Protocol Identifier	Subject Identifier		Visit Description Treatment Period ABD Visit XYZ
	☐☐☐☐☐☐		

MYOCARDIAL INFARCTION (MI) / UNSTABLE ANGINA (UA)

May want to insert prior cardiac hx here…Need to consider that some of this may already be in Past Medical History or may be in a Cardiac Risk Factor eCRF

e.g., Prior myocardial infarction	[Y] ☐Yes [N] ☐No
Prior coronary artery disease	[Y] ☐Yes [N] ☐No
Prior angina	[Y] ☐Yes [N] ☐No

Date and time of onset of Myocardial Infarction (MI) / Unstable Angina (UA) symptoms ☐☐ Day ☐☐☐ Month ☐☐ Year ☐☐☐☐ HR: Min(00:-23:59)

Duration of symptoms at time of presentation ☐☐ hrs ☐☐ mins

Longest episode of chest pain ☐☐ hrs ☐☐ mins

ANGINA SYMPTOMS

New onset of severe angina	[Y] ☐Yes	[N] ☐No
Accelerated angina (increased frequency)	[Y] ☐Yes	[N] ☐No
Angina at rest	[Y] ☐Yes	[N] ☐No
Exertional angina	[Y] ☐Yes	[N] ☐No
Atypical symptoms	[Y] ☐Yes	[N] ☐No
Did the angina/infarction occur after medical or surgical procedure?	[Y] ☐Yes	[N] ☐No

KILLIP-KIMBALL CLASSIFICATION

Check appropriate Killip Classification based on subject's presentation:

☐ Class I: No clinical signs of heart failure

☐ Class II: Rales or crackles in the lungs, an S3 gallop, and elevated jugular venous pressure

☐ Class III: Frank acute pulmonary edema

☐ Class IV: Cardiogenic shock or hypotension (systolic blood pressure less than 90 mmHg), and peripheral vasoconstriction (oliguria, cyanosis or sweating)

URGENT CARE AND/OR HOSPITALISATION

Protocol Identifier	**Subject Identifier**		**Visit Description Treatment Period ABD Visit XYZ**

Did the subject visit the emergency room/chest pain centre? [Y] ☐ Yes [N] ☐ No

If Yes, date and time of emergency room/chest pain centre visit: Day ☐☐ Month ☐☐☐ Year ☐☐☐☐ HR: Min(00:-23:59) ☐☐☐☐

Was subject admitted to the hospital? [Y] ☐ Yes [N] ☐ No

If Yes, admission date and time: Day ☐☐ Month ☐☐☐ Year ☐☐☐☐ HR: Min(00:-23:59) ☐☐☐☐

Was the subject on any of the following medications (anti-angina, antithrombotic agents, anti-arrhythmias or other relevant drugs) at the time the event occurred: [Y] ☐ Yes [N] ☐ No

If Yes, specify:

_____

_____

Are symptoms consistent with myocardial ischemia (e.g., prolonged chest pain, etc.). [Y] ☐ Yes [N] ☐ No

Protocol Identifier	**Subject Identifier**		**Visit Description** **Treatment Period ABD** **Visit XYZ**

MYOCARDIAL INFARCTION (MI) / UNSTABLE ANGINA (UA) (Cont.)

ECG STANDARD 12-LEAD

Was an ECG performed: [Y] ☐Yes [N] ☐No [NE]☐Non Evaluable

If Yes, complete the following:

Date of ECG ☐☐ ☐☐☐ ☐☐☐☐
Day Month Year

Note: If primary data is available to upload, the following ECG data is optional.

✓all that apply:

Protocol Identifier	Subject Identifier		Visit Description Treatment Period ABD Visit XYZ

ECG Findings

☐ Left bundle branch block

☐ Left ventricular hypertrophy

☐ Non-specific ST-T changes

☐ ST elevation

New ST elevation at the J point in two anatomically contiguous leads with the cut-points: ≥ 0.2 mV in men ≥ 40 years (≥ 0.25 mV in men < 40 years) or ≥ 0.15 mV in women in leads V2-V3 and/or ≥ 0.1 mV in other leads.

☐ Transient ST elevation (Less than 20 minutes)

☐ Persistent ST elevation

☐ ST depression

ST depression and T-wave changes
New horizontal or down-sloping ST depression ≥ 0.05 mV in two contiguous leads and/or new T inversion ≥ 0.1 mV in two contiguous leads with prominent R wave or R/S ratio > 1.

☐ Dynamic horizontal/down-sloping depression

☐ T-wave flattening/inversion

☐ Pathological Q waves

- Any Q-wave in leads V2-V3 ≥ 0.02 seconds or QS complex in leads V2 and V3
- Q-wave ≥ 0.03 seconds and ≥ 0.1 mV deep or QS complex in leads I, II, aVL, aVF, or V4-V6 in any two leads of a contiguous lead grouping (I, aVL, V1-V6; II, III, and aVF)[a]

[a]The same criteria are used for supplemental leads V7-V9, and for the Cabrera frontal plane lead grouping.

☐ Myocardial infarction, old

- Pathological Q-waves, as defined above
- R-wave ≥ 0.04 seconds in V1-V2 and R/S ≥ 1 with a concordant positive T-wave in the absence of a conduction defect

Protocol Identifier	**Subject Identifier**		**Visit Description** **Treatment Period ABD** **Visit XYZ**

ECG Findings (Alternative Questions) [option 1]

☐ New or presumed new significant ST-segment-T wave (ST-T) changes

☐ New left bundle branch block

☐ Development of pathological Q waves in the ECG

ECG Findings (Alternative Questions) [option 2]

☐ Clinically significant ST-segment-T wave (ST-T) changes

☐ Left bundle branch block

☐ Pathological Q waves in the ECG

Is there a ECG prior to current event available for comparison? [Y] ☐ Yes [N] ☐ No

If prior ECG available, are there any changes compared to previous tracing? [Y] ☐ Yes [N] ☐ No

Date of ECG ☐☐ Day ☐☐☐ Month ☐☐ Year

✓all that apply:

Previous ECG Findings

☐ Left bundle branch block

☐ Myocardial infarction, old

☐ Non-specific ST-T segment changes

☐ ST segment elevation

☐ ST segment depression

☐ T-wave flattening/inversion

☐ Pathological Q waves

Protocol Identifier	**Subject Identifier**		**Visit Description** **Treatment Period ABD** **Visit XYZ**

MYOCARDIAL INFARCTION (MI) / UNSTABLE ANGINA (UA) (Cont.)

LABORATORY DATA

Enter 'NR' if the laboratory results are not available to report or if a lab error occurred

Was there an abnormal cardiac enzyme biomarker?	[Y] ☐Yes [N] ☐No
If Yes, fill out below:	
Laboratory name_____ **Address**_____ _____	**Lab ID**

Date Sample Take Day Month Year	**Test**	**Results**	**Normal Ranges**		
			Unit	**Upper Limit Normal**	
e.g., 05 JUN 09	**Peak total bilirubin**	**8.0**	**mmol/l**	**17.0**	
	Peak Troponin I				
	Peak High Sensitivity Troponin I				
	Peak Troponin T				
	Peak High Sensitivity Troponin T				
	Peak Creatine Kinase				
	Peak Creatine Kinase MB-mass (concentration**)**				
	Peak Creatine Kinase MB-mass (percentage**)**				
	Peak Creatine Kinase MB-activity (concentration**)**				

List all cardiac enzyme labs available. Add lines for serial values of the same lab as needed.

Protocol Identifier	**Subject Identifier**		**Visit Description** **Treatment Period ABD** **Visit XYZ**

	Troponin I				
	High Sensitivity Troponin I				
	Troponin T				
	High Sensitivity Troponin T				
	Creatine Kinase				
	Creatine Kinase MB-mass (concentration**)**				
	Creatine Kinase MB-mass (percentage**)**				
	Creatine Kinase MB-activity (concentration**)**				

Protocol Identifier	Subject Identifier		Visit Description Treatment Period ABD Visit XYZ

ECHOCARDIOGRAPHY

Was an Echocardiogram performed? [Y] ☐Yes [N] ☐N

If Yes, complete the following:

Date and time of Echocardiogram: ☐☐ **Day** ☐☐☐ **Month** ☐☐ **Year** ☐☐ ☐☐ **Hrs:Mins**

(00:00-23:59)

Ejection Fraction Assessment (systolic function)? [Y] ☐Yes [N] ☐N

If Yes, record percentage ☐☐ **%**

Evidence of diastolic dysfunction? [Y] ☐Yes [N] ☐N

Evidence of significant valvular disease? [Y] ☐Yes [N] ☐N

Evidence of cardiac dilatation? [Y] ☐Yes [N] ☐N
If Yes, indicate which chamber(s) [A] ☐Atrial [V] ☐Ventricular
Evidence of regional wall motion abnormality? [Y] ☐Yes [N] ☐N

Was a prior Echocardiogram performed? [Y] ☐Yes [N] ☐N
If Yes, complete the following:

Date and time of prior Echocardiogram: ☐☐ **Day** ☐☐☐ **Month** ☐☐ **Year** ☐☐ ☐☐ **Hrs:Mins**

(00:00-23:59)

Prior Ejection Fraction Assessment (systolic function)? [Y] ☐Yes [N] ☐N

If Yes, record percentage ☐☐ **%**

Prior evidence of diastolic dysfunction? [Y] ☐Yes [N] ☐N

Evidence of significant valvular disease? [Y] ☐Yes [N] ☐N

Protocol Identifier	**Subject Identifier**		**Visit Description** **Treatment Period ABD** **Visit XYZ**

PHARMACOLOGIC AND/OR EXERCISE STRESS IMAGING REPORTS

Test	**Test Done** Y=Yes N=No	**Date of Test** Day Month Year	**Time of Test** Hr:min 00:00-23.59	**What is the interpretation of result?** 1=Normal 2=Abnormal	**Is there evidence of ischemia?** Y=Yes N=No U=Unknown	**Is there evidence of infarction?** Y=Yes N=No U=Unknown
	e.g., Y	**05 Jun 09**	**10:35**	**1**	**N**	**N**
ECG						
Echo						
Nuclear						
MRT						

PHARMACOLOGIC AND/OR EXERCISE STRESS IMAGING REPORTS (Alternative Questions)

Was any pharmacologic and / or exercise stress imaging test performed? [Y] ☐Yes [N] ☐No

If yes, fill out below:

Were there any changes consistent with ischemia or infarction?	[Y] ☐Yes [N] ☐No
Were the changes new?	[Y] ☐Yes [N] ☐No [U] Unknown

What treatment was initiated?

Treatment	**Date of Treatment** Day Month Year	**Time of Treatment** Hr:min 00:00-23.59			
Pharmacotherapy					
	New or increase in oral nitrates		[Y] ☐Yes [N] ☐N		
	IV nitrates		[Y] ☐Yes [N] ☐N		
	New or increase in beta-blocker		[Y] ☐Yes [N] ☐N		
Coronary Intervention					
Surgical Therapy					

Protocol Identifier	Subject Identifier		Visit Description Treatment Period ABD Visit XYZ

MYOCARDIAL INFARCTION (MI) / UNSTABLE ANGINA (UA) (Cont.)

SURGICAL/MEDICAL PROCEDURES

SURGICAL/MEDICAL PROCEDURES (Continued)

	Procedure Done Y=Yes N=No	**Date of Surgery/Procedure** Day Month Year	**Time of Surgery/Procedure** Hr:Min 00:00-23:59
	e.g., Y	**05 JUN 09**	**10:35**
Percutaneous coronary intervention			
Coronary Artery Bypass Graft			

FINAL DIAGNOSIS

✓only one:

- ☐ Unstable angina
- ☐ Myocardial Infarction-ST segment elevation
- ☐ Myocardial Infarction-Non-ST segment elevation
- ☐ Other cardiac chest pain (e.g., pericarditis, myocarditis)
- ☐ Non-cardiac chest pain

If this event is reported as a Serious Adverse Event (SAE), ensure that this diagnosis is reported on the SAE form.

"Additional Supplemental information (to what has already been highlighted in yellow in the form): Source documents for data requested in the eCRF (e.g., labs, CXR) as well as admission History and Physical and Discharge Summary".