	3					
11	Overall Study Quality							
		○ Diagnostic	1	I:3			DBSTDIA	DBST OVERALL STUDY QUALITY	NEW question
		○ Non- Diagnostic	2					
		☐ LBBB	1	I:3			LBBB4N	LBBB
		☐ RBBB	1	I:3			RBBB4N	RBBB
		☐ Resting ST-T W abnormalities	1	I:3			WABM4N	RESTING ST ABNORMALITIES
		☐ Poor technical quality/non-diagnostic	1	I:3			PTQ4N	POOR TECHNICAL QUALITY
		☐ Other	1	I:3			OTHER4N	OTHER
12	If ECG result is positive, borderline or indeterminate, check all changes that apply	☐ ST Depression	1	I:3			STDEP3	ST DEPRESSION
		☐ ST Elevation	1	I:3			STELE2	ST ELEVATION
		☐ Other, specify	1	I:3			OTH2	OTHER
		_____		S:50			SPEC3	SPECIFY
	Section 4: Symptoms and Reason for Stopping							
13	Did the stress test reproduce the subject's presenting symptoms?	○ Yes	1	I:3			PRDSYMP2	PRODUCE USUAL SYMPTOMS
		○ No	0					
14	Primary reason for stopping.	○ Finished protocol, reached maximal dose of stress agent or target HR achieved	1	I:3			STPREAS2	PRIMARY REASON FOR STOPPING
		○ Chest pain, SOB or other ischemic symptoms reproduced	2					
		○ Fatigue, leg or joint pain, subject request	3					
		○ Hypotension	4					
		○ Ventricular arrhythmia	5					
		○ Supraventricular arrhythmia (e.g. atrial fib)	6					

NR (margin, next to question 12)

	O Other, specify		98					SPECIFY
	_____		S:50				REASSPC2	REASON

Enterable only by CRA, View by CDM

NR	15 Was DBST report received by DCRI?	☐ Yes		1				DBSTREC	DBST REPORT RECD

NR	16 SDV Status	O Complete 100% SDV performed		1	I:3			SDVSTA25	SDV STATUS
		O Not Completed		2					

FORM: VASODILATOR PHARMACOLOGIC STRESS TEST DIAGNOSTIC TESTING (VPST) [RF] [DF]

Section 1: Vasodilator			Code	Attributes	Range	Comments	SAS Name	SAS Label
1 Date of Pharmacologic Stress Test	__ _ _/_ _/_ _ _ _			DATE		2010-2020	PHARMDT	PHARMACOLOGIC TEST DATE
2 For vasodilator pharmacologic modality, was the protocol completed?	Yes , indicate the ○ pharmacologic agent		1	I:3			PROTCMP	PROTOCOL COMPLETED
	○ No		0					
ADD ENTRY:								
3 Pharmacologic	○ Adenosine (Adenoscan)		1	I:3			PHARM	PHARMACOLOGIC
	○ Regadenoson (Lexiscan)		2					
	○ Dipyridamole (Persantine)		3					
	○ Other, specify		98					
	_____			S:50			OTHPHARM	OTHER PHARMACOLOGIC
4 Dose	_____			F:5			PHARMDS	PHARMACOLOGIC DOSE
5 Unit	_____			S:25			PHARMU	PHARMACOLOGICUNIT
Section 2: Physiologic Monitoring								
6 Resting heart rate	_____ bpm			I:3			RESTHR3	RESTING HEART RATE
7 Resting systolic blood pressure	_____ mmHg			I:3			RESTSYS3	RESTING SYSTOLIC PRESSURE
8 Resting diastolic blood pressure	_____ mmHg			I:3			RESTDIA3	RESTING DIASTOLIC PRESSURE
9 Maximum heart rate	_____ bpm			I:3			MAXHR3	MASIMUM HEART RATE
10 Systolic blood pressure at peak stress	_____ mmHg			I:3			PEAKSYS3	PEAK SYSTOLIC PRESSURE
11 Diastolic blood pressure at peak stress	_____ mmHg			I:3			PEAKDIA3	PEAK DIASTOLIC PRESSURE
Section 3: ECG Results								
NR SV 12 ECG result - Changes meet criteria for ischemia?	Negative, no evidence of ○ ischemia		1	I:3			ECGRSLT3	ECG RESULT
	○ Borderline or indeterminate		2					
	○ Positive		3					
	Noninterpretable , indicate ○ all that apply		4					

HIDE

			❏ LBBB	1	I:3			LBBB4	LBBB
			❏ RBBB	1	I:3			RBBB3	RBBB
			❏ Resting ST-T W abnormalities	1	I:3			WABM3	RESTING ST ABNORMALITIES
			❏ Poor technical quality/non-diagnostic	1	I:3			PTQ3	POOR TECHNICAL QUALITY
			❏ Other	1	I:3			OTHER4	OTHER
	12	ECG result - Changes meet criteria for ischemia?	O Negative, no evidence of ischemia	1	I:3			ECGRSL4	ECG RESULT
			O Borderline or indeterminate	2					
			O Positive	3					
	13	Overall Study Quality							
			O Diagnostic	1	I:3			VPSTDIA	VPST OVERALL STUDY QUALITY
			O Non- Diagnostic	2					
			❏ LBBB	1	I:3			LBBB5N	LBBB
			❏ RBBB	1				RBBB5N	RBBB
			❏ Resting ST-T W abnormalities	1				WABM4X	RESTING ST ABNORMALITIES
			❏ Poor technical quality/non-diagnostic	1				PTQ4X	POOR TECHNICAL QUALITY
			❏ Other	1				OTHER5X	OTHER
NR	14	If ECG result is positive, borderline or indeterminate, check all changes that apply	❏ ST Depression	1	I:3			STDEP4	ST DEPRESSION
			❏ ST Elevation	1	I:3			STELE3	ST ELEVATION
			❏ Other, specify	1	I:3			OTH3	OTHER
			_____		S:50			SPEC4	OTHER SPECIFY
		Section 4: Symptoms and Reason for Stopping							
	15	Did the stress test reproduce the subject's presenting symptoms?	O No	0	I:3			PRDSYMP3	PRODUCT USUAL SYMPTOMS
			O Yes	1					
	16	Primary reason for stopping.	O Finished protocol, reached maximal dose of stress agent or target HR achieved	1	I:3			STPREAS3	PRIMARY REASON FOR STOPPING
			O Chest pain, SOB or other ischemic symptoms reproduced	2					
			O Fatigue, leg or joint pain, subject request	3					
			O Hypotension	4					
			O Ventricular arrhythmia	5					
			O Supraventricular arrhythmia (e.g. atrial fib)	6					
			O Other, specify	98					
			_____		S:50			REASSPC3	SPECIFY REASON

NEW…..replaces the former Q12 (see above)

NEW

Enterable only by CRA, View by CDM

17	Was VPST report received by DCRI?	❑ Yes		1	I:3			VPSTREC	**VPST REPORT RECD**

NR	18	SDV Status	O **Complete 100% SDV** performed		1	I:3			SDVSTA26	SDV STATUS
			O Not Completed		2					

Drop Down List 1
1 **Adenosine (Adenoscan)**
2 **Regadenoson (Lexiscan)**
3 **Dipyridamole (Persantine)**

FORM: STRESS ECHO 1 (ECHO1) [RF]
[DF]

Section 1: Stress ECHO					Code	Attributes	Range	Comments	SAS Name	SAS Label
1	Date and time of stress ECHO test	_ _/_/_ _ _ _ _ _:_ _				DATE	2010-2020	UNK for time	ECHO1DTM	ECHO DATETIME
2	Was an echo contrast used in any portion of the study?	○ Yes			1	I:3			ECHOCONT	ECHO CONTRAST
		○ No			0					
		○ Unknown			99					
Section 2: LV Function										
3	Resting LV function	○ Normal			1	I:3			RESTLV1	REST LV FUNCTION
		○ Abnormal - mild			2					
		○ Abnormal - severe (EF < 35%)			3					
		○ Not reported			97					
4	Resting LV dysfunction	○ Regional			1	I:3			RSTLDYS1	LV DYSFUNCTION
		○ Global			2					
		○ Not Reported			97					
		○ Not Applicable			96					
5	Resting wall motion abnormality	○ Yes, indicate all that apply			1	I:3			RSTWMA1	RESTING WALL MOTION ABN
			❑ Septal/Anterior/Apical		1	I:3			SEPWM1	SEPTAL WALL MOTION
			❑ Inferior/Posterior		1	I:3			INFPWM1	INF POST WALL MOTION
			❑ Lateral		1	I:3			LATWM1	LATERAL WALL MOTION
		○ No			0					
		○ Not reported			97					
NR	6 Resting EF %, if available	_____ %				I:3			RESTEF1	PERCENT RESTING EF
7	Peak stress LV function	○ Normal			1	I:3			STSLV1	STRESS LV FUNCTION
		○ Abnormal - mild			2					
		○ Abnormal - severe (EF < 35%)			3					
		○ Not reported			97					
8	LV dilatation at peak stress	○ Yes			1	I:3			LVDLSTS1	PEAK STRESS LV DILATION
		○ No			0					
		○ Not reported			97					
NR	9 Peak stress EF %, if available	_____ %				I:3			PKSTSEF1	PERCENT STRESS PEAK EF

Section 3: Stress ECHO Results

10	Septal/anterior/apical	○ Normal			1	I:3			SEPRSLT1	SEPTAL ANT API RESULT
		○ Resting Wall motion abnormality without ischemia (infarct)			2					
		○ Inducible wall motion abnormality (ischemia)			3					
		○ Mixed abnormality (infarct and ischemia)			4					
		○ Uninterpretable			5					
		○ Not reported			97					
11	Lateral	○ Normal			1	I:3			LATRSLT1	LATERAL RESULT
		○ Resting Wall motion abnormality without ischemia (infarct)			2					
		○ Inducible wall motion abnormality (ischemia)			3					
		○ Mixed abnormality (infarct and ischemia)			4					
		○ Uninterpretable			5					
		○ Not reported			97					
12	Inferior/posterior	○ Normal			1	I:3			INFRSLT1	INFERIOR POST RESULT
		○ Resting Wall motion abnormality without ischemia (infarct)			2					
		○ Inducible wall motion abnormality (ischemia)			3					
		○ Mixed abnormality (infarct and ischemia)			4					
		○ Uninterpretable			5					
		○ Not reported			97					

NR SV 12	Image quality limited	○ Yes, check all that apply	1				IMGLM1	IMAGE QUALITY LIMITED
		☐ Respiratory artifact	1	I:3			RESTART1	RESPIRATORY ARTIFACT
		☐ Poor sound transmission	1	I:3			PRSDTRN1	POOR SOUND TRANS
		☐ Images delayed > 90 sec after exercise	1	I:3			IMGDEL1	IMAGE DELAYED
		☐ Other, specify	1	I:3			OTH4	OTHER
		_____		S:50			SPEC5	SPECIFY
		○ No	0					
		○ Not reported	97					

Hide this question

13	Overall study quality

	○ Diagnostic				1	I:3			ECHO1DIA	ECHO OVERALL IMAGE QUALITY |NEW
	○ Non-diagnostic				2					
		❑ Respiratory artifact			1	I:3			RESTAR1A	RESPIRATORY ARTIFACT
		❑ Poor sound transmission			1	I:3			PRSDTR1A	POOR SOUND TRANS
		❑ Images delayed > 90 sec after exercise			1	I:3			IMGDEL1A	IMAGE DELAYED
		❑ Other, specify			1	I:3			OTH4A	OTHER
						S:50			SPEC5X	SPECIFY

Enterable only by CRA, View by CDM

NR	14	Was stress ECHO test report received by DCRI?	❑ Yes			1				ECHOREC	ECHO REPORT RECEIVED
NR	15	SDV Status	○ Complete 100% SDV performed			1	I:3			SDVSTA27	SDV STATUS
			○ Not Completed			2					

FORM: STRESS ECHO 2 (ECHO2) [RF]
[DF]

Section 1: Incidental Findings

	#	Question		Response			Code				Variable	Label
	1	Were incidental findings evaluated?	O	Yes, incidental findings were evaluated, but none noted.		2	I:3				IFEVAL1	INCIDENTAL FINDINGS EVALUATED
			O	Yes, incidental findings were noted. Select all that apply:		3						
				❑	Moderate or large pericardial effusion or tamponade	1	I:3				ECHOIF1	ECHO FINDINGS 1
				❑	Moderate or severe aortic stenosis	1	I:3				ECHOIF2	ECHO FINDINGS 2
				❑	Moderate or severe mitral stenosis	1	I:3				ECHOIF3	ECHO FINDINGS 3
				❑	Hypertrophic obstructive cardiomyopathy	1	I:3				ECHOIF4	ECHO FINDINGS 4
				❑	Endocarditis	1	I:3				ECHOIF5	ECHO FINDINGS 5
				❑	MV prolapse	1	I:3				ECHOIF6	ECHO FINDINGS 6
				❑	Aortic root dilation/aneurysm	1	I:3				ECHOIF7	ECHO FINDINGS 7
				❑	Moderate or severe aortic insufficiency	1	I:3				ECHOIF8	ECHO FINDINGS 8
				❑	Moderate or severe mitral regurgitation	1	I:3				ECHOIF9	ECHO FINDINGS 9
				❑	Moderate or severe pulmonary hypertension (estimated RV or PA systolic pressure > 50 mmHg)	1	I:3				ECHOIF10	ECHO FINDINGS 10
				❑	Other, specify	1	I:3				ECHOIF12	ECHO FINDINGS 12
					_____		S:50				ECHOSPEC	ECHO FINDINGS SPECIFY
			O	No, incidental findings were not evaluated.		1						
			O	Unknown, no explicit mention of evaluation.		99						
NR	2	If incidental findings were noted, was a follow-up test/procedure recommended?	O	Yes, specify recommended test(s) and recommended time		1	I:3				TSTRECM1	TEST RECOMMENDED
				Specify _____			S:100				SPCTST1	SPECIFY TEST AND TIME
			O	No		0						

Enterable only by CRA, View by CDM

NR	3	SDV Status	○ Complete 100% SDV performed			1	I:3			SDVSTA28	SDV STATUS
			○ Not Completed			2					

FORM: STRESS NUCLEAR 1 (NUC1) [RF] [DF]

	Section 1: Stress Nuclear Test				Code	Attributes	Range	Comments	SAS Name	SAS Label
1	Date and time of stress nuclear test	_ _ /_ /_ _ _ _ _ _:_ _				DATE	2010-2020	unknown for time	NUC1DTM	STRESSNUCLEAR DATE TIME
2	Type of Nuclear Imaging	O SPECT			1	I:3			NUCIMG	TYPE OF NUCLEAR IMAGING
		O PET			2					
	Section 2 - Tracer Administered									
	ADD ENTRY									
3	Indication	O Rest			1	I:3			TRCIND	TRACER INDICATION
		O Stress			2					
		O Reinjection			3					
4	Tracer	O Sestamibi (Cardiolite)			1	I:3			TRCADM	TRACER ADMINISTERED
		O Thallium			2					
		O Tetrofosmin (Myoview)			3					
		O Rubidium			4					
		O 13N-ammonia			5					
		O Other, specify			98					
		_____				S:50			TRCADMSP	TRACER ADMINISTERED SPECIFY
5	Dose	_____				F:5			TRCDOSE	TRACER DOSE
6	Unit of activity	O MBq			1	I:3			TRCU	TRACER UNIT
		O Millicuries			2					
	Section 3: LV Function									
7	Resting LV function	O Normal			1	I:3			RESTLV2	REST LV FUNCTION
		O Abnormal - mild			2					
		O Abnormal - severe (EF < 35%)			3					
		O Not reported			97					
8	Resting LV dysfunction	O Regional			1	I:3			RSTLDYS2	LV DYSFUNCTION
		O Global			2					
		O Not Reported			97					
		O Not Applicable			96					
9	Resting wall motion abnormality	O Yes, indicate all that apply			1	I:3			RSTWMA2	RESTING WALL MOTION ABN
			☐ Septal/Anterior/Apical		1	I:3			SEPWM2	SEPTAL WALL MOTION
			☐ Inferior/Posterior		1	I:3			INFPWM2	INF POST WALL MOTION
			☐ Lateral		1	I:3			LATWM2	LATERAL WALL MOTION
		O No			0					
		O Not reported			97					
NR 10	Resting gated EF %, if available	_____ %				F:5			RSTEF1	PERCENT RESTING EF

	#	Question		Option			Code	Format			Variable	Description
	11	Post-stress LV function	O	Normal			1	I:3			STRSLV1	POST STRESS LV FUNCTION
			O	Abnormal - mild			2					
			O	Abnormal - severe (EF < 35%)			3					
			O	Not reported			97					
	12	Post-stress LV dysfunction	O	Regional			1	I:3			STRLDYS1	LV DYSFUNCTION
			O	Global			2					
			O	Not Reported			97					
			O	Not Applicable			96					
NR	13	Post-stress gated EF%		_____ %				F:5			STRSEF1	PERCENT POST STRESS EF
	14	Post-stress wall motion abnormality	O	Yes, indicate all that apply			1	I:3			STRWMA1	RESTING WALL MOTION ABN
				❑	Septal/Anterior/Apical		1	I:3			SSEPWM2	SEPTAL WALL MOTION
				❑	Inferior/Posterior		1	I:3			SINFPWM1	INF POST WALL MOTION
				❑	Lateral		1	I:3			SLATWM1	LATERAL WALL MOTION
			O	No			0					
			O	Not reported			97					
	15	Transient ischemic dilatation	O	Yes (stated in report)			1	I:3			TID1	TRANSIENT ISC DIL
			O	No (stated in report)			0					
			O	Not reported			97					
		Section 4: Myocardial Perfusion										
	16	Territory: Septal/anterior/apical	O	Normal			1	I:3			MPSEPT1	MYOCARDIAL PERFUSION SEPTAL
			O	Fixed defect (infarct)			2					
			O	Reversible (ischemia)			3					
			O	Mixed defect (infarct and Ischemia)			4					
			O	Uninterpretable			5					
			O	Not reported			97					
	17	Territory: Lateral	O	Normal			1	I:3			MPLAT1	MYOCARDIAL PERF LATERAL
			O	Fixed defect (infarct)			2					
			O	Reversible (ischemia)			3					
			O	Mixed defect (infarct and Ischemia)			4					
			O	Uninterpretable			5					
			O	Not reported			97					
	18	Territory: Inferior/posterior	O	Normal			1	I:3			MPINF1	MYOCARDIAL PERF INF POST
			O	Fixed defect (infarct)			2					
			O	Reversible (ischemia)			3					
			O	Mixed defect (infarct and Ischemia)			4					
			O	Uninterpretable			5					

		○ Not reported			97				
NR SV 19	Image quality limited	○ Yes, check all that apply			1	I:3			IMGLMT1	IMAGE QUALITY LIMITED
		❑ Motion artifact			1	I:3			MOTART1	MOTION ARTIFACT
		❑ Attenuation			1	I:3			ATTEN1	ATTENUATION
		❑ GI uptake			1	I:3			GIUPT1	GI UPTAKE
		○ No			0				
		○ Not reported			97				
19	Overall study quality								
										NUC OVERALL IMAGE QUALITY
		○ Diagnostic			1	I:3			NUC1DIA	
		○ Non-diagnostic			2				
		❑ Motion artifact			1	I:3			MOTART1A	MOTION ARTIFACT
		❑ Attenuation			1	I:3			ATTEN1A	ATTENUATION
		❑ GI uptake			1	I:3			GIUPT1A	GI UPTAKE

We are going to "hide" this question

Enterable only by CRA, View by CDM

NR 20	Was stress nuclear test report received by DCRI?	❑ Yes			1				NUCREC	NUCLEAR REPORT RECEIVED
NR 21	SDV Status	○ Complete 100% SDV performed			1	I:3			SDVSTAT	SDV STATUS
		○ Not Completed			2				

PULLDOWN LIST 1

1 - Rest

2 - Stress

3 - Reinjection

PULLDOWN LIST 2

1 - Sestamibi (Cardiolite)

2 - Thallium

3 - Tetrofosmin (Myoview)

4 - Rubidium

FORM: STRESS NUCLEAR 2 (NUC2) [RF] [DF]
Section 1: Incidental Findings

	#	Question		Response		Code	Format			Variable	Label
	1	Were incidental findings evaluated?	O	Yes, incidental findings were evaluated, but none noted.		2	I:3			IFEVAL2	INCIDENTAL FINDINGS EVALUATED
			O	Yes, incidental findings were noted. Select all that apply:		3					
			❑	Lung		1	I:3			NUCIF1	NUCLEAR FINDINGS 1
			❑	Breast		1	I:3			NUCIF2	NUCLEAR FINDINGS 2
			❑	Axilla		1	I:3			NUCIF3	NUCLEAR FINDINGS 3
			❑	Other		1	I:3			NUCIF4	NUCLEAR FINDINGS 4
				Specify _____			S:50			NUCSPEC	NUCLEAR FINDINGS SPECIFY
			O	No, incidental findings were not evaluated.		1					
			O	Unknown, no explicit mention of evaluation.		99					
NR	2	If incidental findings were noted, was a follow-up test/procedure recommended?	O	Yes, specify recommended test(s) and recommended time		1	I:3			TSTRECM2	TEST RECOMMENDED
				Specify _____			S:100			SPCTST2	SPECIFY TEST AND TIME
			O	No		0					

Enterable only by CRA, View by CDM

	#	Question		Response		Code	Format			Variable	Label
NR	3	SDV Status	O	Complete 100% SDV performed		1	I:3			SDVSTA29	SDV STATUS
			O	Not Completed		2					

SV   Changes to OLD and NEW enrollment

FORM: CTA (CTA) [RF] [DF]

Section 1: Physician Reading

						Code	Attributes	Range	Comments	SAS Name	SAS Label	
1	Date and time CTA performed	_ _ /_ _/_ _ _ _ _ _:_ _					DATE	2010-2020	unk for time	CTA1DTM	DATE AND TIME OF CTA	
2	Is calcium score reported?	O Yes, indicate score				1	I:3			CASCREP	CALCIUM SCORE REPORTED	
		_____					F:9			CASCR1	CALCIUM SCORE	
		O No				0						
NR SV 3	~~Reader ID~~	~~_____~~					~~I:5~~			~~RDRID~~	~~READER ID~~	HIDE
3	Reader ID	_____					I:3			RDRIDN	READER ID	NEW

Section 2: CTA Technical Information

						Code	Attributes	Range	Comments	SAS Name	SAS Label	
4	Hybrid imaging (SPECT or PET/CT)	O Yes				1	I:3			HYBIMG	HYBRID IMAGING	
		O No				0						
5	Was contrast CTA performed?	O Yes				1	I:3			CTRCTA1	CONTRAST CTA	
NR		Contrast CTA heart rate	_____ bpm				I:3			CTAHR	CTA HEART RATE	
		Pre-procedure medications										
		☐ Beta Blocker IV				1	I:3			BTBLIV	BETA BLOCKER IV	
		☐ Beta Blocker PO				1	I:3			BTBLPO	BETA BLOCKER PO	
		☐ Nitroglycerin SL				1	I:3			NTROSL	NITROGLYCERIN SL	
		☐ Other				1	I:3			OTHER5	OTHER	
		☐ Not reported				1	I:3			NOTREP	MEDICATION NOT	
		Contrast agent					I:3			CTRAGT	CONTRAST AGENT	
		O Isovue				1						
		O Omnipaque				2						
		O Optiray				3						
		O Vispaque				4						
		O Other, specify:_____				5	S:50			AGTSP1	SPECIFY	
		O Not reported				97						
		Contrast iodine concentration (mg/dl)					I:3			CONCIOD	IODINE CONCENTRATION	
		O 300				1						

	○ 320			2					
	○ 350			4					
	○ 370			3					
	Other, ○ specify:_____			98	s:50			IODCSP	IODINE CONC SPECIFY
	○ Not reported			97					
○ No				0					

Section 3: Coronary CTA: Select the appropriate option to indicate level of stenosis

6	RCA (any)	○ Normal (0%)			1	I:3			RCASTEN1	RCA STENOSIS
		○ Non-significant/mild or minor (1-49%)			2					
		○ Moderate (50-69%)			3					
		○ Significant/severe (70-99%)			4					
		○ Occluded (100%)			5					
		○ Indeterminate			6					
		○ Not reported			97					
7	Left Main	○ Normal (0%)			1	I:3			LMNSTEN1	LEFT MAIN STENOSIS
		○ Non-significant/mild or minor (1-49%)			2					
		○ Significant/severe (50-99%)			3					
		○ Occluded (100%)			4					
		○ Indeterminate			5					
		○ Not reported			97					
8	LAD (any except proximal LAD)	○ Normal (0%)			1	I:3			LADSTEN1	LAD STENOSIS
		○ Non-significant/mild or minor (1-49%)			2					
		○ Moderate (50-69%)			3					
		○ Significant/severe (70-99%)			4					
		○ Occluded (100%)			5					
		○ Indeterminate			6					
		○ Not reported			97					
9	Proximal LAD	○ Normal (0%)			1	I:3			PRXSTEN1	PROXIMAL STENOSIS
		○ Non-significant/mild or minor (1-49%)			2					
		○ Moderate (50-69%)			3					
		○ Significant/severe (70-99%)			4					
		○ Occluded (100%)			5					
		○ Indeterminate			6					
		○ Not reported			97					
10	LCX (any)	○ Normal (0%)			1	I:3			LCXSTEN1	LCX STENOSIS
		○ Non-significant/mild or minor (1-49%)			2					
		○ Moderate (50-69%)			3					

		○ Significant/severe (70-99%)			4				
		○ Occluded (100%)			5				
		○ Indeterminate			6				
		○ Not reported			97				
11	Overall study quality (adequacy for exclusion or confirmation of significant CAD)	○ Diagnostic			1	I:3		STQUAL1	STUDY QUALITY
		○ Non-diagnostic			2				
			○ Motion artifacts		1	I:3		NONDRS	NONDIAGNOSTIC REASONS
			○ Calcification		2				
			○ Image noise		3				
			○ Other		98				
			○ Unknown		99				
	Section 3: LV Functional Analysis								
12	LV function	○ Normal			1	I:3		LVFUNC1	LV FUNCTION
		○ Abnormal - mild			2				
		○ Abnormal - severe (EF < 35%)			3				
		○ Not reported			97				
13	LV dysfunction	○ Regional			1	I:3		LVDYS1	LV DYSFUNCTION
		○ Global			2				
		○ Not Reported			97				
		○ Not Applicable			96				
14	Wall motion abnormality	○ Yes, indicate all that apply			1	I:3		WMA1	WALL MOTION ABNORMALITY
			❑ Septal/Anterior/Apical		1	I:3		SEPWM3	SEPTAL WALL MOTION
			❑ Inferior/Posterior		1	I:3		INFPWM3	INF POST WALL MOTION
			❑ Lateral		1	I:3		LATWM3	LATERAL WALL MOTION
		○ No			0				
		○ Not reported			97				
NR 15	Gated EF %, if available	_____ %				F:5		GATEDEF1	PERCENT GATED EF
	Enterable only by CRA, View by CDM								
NR 16	Was CTA test report received by DCRI?	❑ Yes			1			CTAREC	CTA REPORT RECEIVED
NR 17	SDV Status	○ Complete 100% SDV performed			1	I:3		SDVSTA30	SDV STATUS
		○ Not Completed			2				

FORM: CTA2 (CTA2) [RF] [DF]

Section 1: Incidental Findings											
1	Were incidental findings evaluated?	O	Yes, incidental findings were evaluated, but none noted.			2	I:3			IFEVAL3	INCIDENTAL FINDINGS EVALUATED
		O	Yes, incidental findings were noted. Select all that apply:			3					
		❑	Coronary anomaly, specify			1	I:3			CTAIF1	CTA FINDINGS 1
				_____			S:50			CTASPEC1	CTA FINDINGS 1 SPECIFY
		❑	Other cardiac finding, specify			1	I:3			CTAIF2	CTA FINDINGS 2
				_____			S:50			CTASPEC2	CT FINDINGS 2 SPEC
		❑	Lung nodules, specify size			1	I:3			CTAIF3	CTA FINDINGS 3
				_____ mm			I:3			LGNDSZ1	LUNG NODULE SIZE
		❑	Pulmonary embolism			1	I:3			CTAIF4	CTA FINDINGS 4
		❑	Pneumonia			1	I:3			CTAIF5	CTA FINDINGS 5
		❑	Aortic dilatation/aneurysm			1	I:3			CTAIF6	CTA FINDINGS 6
		❑	Aortic dissection			1	I:3			CTAIF7	CTA FINDINGS 7
		❑	Hiatal hernia			1	I:3			CTAIF8	CTA FINDINGS 8
		❑	Other non-cardiac findings, specify			1	I:3			CTAIF9	CTA FINDINGS 9
				_____			S:50			CTASPEC9	CT FINDINGS 9 SPEC
		O	No, incidental findings were not evaluated.			1					
		O	Unknown, no explicit mention of evaluation.			99					
NR 2	If incidental findings were noted, was a follow-up test/procedure recommended?	O	Yes, specify recommended test(s) and recommended time			1	I:3			TSTRECM3	TEST RECOMMENDED
				_____			S:100			SPCTST3	SPECIFY TEST AND TIME
		O	No			0					

Enterable only by CRA, View by CDM											
NR 3	SDV Status	O	Complete 100% SDV performed			1	I:3			SDVSTA31	SDV STATUS
		O	Not Completed			2					

FORM: HOSPITAL/ER VISIT (HOSPER) [RF} [DF]

Reminder: If subject hospitalized for unstable angina, shortness of breath, MI
or a stroke, complete the appropriate event form.

					Code	Attributes	Range	Comments	SAS Name	SAS Label
1	Type of visit	○ Hospital			1	I:3			TYPVS	VISIT TYPE
		○ ER			2					
2	Name of hospital	_____				S:200			HOSPNM	HOSPITAL NAME
3	Hospital city	_____				S:200			HOSPCTY	HOSPITAL CITY
4	Hospital state	_____				S:200			HOSPST	HOSPITAL STATE
5	Admission date	____/____/____				DATE	2010-2020	UNK for day and month	ADMDT	ADMISSION DATE
6	Days in Hospital	_____				I:3			HOSPDAY	DAYS IN HOSPITAL
7	Was subject in ICU?	○ Yes			1	I:3			SUBICU	ICU
		○ No			0					
8	Primary reason for hospitalization (Check only one)	○ Chest Pain, Unstable Angina or Myocardial Infarction			1	I:3			HOSPREAS	PRIMARY REASON FOR HOSP
		○ Shortness of Breath			2					
		○ Heart failure			3					
		○ Arrhythmia			4					
		○ Other CV problems			5					
		○ Non CV problem			6					
		○ Unknown			99					
9	~~Did the subject have chest pain, unstable angina (acute coronary syndrome or 'ACS')?~~	~~○ Yes, complete Unstable Angina event form~~			~~1~~	~~I:3~~			~~HVANG~~	~~SUBJECT HAVE UNSTABLE ANGINA~~
		~~○ No~~			~~0~~					
		~~○ Unknown/Don't know~~			~~99~~					
10	~~Did the subject have a heart attack (myocardial infarction/MI)?~~	~~○ Yes, complete MI event form~~			~~1~~	~~I:3~~			~~HVMI~~	~~SUBJECT HAVE MI~~
		~~○ No~~			~~0~~					
		~~○ Unknown/Don't know~~			~~99~~					
11	~~Did the subject have shortness of breath or congestive heart failure?~~	~~○ Yes, complete Unstable Angina event form~~			~~1~~	~~I:3~~			~~HVSOB~~	~~SUBJECT HAVE SOB~~
		~~○ No~~			~~0~~					
		~~○ Unknown/Don't know~~			~~99~~					

9	Did the subject have coronary (heart) balloon angioplasty or stenting (PTCA/PCI)? (If Yes at Day 60, complete REVASC form.)	○ Yes ○ No ○ Unknown/Don't know			1 0 99	I:3			HVPCI	SUBJECT HAVE PCI
10	Did the subject have coronary (heart) bypass surgery (CABG)? (If Yes at Day 60, complete REVASC form.)	○ Yes ○ No ○ Unknown/Don't know			1 0 99	I:3			HVCABG	SUBJECT HAVE CABG
14	~~Did the subject have a stroke or cerebrovascular accident (CVA)?~~	~~○ Yes, complete Stroke event form~~ ~~○ No~~ ~~○ Unknown/Don't know~~			~~1~~ ~~0~~ ~~99~~	~~I:3~~			~~HVSTRK~~	~~SUBJECT HAVE STROKE~~
11	Did the subject have carotid (neck) artery endarterectomy (CEA) surgery?	○ Yes ○ No ○ Unknown/Don't know			1 0 99	I:3			CEASURG	CEA SURGERY
12	Did the subject have carotid (neck) artery balloon angioplasty and/or stenting?	○ Yes ○ No ○ Unknown/Don't know			1 0 99	I:3			CARSTENT	CAROTID ANGIO OR STENT
13	Did the subject have lower extremity (leg) artery bypass surgery (including iliac, femoral, popliteal, etc)?	○ Yes, ○ No ○ Unknown/Don't know			1 0 99	I:3			LEGSURG	LEG BYPASS SURGERY
14	Did the subject have lower extremity (leg) (including iliac, femoral, popliteal, etc) or renal (kidney) artery balloon angioplasty and/or stenting (PTCA/PCI)?	○ Yes ○ No ○ Unknown/Don't know			1 0 99	I:3			LEGSTENT	LEG ANTIO OR STENT
15	Did the subject have lower extremity amputation, not due to trauma or accident?	○ Yes, ○ No ○ Unknown/Don't know			1 0 99	I:3			LEAMP	LOWER EXTREMITY AMPUTATION

Hidden from site - enterable only by FU

NR 15	Were hospital records requested?	○ Yes			1	I:3			RECRQST	RECORDS REQUESTED

NR	16	Were hospital medical records obtained?	○ Yes			1	I:3			RECRECD	RECORDS RECEIVED

Enterable only by CRA, View by CDM

NR	17	SDV Status	○ Complete 100% SDV performed			1	I:3			SDVSTA36	SDV STATUS
			○ Not Completed			2					

FORM: CARDIAC CATHETERIZATION (CC) [RF} [DF]

Section 1 - Test			Code	Attributes	Range	Comments	SAS Name	SAS Label
1 Date and time CC performed	____/____/____ ____ : ____			Date	2010-2020	unk for time	CATH1DTM	CARDIAC CATH DATE TIME
2 Type of procedure	O	Diagnostic catheterization	1	I:3			PROCTYPE	TYPE OF CATH PROCEDURE
	O	Diagnostic catheterization + PCI/PTCA	2					
Section 2: FINDINGS: Select the appropriate option to indicate level of stenosis								
3 RCA (any)	O	Normal (0%)	1	I:3			RCASTEN2	RCA STENOSIS
	O	Non-significant/mild or minor (1-49%)	2					
	O	Moderate (50-69%)	3					
	O	Significant/severe (70-99%)	4					
	O	Occluded (100%)	5					
	O	Indeterminate	6					
	O	Not reported	97					
4 Left Main	O	Normal (0%)	1	I:3			LMNSTEN2	LEFT MAIN STENOSIS
	O	Non-significant/mild or minor (1-49%)	2					
	O	Significant/severe (50-99%)	3					
	O	Occluded (100%)	4					
	O	Indeterminate	5					
	O	Not reported	97					
5 LAD (any except proximal LAD)	O	Normal (0%)	1	I:3			LADSTEN2	LAD STENOSIS
	O	Non-significant/mild or minor (1-49%)	2					
	O	Moderate (50-69%)	3					
	O	Significant/severe (70-99%)	4					
	O	Occluded (100%)	5					
	O	Indeterminate	6					
	O	Not reported	97					
6 Proximal LAD	O	Normal (0%)	1	I:3			PRXSTEN2	PROXIMAL STENOSIS
	O	Non-significant/mild or minor (1-49%)	2					
	O	Moderate (50-69%)	3					
	O	Significant/severe (70-99%)	4					
	O	Occluded (100%)	5					
	O	Indeterminate	6					
	O	Not reported	97					

	7	LCX (any)	○ Normal (0%)			1	I:3		LCXSTEN3	LCX STENOSIS
			○ Non-significant/mild or minor (1-49%)			2				
			○ Moderate (50-69%)			3				
			○ Significant/severe (70-99%)			4				
			○ Occluded (100%)			5				
			○ Indeterminate			6				
			○ Not reported			97				

Section 3: Left Ventriculography

8	LV function	○ Normal		1	I:3		LVFUNC2	LV FUNCTION
		○ Abnormal - mild		2				
		○ Abnormal - severe (EF < 35%)		3				
		○ Not reported		97				
9	LV dysfunction	○ Regional		1	I:3		LVDYS2	LV DYSFUNCTION
		○ Global		2				
		○ Not Reported		97				
		○ Not Applicable		96				
10	Wall motion abnormality	○ Yes, indicate all that apply		1	I:3		WMA2	WALL MOTION ABNORMALITY
		☐ Septal/Anterior/Apical		1	I:3		SEPWM4	SEPTAL WALL MOTION
		☐ Inferior/Posterior		1	I:3		INFPWM4	INF POST WALL MOTION
		☐ Lateral		1	I:3		LATWM4	LATERAL WALL MOTION
		○ No		0				
		○ Not reported		97				

NR	11	EF %, if available	_____ %		F:5		GATEDEF2	PERCENT EF

12	Mitral regurgitation	○ Normal	1	I:3		MITREG1	MITRAL REGURGITATION
		○ Mild	2				
		○ Moderate	3				
		○ Severe	4				
		○ Not done/reported	97				

Section 4 : Radiation Exposure

*	13	Fluoro time	_____ min	_____ sec		I:3		FLUOMIN1	FLUOR TIME MINUTES
						I:3		FLUOSEC1	FLUOR TIME SECONDS

	#	Question	Response		Code	Format	Rule	Variable	Label	
			__ Not Applicable			I:3	ADD rule that if Min/Sec are provided, then Not App must be null	FLUORNA	CC FLUORO NOT APPLICABLE	NEW
NR SV	14	Cine Runs/ # of Runs	_____	_____		F:5		CINE1	CINE NUMBER OF RUNS	HIDE
*	14	Cine Runs/ # of Runs	_____	_____		F:5	Ask PL if this will be for OLD and NEW	CINE1N	CINE NUMBER OF RUNS	
			__ Not Applicable			I:3		CINENA	CC CINE NOT APPLICABLE	NEW
NR	15	Kerma area product or dose area product, if available	_____ mGyxcm2			I:3		KERMA1	KERMA AREA PRODUCT	
		Section 5: Incidental Findings								
	16	Were incidental findings evaluated?	O Yes, incidental findings were evaluated, but none noted.		2	I:3		IFEVAL4	INCIDENTAL FINDINGS EVALUATED	
			O Yes, incidental findings were noted. Select all that apply:		3					
				☐ Coronary anomaly, specify	1	I:3		CCINCF1	CARD CATH INC FINDING 1	
				_____		S:50		CORSPEC1	SPECIFY CORONARY ANOMALY	
				☐ Mitral valve disease (moderate or severe regurgitation or stenosis)	1	I:3		CCINCF2	CARD CATH INC FINDING 2	
				☐ Aortic valve disease (moderate or severe regurgitation or stenosis)	1	I:3		CCINCF3	CARD CATH INC FINDING 3	
				☐ Aortic dilatation/aneurysm	1	I:3		CCINCF4	CARD CATH INC FINDING 4	
				☐ Aortic dissection	1	I:3		CCINCF5	CARD CATH INC FINDING 5	
				☐ Other, specify	1	I:3		CCINCF6	CARD CATH INC FINDING 6	
				_____		s:50				
			O No, incidental findings were not evaluated.		1					
			O Unknown, no explicit mention of evaluation.		99			CCFSPEC1	OTHER SPECIFY	
NR	17	If incidental findings were noted, was a follow-up test/procedure recommended?	O Yes, specify recommended test(s) and recommended time		1	I:3		TSTRECM4	TEST RECOMMENDED	
			_____			S:100		SPCTST4	SPECIFY TEST AND TIME	
			O No		0					

Enterable only by CRA, View by CDM

NR	18	Was card cath test report received by DCRI?	☐ Yes			1				CCREC	CARD CATH REPORT RECEIVED
NR	19	SDV Status	○ Complete 100% SDV performed			1	I:3			SDVSTA37	SDV STATUS
			○ Not Completed			2					

Date if after the DOV for that visit

SV THIS FORM WILL BE VISABLE IN A "VIEW ONLY" CAPACITY FOR THE 121 PATIENTS THAT ALREADY HAVE A REVASC FORM IN THE DATABASE

FORM: REVASCULARIZATION [RF} [DF]

Section 1 - Test

			Code	Attributes	Range	Comments	SAS Name	SAS Label
1	Date and time of procedure	___/___/___ ___ : ___		Date	2010-2020	unk for time	REVASDTM	REVASCULARIZATION DATE TIME
2	Type of revascularization procedure	O PTCA/PCI	1	I:3			VASCPROC	REVASCULARIZATION PROCEDURE
		O CABG	2					
3	Vessels revascularized (check all that apply)	❑ Left Main	1	I:3			LFTMAIN	LEFT MAIN
		❑ LAD	1	I:3			LAD	LAD
		❑ RCA	1	I:3			RCA	RCA
		❑ LCX	1	I:3			LCX	LCX

Radiation Exposure for PTCA/PCI - Complete only if PCI/PTCA is not done as part of the diagnostic cardiac catheterization

			Code	Attributes	Range	Comments	SAS Name	SAS Label
NR SV 5	Cine Runs/ # of Runs	_____		F:5			CINE3	CINE NUMBER OF RUNS
NR 6	Kerma area product or dose area product, if available	_____ mGyxcm2		I:3			KERMA3	KERMA AREA PRODUCT
7	SDV Status	O Complete 100% SDV performed	1	I:3			SDVSTA38	SDV STATUS
		O Not Completed	2					

SV

FORM: REVASCULARIZATION1 [RF} [DF]

Section 1 - Test

			Code	Attributes	Range	Comments	SAS Name	SAS Label
1	Date and time of procedure	___/___/___ ____ : ____		Date	2010-2020	unk for time	REVA1DTM	REVASCULARIZATION DATE TIME
2	Type of revascularization procedure	O PTCA/PCI	1	I:3			VASCPRO1	REVASCULARIZATION PROCEDURE
		O CABG	2					
3	Vessels revascularized (check all that apply)	☐ Left Main	1	I:3			LFTMAIN1	LEFT MAIN
		☐ LAD	1	I:3			LAD11	LAD
		☐ RCA	1	I:3			RCA11	RCA
		☐ LCX	1	I:3			LCX11	LCX

Radiation Exposure for PTCA/PCI - Complete only if PCI/PTCA is not done as part of the diagnostic cardiac catheterization

			Code	Attributes	Range	Comments	SAS Name	SAS Label
* 4	Fluoro time	_____ min		I:3			FLUOMIN131	FLUOR TIME MINUTES
		_____ sec		I:3			FLUOSE131	FLUOR TIME SECONDS
		___Not Applicable		I:3			FLUORNX1	FLUORO NOT APPLICABLE
* 5	Cine Runs/ # of Runs	_____		F:5			CINE3N1	CINE NUMBER OF RUNS
		_____ Not Applicable		I:3			CINEN1X	CINE NOT APPLICABLE
NR 6	Kerma area product or dose area product, if available	_____ mGyxcm2		I:3			KERMA31	KERMA AREA PRODUCT
7	SDV Status	O Complete 100% SDV performed	1	I:3			SDVST381	SDV STATUS
		O Not Completed	2					

FORM: DEATH (DEATH) [DF]

Reminder: Please begin to collect source documents for CEC.
(D/C summary / death narrative / autopsy report / any data pertinent to event)

						Code	Attributes	Range	Comments	SAS Name	SAS Label
1	Date of death			___/___/___				DATE	2009-2020	UNK for day, mionth	DTHDT	DEATH DATE TIME
	Narrative											
	ADD ENTRY:											
NR 2	Please provide narrative (reminder: 250 characters only - field will be truncated to 250 charaters when submitted)							A 250			DTHNARR	DEATH NARRATIVE
NR 3	Trigger number		_____					S:100			ADTRIG	TRIGGER NUMBER
	CEC status						1	I:3			ADBLSTAT	STATUS
		O	DROP DOWN LIST					I:3			ADBLS	CEC STATUS
NR 4			New				1					
			Query				2					
			Phase 1 (2 reviewers)				3					
			Phase 2				4					
			QC				5					
			Complete				6					
			Re-review				7					
			Hold				9					
		O	No action needed				8					
		☐	Duplicate trigger	Duplicate trigger			1	I:3			ADBLDU	DUPLICATE TRIGGER
			specify: _____	specify: _____				S:50			ADBLDN	DUPLICATE TRIGGER NUMBER
		☐	Other	Other			1	I:3			ADBLOT	OTHER NO ACTION
			specify: _____	specify: _____				S:50			ADBLOS	OTHER NO ACTION SPECIFIED
NR 5	o CEC Source Document Query Needed	O	Yes				1	I:3	1 = Yes		ADSDQRY	SOURCE DOC QUERY NEEDED

NR	Field	Input	Code	Format	Range	Range2	Variable	Description
	Trigger Date (Calculate from System When Trigger First at New) - (NOTE: RECALCULATE IF FIELD DELETED / RE-ENTERED)	____ / ____ / ____		DATE	2010 - 2020 (all required)		TRGCRDT	DATE TRIGGER CREATED
	CEC Source Document Query Date (Calculate - Sysdate when box is checked and data Submitted) - (NOTE: RECALCULATE IF FIELD DELETED / RE-ENTERED)	____ / ____ / ____		DATE	2010 - 2020 (all required)		ADSORDT	DATE CEC SOURCE DOC QUERY CREATED
	Trigger Complete Date (Calculate from System When Status = Complete) - (NOTE: RECALCULATE EVERY TIME STATUS = COMPLETE)	____ / ____ / ____		DATE	2010 - 2020 (all required)		TRGCMPDT	DATE TRIGGER COMPLETED
NR 6	CEC status date - POPULATE WITH DATE OF MOST RECENT CHANGE TO CEC STATUS	____ / ____ / ____		DATE	2010 - 2020 (all required)		ADSTADT	DATE OF STATUS
NR 7	Reviewer Number			I:3	I:3		ADRVNUM	REVIEWER NUMBER
NR 8	Suppress Sponsor Billing	☐	1	I:3	I:3		ADSSB1	SUPRESS SPONSOR BILL
NR 9	Reviewer ID	Pulldown list 2 (1 through 5o)		I:3	I:3		ADRV	REVIEWER ID
NR 10	Date Sent	_ _ /_ _/_ _ _ _		DATE	2010-2020		ADSNTDT	SENT DT PHASE 1 REVIEWER
NR 11	Date Returned	_ _ /_ _ _ _ _		DATE	2010-2020		ADRTNDT	DT PHASE 1 REVIEW RETURN
NR 12	Committee	☐ Suppress Sponsor Billing	1	I:3			ADSSBC	SUPRESS SPONS BILL COMMIT
		Date sent ____ / ____ / ____		DATE	2010-2020		ADSNCDT	SENT DT FOR COMMITTEE
		Date returned ____ / ____ / ____		DATE	2010-2020		ADRTCDT	DT OF COMMITTEE RETURN
NR 13	QC	☐ Suppress Sponsor Billing	1	I:3			ADSSBQ	SUPPRESS SPONSOR BILL QC
		Date sent ____ / ____ / ____		DATE	2010-2020		ADSNQDT	SENT DATE FOR QC
		Date returned ____ / ____ / ____		DATE	2010-2020		ADRTQDT	DATE OF QC RETURN
NR 14	Date and time of death:	____/____/____ ____:____		DATE	2010-2020	2010-2020	CECDTHDT	CEC DATE OF DEATH
NR 15	Primary cause of death	O Myocardial Infarction	1	I:3			CECDTHCS	CAUSE OF DEATH
		O Heart Failure/Cardiogenic Shock	2					
		O Non-Hemorrhagic Stroke	3					
		O Intracranial Hemorrhage	4					

	○ Hemorrhage, not intracranial			5				
	○ Sudden Death			6				
		○ Witnessed		1	I:3		CECWITN	DEATH WITNESSED
		○ Unwitnessed		2				
			○ Last seen <24 hrs	1	I:3		CECLSTSN	LAST SEEN
			○ Last seen > or = 24 hrs	2				
	○ Pulmonary Embolism			7				
	○ CV Procedure			8				
		○ CABG		1	I:3		CECCVPRO	CV PROCEDURE
		○ PCI/Stenting		2				
		○ Valvular		3				
	○ Other CV, specify			9				
		Specify:_____			S:200		CECCVSP	OTHER CV SPECIFY
	○ Non-Cardiovascular Event - Specify: Other Cause -			10				
		○ Malignancy		1	I:3		CECOTCSE	OTHER CAUSE OF DEATH
		○ Respiratory Failure		2				
		○ Infection/Sepsis		3				
		○ Accidental/Trauma		4				
		○ Suicide		5				
		○ Liver failure		6				
		○ Renal failure		7				
		○ Other, Specify		8				
		_____			S:200		CECDTHOT	OTHER SPECIFY
	○ Unknown			99				

NR	16	Comments	_____		S:200		ADCMTS	ADJUDICATION COMMENTS
NR	17	Committee Review Signature	____/____/____		DATE	2010-2020	ADCOMDT	COMMITTEE REVIEW SIG DATE
NR	18	CEC Coordinator Signature	____/____/____		DATE	2010-2020	ADCECDT	CEC COORD SIGN DATE
NR	19	Report Printed Today	____/____/____		DATE	2010-2020	ADRPTDT	SYSTEMDATE

Enterable only by CRA, View by CDM

NR	20	SDV Status	○ Complete 100% SDV performed	1	I:3		SDVSTA39	SDV STATUS
			○ Not Completed	2				

FORM: STROKE (STROKE)   [DF]/[RF]

Reminder: Please begin to collect source documents for CEC.
(Admit / history/ physical exam / neurology consult / procedure report prior to event occurring /
CT or MRI reports / D/C summary / any data pertinent to event)

				Code	Attributes	Range	Comments	SAS Name	SAS Label
	1	**Date of stroke**	____/____/____		DATE	2010-2020	**FOR DAY MONTH**	STRKDT	STROKE DATE
		Narrative							
		ADD ENTRY:							
NR	**2**	**Please provide narrative (reminder: 250 characters only - field will be truncated to 250 charaters when submitted)**			A 250			STRNARR	STROKE NARRATIVE
NR	**3**	**Trigger number**	_____		S:100			ADTRIG2	TRIGGER NUMBER
		CEC status		1	I:3			ADBLSTA2	STATUS
			O **DROP DOWN LIST**		I:3			ADBLS2	CEC STATUS
			New	1					
NR	**4**		**Query**	2					
			Phase 1 (2 reviewers)	3					
			Phase 2	4					
			QC	5					
			Complete	6					
			Re-review	7					
			Hold	9					
			O **No action needed**	8					
			☐ **Duplicate trigger**	1	I:3			ADBLDU2	DUPLICATE TRIGGER
			specify: _____		S:50			ADBLDN2	DUPLICATE TRIGGER NUMBER
			☐ **Other**	1	I:3			ADBLOT2	OTHER NO ACTION
			specify: _____		S:50			ADBLOS2	OTHER NO ACTION SPECIFIED

NR	5	o CEC Source Document Query Needed	O Yes		1	I:3	1 = Yes		ADSDQRY2	SOURCE DOC QUERY NEEDED
		Trigger Date (Calculate from System When Trigger First at New) - (NOTE: RECALCULATE IF FIELD DELETED / RE-ENTERED)	____ / ____ / ____			mmm/dd/yyyy	2010 - 2020 (all required)		TRGCR2DT	DATE TRIGGER CREATED
		CEC Source Document Query Date (Calculate - Sysdate when box is checked and data Submitted) - (NOTE: RECALCULATE IF FIELD DELETED / RE-ENTERED)	____ / ____ / ____			mmm/dd/yyyy	2010 - 2020 (all required)		ADSOR2DT	DATE CEC SOURCE DOC QUERY CREATED
		Trigger Complete Date (Calculate from System When Status = Complete) - (NOTE: RECALCULATE EVERY TIME STATUS = COMPLETE)	____ / ____ / ____			mmm/dd/yyyy	2010 - 2020 (all required)		TRGCM2DT	DATE TRIGGER COMPLETED
NR	6	CEC status date - POPULATE WITH DATE OF MOST RECENT CHANGE TO CEC STATUS	____ / ____ / ____			mmm/dd/yyyy	2010 - 2020 (all required)		ADSTA2DT	DATE OF STATUS
NR	7	Reviewer Number				I:3			ADRVNUM2	REVIEWER NUMBER
NR	8	Suppress Sponsor Billing	❑		1	I:3			ADSSB12	SUPRESS SPONSOR BILL
NR	9	Reviewer ID	Pulldown list 2 (1 through 5o)			I:3			ADRV2	REVIEWER ID
NR	10	Date Sent	_ _ /_ /_ _ _			DATE	2010-2020		ADSNT2DT	SENT DT PHASE 1 REVIEWER
NR	11	Date Returned	_ _ /_ _ _ _			DATE	2010-2020		ADRTN2DT	DT PHASE 1 REVIEW RETURN
NR	12	Committee	❑ Suppress Sponsor Billing		1	I:3			ADSSBC2	SUPRESS SPONSOR BILLCOMMITTEE
			Date sent ____ / ____ / ____			DATE	2010-2020		ADSNC2DT	SENT DT FOR COMMITTEE
			Date returned ____ / ____ / ____			DATE	2010-2020		ADRTC2DT	DT OF COMMITTEE RETURN
NR	13	QC	❑ Suppress Sponsor Billing		1	I:3			ADSSBQ2	SUPRESS SPONSOR BILL QC
			Date sent ____ / ____ / ____			DATE	2010-2020		ADSNQ2DT	SENT DATE FOR QC
			Date returned ____ / ____ / ____			DATE	2010-2020		ADRTQ2DT	DATE OF QC RETURN

NR	#	Question			Code		Range	Note	Variable	Label
NR	14	Did Stroke event occur?	O	Yes; If Yes date and time of event:	1	I:3			CECSTRK	CEC STROKE OCCUR
				___/___/___ ___:___		DATE	2010 - 2020	unk for time	CECSTDTM	CEC STROKE DATE TIME
			O	No	0					
NR			O	No, Unable to adjudicate	2					
NR	15	Stroke Type:	O	Primary Hemorrhage	1	I:3			CECSTRTP	CEC STROKE TYPE
			O	Intraparenchymal Hemorrhage	1	I:3			CECHEMOR	CEC HEMORRAGE
			O	Intraventricular Hemorrhage	2					
			O	Subarachnoid Hemorrhage	3					
			O	Subdural Hemorrhage	4					
			O	Cerebral Infarction	2					
			O	Infarction with Hemorrhagic conversion	3					
			O	Uncertain type	4					
NR	16	Did this stroke occur within 72 hours of a procedure?	O	Yes, indicate procedure	1	I:3			CECSTROC	CEC STROKE 72 HOURS
				O Diagnostic cath		I:3			CECPRCOC	PROCEDURE OCCURRED
				O PCI						
				O CABG						
				O Non-invasive CV Testing					CECTEST	NONINVASIVE CV TEST
				O CTA	1					
				O ETT	2	I:3				
				O SPECT	3					
				O ECHO	4					
				O Other	98					
				Specify_____					CECTSTSP	TEST SPECIFY
			O	Other	98	S:50				
				Specify_____		S:50			CECPROSP	PROCEDURE SPECIFY
			O	No	0					
NR	17	Comments		_____		S:200			ADJCMTS2	ADJUDICATION COMMENTS
NR	18	Committee Review Signature		___/___/___		DATE	2010-2020		ADCOM2DT	COMMITTEE REVIEW SIG DATE
NR	19	CEC Coordinator Signature		___/___/___		DATE	2010-2020		ADCEC2DT	CEC COORD SIGN DATE

NR	20	Report Printed Today	___ / ___ / ___			DATE	2010-2020			ADRPT2DT	SYSTEMDATE

Enterable only by CRA, View by CDM

NR	21	SDV Status	O Complete 100% SDV performed		1	I:3			SDVSTA40	SDV STATUS
			O Not Completed		2					

FORM: MYOCARDIAL INFARCTION (MI)
[DF]/[RF]

Reminder: Please begin to collect source documents for CEC.
(Admit note / history / physical exam / D/C summary / cardiac marker labs with ULNs / ECGs /
relevant diagnostic and procedure reports / any data pertinent to event)

				Code	Attributes	Range	Comments	SAS Name	SAS Label
1	**Date Of MI**	___/___/___ ___:___			**DATE**	**2010-2020**	**Allow UNK for D/M**	**MIDT**	**MI DATE**
	Narrative								
	ADD ENTRY:								
NR 2	**Please provide narrative (reminder: 250 characters only - field will be truncated to 250 charaters when submitted)**				**A 250**			**MINARR**	**MI NARRATIVE**
NR 3	**Trigger number**	_____			**S:100**			**ADTRIG3**	**TRIGGER NUMBER**
	CEC status			1	**I:3**			**ADBLSTA3**	**STATUS**
		○ **DROP DOWN LIST**			**I:3**			**ADBLS3**	**CEC STATUS**
		New		1					
		Query		2					
		Phase 1 (2 reviewers)		3					
NR 4		**Phase 2**		4					
		QC		5					
		Complete		6					
		Re-review		7					
		Hold		9					
		○ **No action needed**		8					
		☐ **Duplicate trigger**		1	**I:3**			**ADBLDU3**	**DUPLICATE TRIGGER**
		specify: _____			**S:50**			**ADBLDN3**	**DUPLICATE TRIGGER NUMBER**

NR	#	Description	Field	Code	Type	Range		Variable	Label
			☐ Other	1	I:3			ADBLOT3	OTHER NO ACTION
			specify: _____		S:50			ADBLOS3	OTHER NO ACTION SPECIFIED
NR	5	o CEC Source Document Query Needed	○ Yes	1 = Ye	I:3			ADSDQRY3	SOURCE DOC QUERY NEEDED
		Trigger Date (Calculate from System When Trigger First at New) - (NOTE: RECALCULATE IF FIELD DELETED / RE-ENTERED)	____ / ____ / ____		mmm/dd/yyyy	2010 - 2020 (all required)		TRGCR3DT	DATE TRIGGER CREATED
		CEC Source Document Query Date (Calculate - Sysdate when box is checked and data Submitted) - (NOTE: RECALCULATE IF FIELD DELETED / RE-ENTERED)	____ / ____ / ____		mmm/dd/yyyy	2010 - 2020 (all required)		ADSOR3DT	DATE CEC SOURCE DOC QUERY CREATED
		Trigger Complete Date (Calculate from System When Status = Complete) - (NOTE: RECALCULATE EVERY TIME STATUS = COMPLETE)	____ / ____ / ____		mmm/dd/yyyy	2010 - 2020 (all required)		TRGCM3DT	DATE TRIGGER COMPLETED
NR	6	CEC status date - POPULATE WITH DATE OF MOST RECENT CHANGE TO CEC STATUS	____ / ____ / ____		mmm/dd/yyyy	2010 - 2020 (all required)		ADSTA3DT	DATE OF STATUS
NR	7	Reviewer Number			I:3			ADRVNUM3	REVIEWER NUMBER
NR	8	Suppress Sponsor Billing	☐	1	I:3			ADSSB13	SUPRESS SPONSOR BILL
NR	9	Reviewer ID	Pulldown list 2 (1 through 5o)		I:3			ADRV3	REVIEWER ID
NR	10	Date Sent	_ _ /_ /_ _ _ _		DATE	2010-2020		ADSNT3DT	SENT DT PHASE 1 REVIEWER
NR	11	Date Returned	_ _ /_ _ _ _ _		DATE	2010-2020		ADRTN3DT	DT PHASE 1 REVIEW RETURN
NR	12	Committee	☐ Suppress Sponsor Billing	1	I:3			ADSSBC3	SUPRESS SPONSOR BILLCOMMITTEE
			Date sent ____ / ____ / ____		DATE	2010-2020		ADSNC3DT	SENT DT FOR COMMITTEE
			Date returned ____ / ____ / ____		DATE	2010-2020		ADRTC3DT	DT OF COMMITTEE RETURN

NR											
NR 13	QC	☐ Suppress Sponsor Billing			1	I:3			ADSSBQ3	SUPPRESS SPONSOR BILL QC
		Date sent ____ / ____ / ____				DATE	2010-2020		ADSNQ3DT	SENT DATE FOR QC
		Date returned ____ / ____ / ____				DATE	2010-2020		ADRTQ3DT	DATE OF QC RETURN
NR 14	Did MI Occur Post Randomization?	○ Yes; If Yes date and time of event:			1	I:3			CECPSTMI	CEC POST RAND MI OCCUR
		____/____/____ ____:____				DATE	2010 - 2020		CECMIDTM	CEC MI DATE TIME
		○ No			0					
NR		○ No, Unable to adjudicate			2					
NR 15	Type of MI :	○ Spontaneous			1	I:3			CECMUITY	CEC MI TYPE
	(Check one most applicable)	○ Peri-PCI			2					
		○ Peri-CABG			3					
		○ Peri-Death			4					
		○ Peri-non-invasive test			5					
NR 16	Evidence by cardiac enzymes:	○ No			0	I:3			CECEVDNC	CEC EVIDENCE CARDIAC ENZYME
		○ Yes			1					
NR 17	Peak CK	_____				F:9			CECCUKVA	CEC UAMI CK VALUE
		ULN_____				F:9			CECCUKU	CEC UAMI CK ULN
NR 18	Peak CKMB	_____				F:9			CECUKMBV	CEC UAMI CKMB VALUE
		ULN_____				F:9			CDCUKMBU	CEC UAMI CKMB UNIT
NR 19	Peak Troponin I	_____				F:9			CECTRPIV	CEC MI TROPONIN I VALUE
		ULN_____				F:9			CECTRPIU	CEC MI TROPONIN I ULN
NR 20	Peak Troponin T	_____				F:9			CECTRPTV	CEC MI TROPONIN T VALUE
		ULN_____				F:9			CECTRPTU	CEC MI TROPONIN T ULN
NR 21	Are there new Q waves (>40ms) associated with this event?	○ Yes			1	I:3			CECQWAVE	CEC UAMI Q WAVE

		○ No			0					
		○ Unknown			99					
NR	22 Comments	_____			S:200			ADJCMTS3	**ADJUDICATION** COMMENTS
NR	23 Committee Review Signature	____ / ____ / ____			DATE	2010-2020		ADCOM3DT	**COMMITTEE REVIEW SIG** DATE
NR	24 CEC Coordinator Signature	____ / ____ / ____			DATE	2010-2020		ADCEC3DT	**CEC COORD** SIGN DATE
NR	25 Report Printed Today	____ / ____ / ____			DATE	2010-2020		ADRPT3DT	SYSTEMDATE

Enterable only by CRA, View by CDM

NR	26 SDV Status	○ Complete 100% SDV performed		1	I:3			SDVSTA41	SDV STATUS
		○ Not Completed		2					

FORM: PERI-PROCEDURAL MAJOR BLEEDING (BLEED) [DF]/[RF]

Reminder: Please begin to collect source documents for CEC.
(History/ physical exam / procedure report prior to event occurring / transfusion
records / hematology labs (hgb & hct) / data documenting treatment / any data
pertinent to event)

			Code	Attributes	Range	Comments	SAS Name	SAS Label
1	**Date of bleeding event**	____/____/____		Date	2010-2020	UNK for day month	BBLDDT	BLEED DATE
	Narrative							
	ADD ENTRY:							
NR 2	**Please provide narrative (reminder: 250 characters only - field will be truncated to 250 charaters when submitted)**			A 250			BLDNARR	BLEED NARRATIVE
NR 3	**Trigger number**	_____		S:100			ADTRIG4	TRIGGER NUMBER
	CEC status		1	I:3			ADBLSTA4	STATUS
		○ DROP DOWN LIST		I:3			ADBLS4	CEC STATUS
		New	1					
NR 4		Query	2					
		Phase 1 (2 reviewers)	3					
		Phase 2	4					
		QC	5					
		Complete	6					
		Re-review	7					
		Hold	9					
		○ No action needed	8					
		☐ Duplicate trigger	1	I:3			ADBLDU4	DUPLICATE TRIGGER
		specify: _____		S:50			ADBLDN4	DUPLICATE TRIGGER NUMBER

NR	#	Label	Field		Count	Format	Range		Variable	Description	
			☐ Other		1	I:3			ADBLOT4	OTHER NO ACTION	
			specify: _____			S:50			ADBLOS4	OTHER NO ACTION SPECIFIED	
NR	5	o CEC Source Document Query Needed	o Yes		1	I:3	1 = Yes		ADSDQRY4	SOURCE DOC QUERY NEEDED	23
		Trigger Date (Calculate from System When Trigger First at New) - (NOTE: RECALCULATE IF FIELD DELETED / RE-ENTERED)	____ / ____ / ____			mmm/dd/yyyy	2009 - 2020 (all required)		TRGCR4DT	DATE TRIGGER CREATED	20
		CEC Source Document Query Date (Calculate - Sysdate when box is checked and data Submitted) - (NOTE: RECALCULATE IF FIELD DELETED / RE-ENTERED)	____ / ____ / ____			mmm/dd/yyyy	2009 - 2020 (all required)		ADSOR4DT	DATE CEC SOURCE DOC QUERY CREATED	33
		Trigger Complete Date (Calculate from System When Status = Complete) - (NOTE: RECALCULATE EVERY TIME STATUS = COMPLETE)	____ / ____ / ____			mmm/dd/yyyy	2009 - 2020 (all required)		TRGCM4DT	DATE TRIGGER COMPLETED	22
NR	6	CEC status date - POPULATE WITH DATE OF MOST RECENT CHANGE TO CEC STATUS	____ / ____ / ____			mmm/dd/yyyy	2009 - 2020 (all required)		ADSTA4DT	DATE OF STATUS	14
NR	7	Reviewer Number				I:3			ADRVNUM4	REVIEWER NUMBER	
NR	8	Suppress Sponsor Billing	☐		1	I:3			ADSSB14	SUPRESS SPONSOR BILL	
NR	9	Reviewer ID	Pulldown list 2 (1 through 5o)			I:3			ADRV4	REVIEWER ID	
NR	10	Date Sent	_ _/_ _/_ _ _ _			DATE	2010-2020		ADSNT4DT	SENT DT PHASE 1 REVIEWER	
NR	11	Date Returned	_ _/_ _/_ _ _ _			DATE	2010-2020		ADRTN4DT	DT PHASE 1 REVIEW RETURN	
NR	12	Committee	☐ Suppress Sponsor Billing		1	I:3			ADSSBC4	SUPRESS SPONSOR BILLCOMMITTE E	

		Date sent ____ / ____ / ____				DATE	2010-2020		ADSNC4DT	SENT DT FOR COMMITTEE
		Date returned ____ / ____ / ____				DATE	2010-2020		ADRTC4DT	DT OF COMMITTEE RETURN
NR 13	QC	❑ Suppress Sponsor Billing			1	I:3			ADSSBQ4	SUPPRESS SPONSOR BILL QC
		Date sent ____ / ____ / ____				DATE	2010-2020		ADSNQ4DT	SENT DATE FOR QC
		Date returned ____ / ____ / ____				DATE	2010-2020		ADRTQ4DT	DATE OF QC RETURN
NR 14	Did bleeding event occur?	○ Yes; If Yes, indicate date and time of onset:			1	I:3			BLDEVNT	ADJUDICATED BLEEDING EVENT
		____ / ____ / ____ ____:____				DATE	2010-2020	2009 - 2014 (all required - hour and minute can be unk)	ABLDDTM	ADJ DATE TIME OF BLEEDING
		○ No			0					
NR		○ No, Unable to adjudicate			2					
NR 15	Bleeding Type	○ Major			1	I:3			BLDTYP	ADJUDICATED TYPE CRITERIA
		○ Minor			2					
NR 16	Criteria Met	❑ Hgb/Hct drop			1	I:3			HHCRIT	HGB HCT CRITERIA
		❑ Transfusion			1	I:3			TRANCRIT	TRANSFUSION CRITERIA
		❑ Re-operation or invasive intervention			1	I:3			INTERCRIT	INTERVENTION CRIT
		❑ Bleeding at a critical anatomic site			1	I:3			SITECRIT	ANAT SITE CRITERIA
NR 17	Bleeding Site	❑ Bleeding associated with cardiac surgery (including CABG and incision)			1	I:3			BXSURG	BLEED CARDIAC SURG
		❑ Retroperitoneal			1	I:3			BZRETRO	REPTROPERITIONEAL
		❑ Hematoma			1	I:3			BZTOMA	HEMATOMA
		❑ Pericardial			1	I:3			BZPCARD	PERICARDIal
		❑ Intra-articular			1	I:3			BZIART	INTRA-ARTICULAR
		❑ Intracranial			1	I:3			BZICRA	INTRACRANIAL
		❑ Intraspinal			1	I:3			BZINTS	INTRASPINAL

		☐ Bleeding associated with non-cardiac surgery			1	I:3			BXNCS	BLEED NON CARD SURG
		☐ Gastrointestinal (including upper and lower sources)			1	I:3			BZGI	GASTROINTESTINAL
		☐ Macroscopic (gross) Hematuria			1	I:3			BZURIA	HEMATURIA
		☐ Hemoptysis			1	I:3			BZHPT	HEMOPTYSIS
		☐ Bruising			1	I:3			BZBRU	BRUISING
		☐ Epistaxis			1	I:3			BZSTAX	EPISTAXIS
		☐ Intramuscular (with compartment syndrome)			1	I:3			BZMUSC	INTRAMUSCULAR WITH COMP
		☐ Intramuscular (without compartment syndrome)							BAMUSCW	INTRAMUSCULAR WITHOUT COMP
		☐ Intra-ocular/Retinal			1	I:3			BZIOC	INTRA-OCULAR
		☐ Other			1	I:3			BZOTBD	OTHER CLINICAL PRESENTATION
		_____			1	S:100			BZSPBLD	OTHER SPECIFIED BLEED
NR	18	Number of PRBC's transfused for this bleed	_____ units			I:3			NUMPRBC	NUMBER PRBC TRANSFUSED
			OR							
			O Uncertain/unknown		99	I:3			PRBCUNK	NUMBER PRBC UNKNOWN
NR	19	Pre-Bleed Hemoglobin	Hemoglobin result	_____		F:9			ADJPREHB	ADJ PRE BLEED HGB
			Unit			I:3		CDD = ADJPREHB_UNIT	ADJPREUN	ADJ PRE BLEED HGB
				O g/dl or gm%	1					
				O g/L	2					
				O mmol/L	3					
NR	20	Lowest Hemoglobin	Hemoglobin result	_____		F:9			ADJLOWHB	ADJ LOWEST HGB
			Unit			I:3		CDD = ADJLOWHB_UNIT	ADJLOWUN	ADJ LOWEST HGB UNIT
				O g/dl or gm%	1					
				O g/L	2					
				O mmol/L	3					
NR	21	Pre-Bleed Hematocrit	Hematocrit result	_____ %		I:3			ADJPREHT	ADJ PRE BLEED HCT

NR	22	Lowest Hematocrit	Hematocrit result	_____ %			I:3			ADJLOWHT	ADJ LOWEST HCT
NR	23	Did the bleed occur within 72 hours of a procedure?	O Yes, indicate procedure			1	I:3			BLDOCPRO	BLEED 72 HOUR PROCEDURE
			O Diagnostic cath			1	I:3			BLDPROC	BLEED PROCEDURE
			O PCI			2					
			O CABG			3					
			O Non-invasive CV Testing			4					
			O CTA			1	I:3			BLEEDTST	TESTING
			O ETT			2					
			O SPECT			3					
			O ECHO			4					
			O Other			98					
			Specify				S:50			TESTSPEC1	SPECIFY TESTING
			O Other			98					
			Specify				S:50			BLDSPEC	SPECIFY
			O No			0					
NR	24	Comments	_____				S:200			ADJCMTS4	ADJUDICATION COMMENTS
NR	25	Committee Review Signature	____ / ____ / ____				DATE	2010-2020		ADCOM4DT	COMMITTEE REVIEW SIG DATE
NR	26	CEC Coordinator Signature	____ / ____ / ____				DATE	2010-2020		ADCEC4DT	CEC COORD SIGN DATE
NR	27	Report Printed Today	____ / ____ / ____				DATE	2010-2020		ADRPT4DT	SYSTEMDATE

Enterable only by CRA, View by CDM

NR	26	SDV Status	O Complete 100% SDV performed			1	I:3			SDVSTA42	SDV STATUS
			O Not Completed			2					

FORM: RENAL (RENAL)
[DF]/[RF]

Reminder: Please begin to collect source documents for CEC.
(History / physical exam / procedure report prior to event occurring / lab results
for Creatinine, BUN, eGFR / documentation of treatment / D/C summary / any data
pertinent to event)

					Code	Attributes	Range	Comments	SAS Name	SAS Label
1	Date of renal event	____/____/____				Date	2010-2020	UNK for day month	RNLDT	RENAL FAILURE DATE
	Narrative									
	ADD ENTRY:									
NR 2	**Please provide narrative (reminder: 250 characters only - field will be truncated to 250 charaters when submitted)**					A 250			RNLNARR	RENAL FAILURE NARRATIVE
NR 3	Trigger number	_____				S:100			ADTRIG5	TRIGGER NUMBER
	CEC status				1	I:3			ADBLSTA5	STATUS
		O DROP DOWN LIST				I:3			ADBLS5	CEC STATUS
		New			1					
NR 4		Query			2					
		Phase 1 (2 reviewers)			3					
		Phase 2			4					
		QC			5					
		Complete			6					
		Re-review			7					
		Hold			9					
		O No action needed			8					
			☐ Duplicate trigger		1	I:3			ADBLDU5	DUPLICATE TRIGGER
			specify: _____			S:50			ADBLDN5	DUPLICATE TRIGGER NUMBER
			☐ Other		1	I:3			ADBLOT5	OTHER NO ACTION
			specify: _____			S:50			ADBLOS5	OTHER NO ACTION SPECIFIED

17

NR	5	o CEC Source Document Query Needed	o Yes			1	I:3			ADSDQRY5	SOURCE DOC QUERY NEEDED
		Trigger Date (Calculate from System When Trigger First at New) - (NOTE: RECALCULATE IF FIELD DELETED / RE-ENTERED)	___ / ___ / ___				mmm/dd/yyyy	2010 - 2020 (all required)		TRGCR5DT	DATE TRIGGER CREATED
		CEC Source Document Query Date (Calculate - Sysdate when box is checked and data Submitted) - (NOTE: RECALCULATE IF FIELD DELETED / RE-ENTERED)	___ / ___ / ___				mmm/dd/yyyy	2010 - 2020 (all required)		ADSOR5DT	DATE CEC SOURCE DOC QUERY CREATED
		Trigger Complete Date (Calculate from System When Status = Complete) - (NOTE: RECALCULATE EVERY TIME STATUS = COMPLETE)	___ / ___ / ___				mmm/dd/yyyy	2010 - 2020 (all required)		TRGCM5DT	DATE TRIGGER COMPLETED
NR	6	CEC status date - POPULATE WITH DATE OF MOST RECENT CHANGE TO CEC STATUS	___ / ___ / ___				mmm/dd/yyyy	2010 - 2020 (all required)		ADSTA5DT	DATE OF STATUS
NR	7	Reviewer Number					I:3			ADRVNUM5	REVIEWER NUMBER
NR	8	Suppress Sponsor Billing	❑			1	I:3			ADSSB15	SUPRESS SPONSOR BILL
NR	9	Reviewer ID	Pulldown list 2 (1 through 50)				I:3			ADRV5	REVIEWER ID
NR	10	Date Sent	_ _ /_ /_ _ _				DATE	2010-2020		ADSNT5DT	SENT DT PHASE 1 REVIEWER
NR	11	Date Returned	_ _ /_ _ _ _				DATE	2010-2020		ADRTN5DT	DT PHASE 1 REVIEW RETURN
NR	12	Committee	❑ Suppress Sponsor Billing			1	I:3			ADSSBC5	SUPRESS SPONSOR BILLCOMMITTEE
			Date sent ___ / ___ / ___				DATE	2010-2020		ADSNC5DT	SENT DT FOR COMMITTEE
			Date returned ___ / ___ / ___				DATE	2010-2020		ADRTC5DT	DT OF COMMITTEE RETURN
NR	13	QC	❑ Suppress Sponsor Billing			1	I:3			ADSSBQ5	SUPRESS SPONSOR BILL QC
			Date sent ___ / ___ / ___				DATE	2010-2020		ADSNQ5DT	SENT DATE FOR QC

					DATE	2010-2020		ADRTQ5DT	DATE OF QC RETURN
		Date returned ____ / ____ / ____							
NR 14	Did the subject develop renal failure?	O Yes		1	I:3			ADJRNFL	ADJUDICATED RENAL FAILURE
		O No		0					
NR		O No, Unable to adjudicate		2					
NR 15	Date and Time of Renal event	_ _/_ _/_ _ _ _ _ _:_ _			DATE	2010-2020		ADJRNDTM	ADJUDICATED RENAL DATE TIME
NR 16	Did the renal failure occur within 72 hours of a procedure?	O Yes, indicate procedure		1	I:3			RNLOCPRO	RENAL EVENT 72 HOUR PROC
		O Diagnostic cath		1	I:3			RNLPROC	RENAL EVENT PROCEDURE
		O PCI		2					
		O CABG		3					
		O Non-invasive CV Testing		4					
		O CTA		1	I:3			RNEVTST	RENAL EVENT TESTING
		O ETT		2					
		O SPECT		3					
		O ECHO		4					
		O Other		98					
		Specify:____			S:50			TESTSPEC2	SPECIFY TESTING
		O Other Procedure		98					
		Specify :_____			S:50			RNLSPEC	SPECIFY
		O No		0					
NR 17	Did the patient require renal replacement therapy?	O Yes, indicate type of mechanical fluid removal received		1	I:3			CECTHER	CEC RENAL REPLACEMENT
		O Hemodialysis		1	I:3			CECTYRCD	CEC TYPE RECEIVED
		O Ultrafiltration		2					
		O Hemofiltration		3					
		O Peritoneal Dialysis		4					
		O Peritoneal Dialysis		4					
		O No		0					
NR 18	Were labs collected pre-procedure?	O Yes, indicate test results		1	I:3			CECPRLAB	CEC PRE LABS COLLECTED
		O No		0					
	Pre-procedure serum creatinine	Result _____		1	F:9			CECPRCR	CEC PRE SERUM CREATININE
		Unit			I:3			CECPRCRU	CEC PRE CREATININE UNIT
		O mg/dl		1					
		O mmol/L		2					
	Pre-procedure eGFR	Result _____		1	F:9			CECPRGFR	CEC PRE EGFR

NR	Question	Response	Value	Format	Range	Condition	Variable	Label
		Unit		I:3				CEC EGFR UNIT
		○ ml/min	1			CECPRGFU = ml/min	CECPRGFU	
19	Were labs collected post-procedure?	○ Yes, indicate lab values	1	I:3			CECPSLAB	CEC POST LABS COLLECTED
		○ No	0					
	Highest serum creatinine	Result _____	1	F:9			CECPSCR	CEC POST SERUM CREATININE
		Unit		I:3			CECSCRU	CEC POST CREATININE UNIT
		○ mg/dl	1					
		○ mmol/L	2					
	Lowest Pre-procedure eGFR	Result _____	1	F:9			CECPSGFR	CEC POST EGFR
		Unit		I:3			CECPSGFU	CEC POST EGFR UNIT
		○ ml/min	1					
20	Comments	_____		S:200			ADJCMTS5	ADJUDICATION COMMENTS
21	Committee Review Signature	____ / ____ / ____		DATE	2010-2020		ADCOM5DT	COMMITTEE REVIEW SIG DATE
22	CEC Coordinator Signature	____ / ____ / ____		DATE	2010-2020		ADCEC5DT	CEC COORD SIGN DATE
23	Report Printed Today	____ / ____ / ____		DATE	2010-2020		ADRPT5DT	SYSTEMDATE

Enterable only by CRA, View by CDM

NR	Question	Response	Value	Format	Range	Condition	Variable	Label
24	SDV Status	○ Complete 100% SDV performed	1	I:3			SDVSTA43	SDV STATUS
		○ Not Completed	2					

FORM: UNSTABLE ANGINA HOSPITALIZATION (ANGINA) [DF]/[RF]

Reminder: Please begin to collect source documents for CEC.
(Admit note / history / physical exam / D/C summary / cardiac marker labs with ULNs / ECGs /
intervention & procedure reports / stress test / any data pertinent to event)

						Code	Attributes	Range	Comments	SAS Name	SAS Label
1	Date of unstable angina hospitalization admission			___/___/___ ___:___				DATE	2010-2020	UNK for day, month	UNANGDT	UNSTABLE ANGINA DATE
	Narrative											
	ADD ENTRY:											
NR 2	Please provide narrative (reminder: 250 characters only - field will be truncated to 250 charaters when submitted)							A 250			UNANGNAR	UNSTABLE ANGINA NARRATIVE
NR 3	Trigger number		_____					S:100			ADTRIG6	TRIGGER NUMBER
NR 4	CEC status						1	I:3			ADBLSTA6	STATUS
		O DROP DOWN LIST						I:3			ADBLS6	CEC STATUS
		New					1					
		Query					2					
		Phase 1 (2 reviewers)					3					
		Phase 2					4					
		QC					5					
		Complete					6					
		Re-review					7					
		Hold					9					
		O No action needed					8					
			☐ Duplicate trigger	Duplicate trigger			1	I:3			ADBLDU6	DUPLICATE TRIGGER
			specify: _____	specify: _____				S:50			ADBLDN6	DUPLICATE TRIGGER NUMBER
			☐ Other	Other			1	I:3			ADBLOT6	OTHER NO ACTION
			specify: _____	specify: _____				S:50			ADBLOS6	OTHER NO ACTION SPECIFIED

NR	5	o CEC Source Document Query Needed ○ Yes				1	I:3	1 = Yes	ADSDQRY6	SOURCE DOC QUERY NEEDED
		Trigger Date (Calculate from System When Trigger First at New) - (NOTE: RECALCULATE IF FIELD DELETED / RE-ENTERED) ____ / ____ / ____					mmm/dd/yyyy	2010 - 2020 (all required)	TRGCR6DT	DATE TRIGGER CREATED
		CEC Source Document Query Date (Calculate - Sysdate when box is checked and data Submitted) - (NOTE: RECALCULATE IF FIELD DELETED / RE-ENTERED) ____ / ____ / ____					mmm/dd/yyyy	2010 - 2020 (all required)	ADSOR6DT	DATE CEC SOURCE DOC QUERY CREATED
		Trigger Complete Date (Calculate from System When Status = Complete) - (NOTE: RECALCULATE EVERY TIME STATUS = COMPLETE) ____ / ____ / ____					mmm/dd/yyyy	2010 - 2020 (all required)	TRGCM6DT	DATE TRIGGER COMPLETED
NR	6	CEC status date - POPULATE WITH DATE OF MOST RECENT CHANGE TO CEC STATUS ____ / ____ / ____					mmm/dd/yyyy	2010 - 2020 (all required)	ADSTA6DT	DATE OF STATUS
NR	7	Reviewer Number					I:3		ADRVNUM6	REVIEWER NUMBER
NR	8	Suppress Sponsor Billing	❑			1	I:3		ADSSB16	SUPRESS SPONSOR BILL
NR	9	Reviewer ID	Pulldown list 2 (1 through 5o)				I:3		ADRV6	REVIEWER ID
NR	10	Date Sent	_ _ /_ _/_ _ _ _				DATE	2010-2020	ADSNT6DT	SENT DT PHASE 1 REVIEWER
NR	11	Date Returned	_ _ _/_ _ _ _ _				DATE	2010-2020	ADRTN6DT	DT PHASE 1 REVIEW RETURN
NR	12	Committee	❑ Suppress Sponsor Billing			1	I:3		ADSSBC6	SUPRESS SPONSOR BILLCOMMITTEE
			Date sent ____ / ____ / ____				DATE	2010-2020	ADSNC6DT	SENT DT FOR COMMITTEE
			Date returned ____ / ____ / ____				DATE	2010-2020	ADRTC6DT	DT OF COMMITTEE RETURN
NR	13	QC	❑ Suppress Sponsor Billing			1	I:3		ADSSBQ6	SUPPRESS SPONSOR BILL QC
			Date sent ____ / ____ / ____				DATE	2010-2020	ADSNQ6DT	SENT DATE FOR QC
			Date returned ____ / ____ / ____				DATE	2010-2020	ADRTQ6DT	DATE OF QC RETURN

NR	#	Question	Response	Input			Code	Format	Range	Note	Variable	Label
NR	14	**Did the subject experience an unstable angina hospitalization?**	O	**Yes, indicate date and time**			1	I:3			ADJUAEVT	UNSTABLE ANGINA HOSP
				Date and time of admission _ _ _/_ _/_ _ _ _ _ _:_ _				DATE	2010-2020	unk for day, time	ADJUADTM	ADJUDICATED ANGING DATE TIME
			O	**No**			0					
NR			O	**No, Unable to adjudicate**			2					
NR	15	**Did the subject experience any ischemic symptoms? (check all that apply)**	❑	**Chest pain or other symptoms representing ischemic discomfort lasting 10 minutes or more at rest within 48 hours of hospitalization**			1	I:3			CECCPN1	CHEST PAIN WITH 48 HOURS
			❑	**Chest pain or other symptoms representing ischemic discomfort in an accelerating pattern within 48 hours of hospitalization**			1	I:3			CECCPN2	CHEST PAIN ACC IN 48 HOURS
NR	16	**Evidence of ischemia or significant stenosis (check all that apply)**	❑	**Dynamic ST changes on ECG**			1	I:3			CECSTCHG	ST CHANGES ON ECG
			❑	**Ischemia on stress testing**			1	I:3			CECEST	ISCHEMIA ON EST
			❑	**Significant stenosis on angiography (CT or invasive)**			1	I:3			CECSGANG	SIGNIFICANT STENOSIS
			❑	**Revascularization**			1	I:3			CECREVAS	REVASCULARIZATION
NR	17	**Comments**	_____					S:200			ADJCMTS6	ADJUDICATION COMMENTS
NR	18	**Committee Review Signature**	____ / ____ / ____					DATE	2010-2020		ADCOM6DT	COMMITTEE REVIEW SIG DATE
NR	19	**CEC Coordinator Signature**	____ / ____ / ____					DATE	2010-2020		ADCEC6DT	CEC COORD SIGN DATE
NR	20	**Report Printed Today**	____ / ____ / ____					DATE	2010-2020		ADRPT6DT	SYSTEMDATE

Enterable only by CRA, View by CDM

NR	#	Question	Response	Input	Code	Format	Variable	Label
NR	21	**SDV Status**	O	**Complete 100% SDV performed**	1	I:3	SDVSTA44	SDV STATUS
			O	**Not Completed**	2			

FORM: ANAPHYLAXIS (ANAPHY) [DF]/[RF]

Reminder: Please begin to collect source documents for CEC.
(History / physical exam / procedure report prior to event occurring / documentation of treatment /
D/C summary / any data pertinent to event)

					Code	Attributes	Range	Comments	SAS Name	SAS Label
	1	Date of peri-procedural anaphylaxis		___/___/___ ____:_____			DATE	2010-2020	UNK for day, month	ANADT	ANAPHYLAXIS DATE
		Narrative									
NR	2	Please provide narrative (reminder: 250 characters only - field will be truncated to 250 charaters when submitted)					A 250			APHNARR	ANAPHYLAXIS NARRATIVE
NR	3	Trigger number		_____			S:100			ADTRIG7	TRIGGER NUMBER
		CEC status				1	I:3			ADBLSTA7	STATUS
			O	DROP DOWN LIST			1	I:3			ADBLS7	CEC STATUS
				New		1					
				Query		2					
NR	4			Phase 1 (2 reviewers)		3					
				Phase 2		4					
				QC		5					
				Complete		6					
				Re-review		7					
				Hold		9					
			O	No action needed		8					
			☐	Duplicate trigger		1	I:3			ADBLDU7	DUPLICATE TRIGGER
				specify: _____			S:50			ADBLDN7	DUPLICATE TRIGGER NUMBER
			☐	Other		1	I:3			ADBLOT7	OTHER NO ACTION
				specify: _____			S:50			ADBLOS7	OTHER NO ACTION SPECIFIED
NR	5	o CEC Source Document Query Needed	O	Yes		1	I:3	1 = Yes		ADSDQRY7	QUERY NEEDED
		Trigger Date (Calculate from System When Trigger First at New) - (NOTE: RECALCULATE IF FIELD DELETED / RE-ENTERED)		____ / ____ / ____			mmm/dd/yyyy	2010 - 2020 (all required)		TRGCR7DT	DATE TRIGGER CREATED

		CEC Source Document Query Date (Calculate - Sysdate when box is checked and data Submitted) - (NOTE: RECALCULATE IF FIELD DELETED / RE-ENTERED)	____ / ____ / ____			mmm/dd/yy yy	2010 - 2020 (all required)		ADSOR7DT	DATE CEC SOURCE DOC QUERY CREATED
		Trigger Complete Date (Calculate from System When Status = Complete) - (NOTE: RECALCULATE EVERY TIME STATUS = COMPLETE)	____ / ____ / ____			mmm/dd/yy yy	2010 - 2020 (all required)		TRGCM7DT	DATE TRIGGER COMPLETED
NR	6	CEC status date - POPULATE WITH DATE OF MOST RECENT CHANGE TO CEC STATUS	____ / ____ / ____			mmm/dd/yy yy	2010 - 2020 (all required)		ADSTA7DT	DATE OF STATUS
NR	7	Reviewer Number				I:3			ADRVNUM7	REVIEWER NUMBER
NR	8	Suppress Sponsor Billing	☐		1	I:3			ADSSB17	SUPRESS SPONSOR BILL
NR	9	Reviewer ID	Pulldown list 2 (1 through 5o)			I:3			ADRV7	REVIEWER ID
NR	10	Date Sent	_ _ /_ _/_ _ _ _			DATE	2010-2020		ADSNT7DT	SENT DT PHASE 1 REVIEWER
NR	11	Date Returned	_ _ /_ _ _ _ _			DATE	2010-2020		ADRTN7DT	DT PHASE 1 REVIEW RETURN
NR	12	Committee	☐ Suppress Sponsor Billing		1	I:3			ADSSBC7	SUPRESS SPONSOR BILLCOMMITTEE
			Date sent ____ / ____ / ____			DATE	2010-2020		ADSNC7DT	SENT DT FOR COMMITTEE
			Date returned ____ / ____ / ____			DATE	2010-2020		ADRTC7DT	DT OF COMMITTEE RETURN
NR	13	QC	☐ Suppress Sponsor Billing		1	I:3			ADSSBQ7	SUPPRESS SPONSOR BILL QC
			Date sent ____ / ____ / ____			DATE	2010-2020		ADSNQ7DT	SENT DATE FOR QC
			Date returned ____ / ____ / ____			DATE	2010-2020		ADRTQ7DT	DATE OF QC RETURN
NR	14	Did the subject experience an anaphylaxis event?	○ Yes		1	I:3			ADJANAEV	ADJUDICATED ANAPHYLAXIS EVENT
			○ No		0					
NR	NR		○ No, Unable to adjudicate	No, Unable to adjudicate	2					

NR						Type	Range		Var Name	Label
NR	15	Date and time of event	_ _ /_ /_ _ _ _ _ _:_ _			DATE	2010-2020	unk for day and time	ADJANDTM	ADJUD ANAPHY DATE TIME
NR	16	Did the anaphylaxis event occur within 72 hours of a procedure?	O Yes, indicate procedure		1	I:3			ANAOCPRO	ANAPHYLAXIS 72 HOUR PROCEDURE
			O Diagnostic cath		1	I:3			ANAPROC	ANAPHYLAXIS PROCEDURE
			O PCI		2					
			O CABG		3					
			O Non-invasive CV Testing		4					
			O CTA	1	I:3			ANATST	ANAPHYLAXIS TESTING
			O ETT	2					
			O SPECT	3					
			O ECHO	4					
			O Other	98					
			Specify_____		S:50			TESTSPEC3	SPECIFY TESTING
			O Other	98					
			Specify_____		S:50			ANASPEC	SPECIFY
			O No		0					
NR	17	Indicate all criteria that apply	☐ Significant reaction with BP drop (treated with inotropes)		1	I:3			CECBPDP	BP DROP REACTION
			☐ Respiratory failure requiring mechanical support		1	I:3			CECRESP	RESPIRATORY FAILURE
NR	18	Comments	_____			S:200			ADJCMTS7	ADJUDICATION COMMENTS
NR	19	Committee Review Signature	____ / ____ / ____			DATE	2010-2020		ADCOM7DT	COMMITTEE REVIEW SIG DATE
NR	20	CEC Coordinator Signature	____ / ____ / ____			DATE	2010-2020		ADCEC7DT	CEC COORD SIGN DATE
NR	21	Report Printed Today	____ / ____ / ____			DATE	2010-2020		ADRPT7DT	SYSTEMDATE
		Enterable only by CRA, View by CDM								
NR	22	SDV Status	O Complete 100% SDV performed		1	I:3			SDVSTA45	SDV STATUS
			O Not Completed		2					

FORM: ECG STRESS TEST CORE LAB (EEST_CL) [RF] [DF]

		Section 1: Exercise ECG Date			Code	Attributes	Range	Comments	SAS Name	SAS Label
NR	1	Date and time of exercise ECG stress test	_ _ /_ _/_ _ _ _ _ _:_ _			DATE	2010-2020	UNK for time	EEST2DTM	EXERCISE ECG DATE TIME
		Is this primary read for analysis?	O Yes		1	I:3			EESTPRIM	EEST Primary Read
			O No, read for variabilty analysis		0					
		Section 2: Rest ECG before Stress								
NR	2	Heart rate	_____bpm			I:3			HRTRTE1	HEART RATE
NR	3	Rhythm at time of recording	O Sinus		1	I:3			ECGRHYM2	ECG RHYTHM
			O Atrial Fibrillation/Flutter		2					
			O SVT		3					
			O 2nd or 3rd degree AV Block		4					
			O Bigeminy/Trigeminy		5					
			O Ventricular Tachycardia		6					
			O Ventricular Pacing		7					
			O atrial pacing		8					
			O junctional rhythm		9					
			O ideoventricular rhythm		10					
			O multifocal atrial tachycardia		11					
			O Undetermined/Unknown		99					
			O Other		98					
	4	ECG interpretation	O Normal		1	I : 3			ECGINT	ECG INTERPRETATION
			O Abnormal , check all the following that were present		2					
				☐ RBBB	1	I : 3			RBBB5	RBBB
				☐ LBBB	1	I : 3			LBBB	LBBB
				☐ WPW (Wolf Parkinson White)	1	I : 3			WPW	WPW
				☐ Prior infarct (Q waves)	1	I : 3			PRINFAR	PRIOR INFARCT
				☐ ST depressions	1	I : 3			STDEP6	ST DEPRESSIONS
				☐ ST elevations	1	I : 3			STELE5	ST ELEVATIONS
				☐ LVH with repolarization	1	I : 3			LVH	LVH W POLARIZATION
				☐ IVCD	1	I : 3			IVCD	IVCD
				☐ Twave abnormalities	1	I : 3			TWAVEAB	Twave abnormalities
				☐ non sustained atrial arrhythmia	1	I : 3			NONSUSAT	Non Sustained atrial arrhythmia
				☐ non sustained ventricular arrhythmia	1	I : 3			NONSUVEN	Non sustained ven arrhythmia
				☐ Other	1	I : 3			OTH6	OTHER
		Section 3: Stress ECG Results								

	#	Question	Option		Val				Code	Description
NR SV	5	ECG result - Changes meet criteria for ischemia?	○ Negative, no evidence of ischemia		1	I:3			ECGRSLT4	ECG RESULT
			○ Borderline or indeterminate		2					
			○ Positive		3					
			○ Noninterpretable , indicate all that apply		4					
			❑ LBBB		1	I:3			LBBB5	LBBB
			❑ RBBB		1	I:3			RBBB4	RBBB
			❑ Resting ST-T W abnormalities		1	I:3			WABM4	RESTING ST ABNORMALITIES
			❑ Poor technical quality/non-diagnostic		1	I:3			PTQ4	POOR TECHNICAL QUALITY
			❑ Other		1	I:3			OTHER6	OTHER
	5	ECG result - Changes meet criteria for ischemia?	○ Negative, no evidence of ischemia		1	I:3			ECGRSLT5	ECG RESULT
			○ Borderline or indeterminate		2					
			○ Positive		3					
		Overall study quality	○ Diagnostic		1	I:3			IMGLM4	EEST OVERALL IMAGE QUALITY
			○ Non-diagnostic		2					
			❑ LBBB		1	I:3			LBBB6	LBBB
			❑ RBBB		1	I:3			RBBB5X	RBBB
			❑ Resting ST-T W abnormalities		1	I:3			WABM5	RESTING ST ABNORMALITIES
			❑ Poor technical quality/non-diagnostic		1	I:3			PTQ5	POOR TECHNICAL QUALITY
			❑ Other		1	I:3			OTHER7X	OTHER
NR	6	If ECG result is positive, borderline or indeterminate, check all changes that apply	❑ ST depression		1	I:3			STDEP5	ST DEPRESSION
			❑ ST elevation		1	I:3			STELE4	ST ELEVATION
			❑ Transient T wave changes		1	I:3			TTWAVE	Transient Twave changes
			❑ Other		1	I:3			OTH5	OTHER
			OTH, SPEC:___			S:50			SPEC6	OTHER SPECIFY
	7	ECG Result - Were there any arrhythmias recorded during stress?	○ Yes , check all that apply		1	I:3			ECGARRH	ECG ARRYTHMIAS
			❑ Bradycardia		1	I:3			BRDY	BRADYCARDIA
			❑ Supraventricular tachycardia		1	I:3			VENTACH	SUPRAVENTRICULAR TACH
			❑ Nonsustained V-tach		1	I:3			NSUSVTCH	NON SUSTAINED V TACH

We are going to "hide" this question

		☐ Sustained V-tach	1	I:3			SUSVTCH	SUSTAINED V TACH
		☐ Ventricular fibrillation	1	I:3			VENTFIB	VENT FIBRILLATION
		☐ Ventricular pacemaker	1	I:3			VENTPCE	VENT PACEMAKER
		☐ Other	1	I:3			OTHER7	OTHER
	○ No		0					

SV Changes to OLD and NEW enrollment

FORM: STRESS ECHO CORE LAB (ECHO_CL) [DF}

Section 1: Stress ECHO

				Code	Attributes	Range	Comments	SAS Name	SAS Label
1	Date and time of stress ECHO test	_ _ /_ _/_ _ _ _ _ _:_ _			DATE	2010-2020	UNK for time (hr/min)	ECHO2DTM	ECHO DATE TIME
2	Was an echo contrast used in any portion of the study?	O Yes		1	I:3			ECCLCONT	ECHO CL CONTRAST
		O No		0					
		O Unknown		99					
	Is this primary read for analysis?	O Yes		1	I:3			ECHOPRIM	ECHO Primary Read
		O No, read for variabilty analysis		0					
	Section 1: LV Function								
3	Resting LV function	O Normal		1	I:3			RESTLV3	REST LV FUNCTION
		O Abnormal - mild		2					
		O Abnormal - severe (EF < 35%		3					
		O Not Reported		97					
4	LV dysfunction	O Regional		1	I:3			RSTLDYS3	LV DYSFUNCTION
		O Global		2					
		O Not Reported		97					
		O Not Applicable		96					
5	Resting wall motion abnormality	O Yes, please indicate all that apply		1	I:3			RSTWMA3	RESTING WALL MOTION ABN
		☐ Septal/Anterior/Apical		1				SEPWM5	SEPTAL WALL MOTION
		☐ Inferior/Posterior		1				INFPWM5	INF POST WALL MOTION
		☐ Lateral		1				LATWM5	LATERAL WALL MOTION
		O No		0					
		O Not reported		97					
NR 6	Resting EF %, if available	_____ %			I:3			RESTEF2	PERCENT RESTING EF
7	Peak stress LV function	O Normal		1	I:3			STSLV2	STRESS LV FUNCTION
		O Abnormal - mild		2					
		O Abnormal - severe (EF < 35%		3					
		O Not Reported		97					
8	LV dilatation at peak stress	O Yes		1	I:3			LVDLSTS2	PEAK STRESS LV DILATION

			O No		0				
			O Not reported		97				
NR	9	Peak stress EF %, if available	_____ %			I:3		PKSTSEF2	PERCENT STRESS PEAK EF
		Section 2: Stress ECHO Results							
	10	Septal/Anterior/Apical	O Normal		1	I:3		SEPRSLT2	SEPTAL ANT API RESULT
			O Resting wall motion abnormality without ischemia (infarct)		2				
			O Inducible wall motion abnormality (ischemia)		3				
			O Mixed abnormality (infarct and ischemia)		4				
			O Uninterpretable		5				
			O Not reported		97				
	11	Lateral	O Normal		1	I:3		LATRSLT2	LATERAL RESULT
			O Resting Wall motion abnormality without ischemia (infarct)		2				
			O Inducible wall motion abnormality (ischemia)		3				
			O Mixed abnormality (infarct and ischemia)		4				
			O Uninterpretable		5				
			O Not reported		97				
	12	Inferior/Posterior	O Normal		1	I:3		INFRSLT2	INFERIOR POST RESULT
			O Resting Wall motion abnormality without ischemia (infarct)		2				
			O Inducible wall motion abnormality (ischemia)		3				
			O Mixed abnormality (infarct and ischemia)		4				
			O Uninterpretable		5				
			O Not reported		97				
NR SV	12	Image Quality limited	O Yes, check all that apply		1	I:3		IMGLM2	IMAGE QUALITY LIMITED
			☐ Respiratory Artifact		1	I:3		RESTART2	RESPIRATORY ARTIFACT
			☐ Poor sound transmission		1	I:3		PRSDTRN2	POOR SOUND TRANS

We are going to "hide" this question

Images delayed > 90 ☐ sec after exercise ☐ Other, specify _____ ○ No ○ Not reported	1 1 0 97	I:3 I:3 S:50		IMGDEL2 OTH7 SPEC	IMAGE DELAYED OTHER SPECIFY

13 Overall study quality

○ Diagnostic ○ Non-diagnostic	1 2	I:3		IMGLM3	ECHO CL OVERALL IMAGE QUALITY
○ Respiratory artifact ○ Poor sound transmission ○ Images delayed > 90 sec after exercise ○ Other	1 2 3 98	I:3		ECHCLQUA	ECHO CL NON DIAGNOSTIC

FORM: STRESS NUCLEAR CORE LAB (NUC_CL) [DF]

Section 1: Stress Nuclear Test

				Code	Attributes	Range	Comments	SAS Name	SAS Label
1	Date and Time of Stress Nuclear Test	_ _/_ _/_ _ _ _ _ _:_ _			DATE	2010-2020	unk for time	NUC2DTM	STRESS NUCLEAR DATE TIME
	Is this primary read for analysis?	O Yes		1	I:3			NUCPRIM	Nuclear Core Primary Read
		O No, read for variabilty analysis		0					

Section 1: LV Function

				Code	Attributes	Range	Comments	SAS Name	SAS Label
2	Resting LV function	O Normal		1	I:3			RESTLV4	REST LV FUNCTION
		O Abnormal - mild		2					
		O Abnormal - severe (EF < 35%)		3					
		O Not reported		97					
3	Resting LV dysfunction	O Regional		1	I:3			RSTLDYS4	LV DYSFUNCTION
		O Global		2					
		O Not Reported		97					
		O Not Applicable		96					
4	Resting wall motion abnormality	O Yes, indicate all that apply		1	I:3			RSTWMA4	RESTING WALL MOTION ABN
			☐ Septal/Anterior/Apical	1	I:3			SEPWM6	SEPTAL WALL MOTION
			☐ Inferior/Posterior	1	I:3			INFPWM6	INF POST WALL MOTION
			☐ Lateral	1	I:3			LATWM6	LATERAL WALL MOTION
		O No		0					
		O Not reported		97					
NR 5	Resting gated EF %, if available	_____ %			F:5			RSTEF2	PERCENT RESTING EF
6	Post-stress LV function	O Normal		1	I:3			STRSLV2	POST STRESS LV FUNCTION
		O Abnormal - mild		2					
		O Abnormal - severe (EF < 35%)		3					
		O Not reported		97					
7	Post-stress LV dysfunction	O Regional		1	I:3			STRLDYS2	LV DYSFUNCTION
		O Global		2					
		O Not Reported		97					
		O Not Applicable		96					

8	Post-stress wall motion abnormality	O Yes, indicate all that apply		1	I:3			STRWMA2	RESTING WALL MOTION ABN
		❑	Septal/Anterior/Apical	1	I:3			SSEPWM3	SEPTAL WALL MOTION
		❑ Inferior/Posterior		1	I:3			SINFPWM2	INF POST WALL MOTION
		❑ Lateral		1	I:3			SLATWM2	LATERAL WALL MOTION
		O No		0					
		O Not reported		97					
NR	9	Post-stress gated EF%	_____ %		F:5			STRSEF2	PERCENT POST STRESS EF
	10	Transient Ischemic Dilatation	O Yes (stated in report)	1				TID2	TID
		O No (stated in report)		0					
		O Not Done		97					
	Section 2: Myocardial Perfusion								
	11	Territory: Septal/Anterior/Apical	O Normal	1	I:3			MPSEPT2	MYOCARDIAL PERFUSION SEPTAL
		O Fixed defect (infarct)		2					
		O Reversible (ischemia)		3					
		O Mixed defect (infarct and Ischemia)		4					
		O Uninterpretable		5					
		O Not reported		97					
	12	Territory: Lateral	O Normal	1	I:3			MPLAT2	MYOCARDIAL PERF LATERAL
		O Fixed defect (infarct)		2					
		O Reversible (ischemia)		3					
		O Mixed defect (infarct and Ischemia)		4					
		O Uninterpretable		5					
		O Not reported		97					
	13	Territory: Inferior/Posterior	O Normal	1	I:3			MPINF2	MYOCARDIAL PERF INF POST
		O Fixed defect (infarct)		2					
		O Reversible (ischemia)		3					
		O Mixed defect (infarct and Ischemia)		4					
		O Uninterpretable		5					
		O Not reported		97					
NR SV	14	Image Quality Limited	O Yes, check all that apply	1	I:3			IMGLMT2	IMAGE QUALITY LIMITED
		❑ Motion Artifact		1	I:3			MOTART2	MOTION ARTIFACT
		❑ Attenuation		1	I:3			ATTEN2	ATTENUATION

We are going to "hide" this question

	☐ GI Uptake	1	I:3			GIUPT2	GI UPTAKE
	○ No	0					
	○ Not reported	97					
14 Overall study quality							
	○ Diagnostic	1	I:3			IMGLMT3	NUC CL OVERALL IMAGE QUALITY
	○ Non-diagnostic	2					
	○ Motion artifact	1	I:3			NUCCLMO	NUC CL NON DIAGNOSTIC
	○ Attenuation	2					
	○ GI uptake	3					

SV   Changes to OLD and NEW enrollment
FORM: CTA TECHNICAL ASSESSMENT CORE LAB(CTA_CL) [DF]
Section 1: CTA Date

			Code	Attributes	Range	Comments	SAS Name	SAS Label
Reader #	O __ __ __		1	I:3			CTARENO	CTA Reader Number
Reader Assignment	O Reader 1		1	I:3			CTAASSIG	CTA Reader Assigment
	O Reader 2		2					
Is this primary read for analysis?	O Yes		1	I:3				CTA Primary Read
	O No, read for variabilty analysis		0				CTAPRIM	
1 Date and Time CTA Performed	__ __/__/____ __:__			DATE	2010-2020	unk for time	CTA2DTM	DATE AND TIME OF CTA
Section 2:								
2 Was calcium scan performed?	O Yes	Pull this data forward from CTA - [CASCREP]	1	I:3			CASCAN2	CALCIUM SCAN
	O No		0					
3 Was contrast CTA performed?	O Yes	Pull this data forward from CTA - [CTRCTA1]	1	I:3			CTRCTA2	CONTRAST CTA
	O No		0					
NR 4 Calcium Score	_____	Pull this data forward from CTA - [CASCR1]		I:3			CASCR2	CALCIUM SCORE
Section 3: Coronary CTA: Enter the appropriate number to indicate level of stenosis								
5 RCA (any)	O Normal (0%)		1	I:3			RCASTEN3	RCA STENOSIS
	O Non-significant/mild or minor (1-49%)		2					
	O Moderate (50-69%)		3					
	O Significant/severe (70-99%)		4					
	O Occluded (100%)		5					
	O Indeterminate		6					
	O Not reported		97					
6 Left Main	O Normal (0%)		1	I:3			LMNSTEN3	LEFT MAIN STENOSIS
	O Non-significant/mild or minor (1-49%)		2					
	O Significant/severe (50-99%)		3					
	O Occluded (100%)		4					

#	Question	Option		Value	Format			Variable	Label	Note
		O Indeterminate		5						
		O Not reported		97						
7	LAD (any except proximal LAD)	O Normal (0%)		1	I:3			LADSTEN3	LAD STENOSIS	
		O Non-significant/mild or minor (1-49%)		2						
		O Moderate (50-69%)		3						
		O Significant/severe (70-99%)		4						
		O Occluded (100%)		5						
		O Indeterminate		6						
		O Not reported		97						
8	Proximal LAD	O Normal (0%)		1	I:3			PRXSTEN3	PROXIMAL STENOSIS	
		O Non-significant/mild or minor (1-49%)		2						
		O Moderate (50-69%)		3						
		O Significant/severe (70-99%)		4						
		O Occluded (100%)		5						
		O Indeterminate		6						
		O Not reported		97						
9	LCX (any)	O Normal (0%)		1	I:3			LCXSTEN2	LCX STENOSIS	
		O Non-significant/mild or minor (1-49%)		2						
		O Moderate (50-69%)		3						
		O Significant/severe (70-99%)		4						
		O Occluded (100%)		5						
		O Indeterminate		6						
		O Not reported		97						
NR SV ~~10~~	Overall Study Quality	O Interpretable		1	I:3			STQUAL2	STUDY QUALITY	We are going to "hide" this question
		O Uninterpretable		2						
10	~~Overall study quality (adequacy for exclusion or confirmation of significant CAD)~~	O Diagnostic		1	I:3			STQUAL3	CTA_CL STUDY QUALITY OVERALL	
		O Non-diagnostic		2						
			O Motion artifacts	1	I:3			CTACLNON	CTA_CL NON DIAGNOSTIC	
			O Calcification	2						
			O Image noise	3						
			O Other	4						
			O Unknown	98						
	Section 4: LV Functional Analysis									
11	LV function	O Normal		1	I:3			LVFUNC3	LV FUNCTION	

		○	Abnormal - mild		2				
		○	Abnormal - severe (EF < 35%)		3				
		○	Not reported		97				
	12	LV dysfunction	○ Regional		1	I:3			LVDYS3	LV DYSFUNCTION
			○ Global		2				
			○ Not Reported		97				
			○ Not Applicable		96				
	13	Wall motion abnormality	○ Yes, indicate all that apply		1	I:3			WMA3	WALL MOTION ABNORMALITY
			❑ Septal/Anterior/Apical		1	I:3			SEPWM7	SEPTAL WALL MOTION
			❑ Inferior/Posterior		1	I:3			INFPWM7	INF POST WALL MOTION
			❑ Lateral		1	I:3			LATWM7	LATERAL WALL MOTION
			○ No		0				
			○ Not reported		97				
NR	14	Gated EF %, if available	_____ %			F:5			GATEDEF3	PERCENT GATED EF

FORM: INSIGNIFICANT CAD (INCAD) [RF]

Cardiac Catheterization- DCRI Clinical Read Form

		Code	Attributes	Range	Comments	SAS Name	SAS Label
Date Cardiac Catheterization Performed	___/___/___		DATE	2010 - 2020		CCVSDT	VISIT DATE
Findings: Less than 50% stenosis observed							
Left main O Yes		1	I:3			FINDLM	Stenosis Left main
O No		0					
O Unknown		99					
LAD O Yes		1	I:3			FINDLAD	Stenosis LAD
O No		0					
O Unknown		99					
Diagonal O Yes		1	I:3			FINDDIA	Stenosis Diagonal
O No		0					
O Unknown		99					
LCX O Yes		1	I:3			FINDLCX	Stenosis LCX
O No		0					
O Unknown		99					
Marginal O Yes		1	I:3			FINDMAR	Stenosis Marginal
O No		0					
O Unknown		99					
RCA O Yes		1	I:3			FINDRCA	Stenosis RCA
O No		0					
O Unknown		99					
PDA O Yes		1	I:3			FINDPDA	Stenosis PDA
O No		0					
O Unknown		99					
FFR done during procedure?	O Yes	1	I:3			FFRPROD	FFR During Procedure
	O No	0					
	O Unknown	99					
IVUS done during procedure?	O Yes	1	I:3			IVUSPROD	IVUS During Procedure

	○	No	0					
	○	Unknown	99					
Ejection fraction, if available		_____ %		I:3			EJECTFRA	Ejection Fraction
Was an intervention (PCI/PTCA) performed?	○	Yes	1	I:3			INTERVEN	Intervention performed
	○	No	0					
	○	Unknown	99					

Section 2: PHASE 1 - Reviewer - Add Entry

Field	Input		Value	Type		Code	Description
Reviewer Number				I:3		ADRVNUM8	REVIEWER NUMBER
Suppress Sponsor Billing	❑		1	I:3		ADSSB18	SUPRESS SPONSOR BILL
Reviewer ID	Pulldown list 2 (1 through 5o)		1	I:3		ADRV8	REVIEWER ID
Date Sent	_ _ /_ _/_ _ _ _		DATE	2010-2020		ADSNT8DT	SENT DT PHASE 1 REVIEWER
Date Returned	_ _ /_ _ _ _ _		DATE	2010-2020		ADRTN8DT	DT PHASE 1 REVIEW RETURN

Section 3: Committee

Field	Input		Value	Type		Code	Description
Committee	❑ Suppress Sponsor Billing		1	I:3		ADSSBC8	SUPRESS SPONSOR BILLCOMMITTEE
	Date sent ____ / ____ / ____		DATE	2010-2020		ADSNC8DT	SENT DT FOR COMMITTEE
	Date returned ____ / ____ / ____		DATE	2010-2020		ADRTC8DT	DT OF COMMITTEE RETURN
QC	❑ Suppress Sponsor Billing		1	I:3		ADSSBQ8	SUPPRESS SPONSOR BILL QC
	Date sent ____ / ____ / ____		DATE	2010-2020		ADSNQ8DT	SENT DATE FOR QC
	Date returned ____ / ____ / ____		DATE	2010-2020		ADRTQ8DT	DATE OF QC RETURN

Section 4: Results

Field	Input		Value	Type	unk for day, time	Code	Description
Date of Cardiac Cath	_ _ /_ _/_ _ _ _		DATE	2010-2020		CATHDTR	Date of Cardiac Cath
Was there any evidence of less than 50% coronary artery stenosis of all major epicardial vessels on cardiac catheterization?	○ Yes		1	I:3		ADLESS50	Evidence Less Than 50
	○ No		0	I:3			
	○ Unable to adjudicate due to insufficient data		3				
Was the angiographic film reviewed by the CEC during adjudication?	○ Yes		1	I:3		ADREVD	Angio Film Reviewed
	○ No		0				

Section 5: CEC Finalization

Field	Input		Value	Type		Code	Description
Comments	_____ _			S:200		ADJCMTS8	ADJUDICATION COMMENTS
Committee Review Signature	____ / ____ / ____		DATE	2010-2020		ADCOM8DT	COMMITTEE REVIEW SIG DATE
CEC Coordinator Signature	____ / ____ / ____		DATE	2010-2020		ADCEC8DT	CEC COORD SIGN DATE
Report Printed Today	____ / ____ / ____		DATE	2010-2020		ADRPT8DT	SYSTEMDATE

Enterable only by CRA, View by CDM

Field	Input		Value	Type		Code	Description
SDV Status	○ Complete 100% SDV performed		1	I:3		SDVSTA46	SDV STATUS
	○ Not Completed		2				