Protocol No: LA-RSH/103/2012	Site ID: | | | - | | | - | D | Patient ID:_____

Case Report Form (Baseline Data Collection)
Class D Hospital –Direct Admission/EMRI Transfer

A prospective, controlled study of assertive and timely reperfusion for patients with ST-segment elevation myocardial infarction (STEMI) in Tamil Nadu.

Protocol No : LA-RSH/103/2012	**Protocol Version & Date : Version 2.0, 18-Apr-2012**
CRF (Baseline Data Collection) : Version 1.0	**Sponsor : STEMI India Group**

Treating Hospital	
Name of the Hospital:	
Address :	

Patient Details		**Alternate Contact Details**	
Name:		Name:	
Telephone No.:		Telephone No.:	
Address :		Address :	

Demography and Personal History		
Date of Visit : ____/_____/_____ DD MMM YYYY	Age:_____years	Gender : 1☐ Male 2☐ Female
Occupation:_____	Tobacco Smoking Status	1☐ Non Smoker 2☐ Current Smoker 3☐ Past Smoker 4☐ Smoking Status Unknown 5☐ Passive 99☐ Others, please specify _____
If smoking, please provide the details:		
Number:_____	Duration:_____	Type:_____

Protocol No: LA-RSH/103/2012

Site ID: | | | - | | | - | D |

Patient ID:_____

Clinical examination		
Height: _____ cm	Weight: _____ kg	BMI : _____Kg/m^2
Blood Pressure:_____/_____ mm of Hg Systolic Diastolic	Heart Rate : _____ Beats/min	

Patient admission to hospital:	1☐Direct Admission 2☐Direct EMRI Transfer 3☐ Referring Hospital/Clinic

If the Patient admission was through Direct EMRI Transfer, please fill the below details:

EMRI			
Date and Time of Call to EMRI	____/_____/_____ DD MMM YYYY	____:_____ HH MM	☐ Not available
Date and Time of EMRI despatch	____/_____/_____ DD MMM YYYY	____:_____ HH MM	☐ Not available
Time of Arrival at Patient site:	____:_____ HH MM	☐ Not available	
Time of departure from scene:	____:_____ HH MM	☐ Not available	

Diagnosis			
Presenting complaints:	1☐ Chest pain 2☐ Palpitations 3☐ Pain in other locations (Arm pain, Jaw Pain…….)	4☐Diaphoresis 5☐Syncope 6☐ Dyspnea 99☐ Others, specify_____	
Date and Time of Arrival at Hospital	____/_____/_____ DD MMM YYYY	____:_____ HH MM	☐ Not available
Mode of Transportation:	1☐ Private 2☐ Public 3☐ Ambulance 9☐ Not Applicable		
If Ambulance, Please provide the below details:			
Ambulance call time: ____:_____ HH MM	Ambulance arrival time: ____:_____ HH MM	☐ Not available	
Date and Time of Symptom Onset:	____/_____/_____ DD MMM YYYY	____:_____ HH MM	☐ NA
Location of ECG Recording:	3☐ Ambulance 1☐ Hospital 2☐ Referring Hospital/Clinic 9☐ Not Applicable		
Initial ECG Time:	____:_____ HH MM	☐ Not available	
Time of STEMI confirmation:	____:_____ HH MM	☐ Not available	
Location of infarction (as per ECG)			

Medication at Previous Hospital/ During Transfer	
Was any medication administered to the patient at previous hospital/during transfer?	1☐ Yes 0☐ No

If Yes, please provide the below details:

Medication	Route	Dose	Date of Administration (DD/MMM/YYYY)	Time of Administration (HH:MM)

Fibrinolytic Checklist			
Sl.No		**Responses**	
1.	Is Systolic BP greater than 180 mm Hg ?	1☐ Yes	0☐ No
2.	Is Diastolic BP greater than 110 mm Hg?	1☐ Yes	0☐ No
3.	Is Right vs. left arm systolic BP difference greater than 15 mm Hg ?	1☐ Yes	0☐ No
4.	History of structural central nervous system disease ?	1☐ Yes	0☐ No
5.	Significant closed head/facial trauma within the previous 3 months ?	1☐ Yes	0☐ No
6.	Recent (within 6 wks) major trauma, surgery (including laser eye surgery) GI/GU bleed ?	1☐ Yes	0☐ No
7.	Bleeding or clotting problem or on blood thinners?	1☐ Yes	0☐ No
8.	CPR greater than 10 minutes?	1☐ Yes	0☐ No
9.	Pregnant Female?	1☐ Yes	0☐ No
10.	Serious systemic disease (eg. advanced / terminal cancer, severe liver or kidney disease) ?	1☐ Yes	0☐ No
11.	Does the patient have severe heart failure or cardiogenic shock such that PCI is preferable?	1☐ Yes	0☐ No
12.	Pulmonary edema (rales greater than halfway up)	1☐ Yes	0☐ No
13.	Systemic hypoperfusion (cool, clammy)	1☐ Yes	0☐ No

Medication Prior to Thrombolysis					
Medication	Route of Administration	Actual Dosage Administered		Administration	
		Mg	U	DD/MMM/YYY	HH : MM
☐ Aspirin					
☐ Clopidogrel					
☐Unfractionated Heparin					
☐Low Molecular Weight Heparin, specify_____					

Thrombolysis							
Was the subject Thrombolysed:	1☐ Yes 0☐ No						
If Yes, Please provide the below details:							
Thrombolytic Agent	Route of Administration	Actual Dosage Administered		Start of Thrombolysis		Completion of Thrombolysis	
		Mg	U	DD/MMM/YYY	HH : MM	DD/MMM/YYY	HH : MM
☐ Streptokinase							
☐ Tenectaplase							
☐Others, Specify _____							
90-120 min ECG Time:	____:____ HH MM			☐ NA			

Other Medication During Hospitalization	
Was any other medication administered to the patient during hospitalization?	1☐ Yes 0☐ No

If Yes, please provide the below details:

Medication	Route	Dose	Date of Administration (DD/MMM/YYYY)	Time of Administration (HH:MM)

Discharge Summary	
Date of Discharge:	____/_____/_____ DD MMM YYYY
Recommendations:	1☐ Conservative Treatment 2☐ Referred to Class A/B hospital 3☐ Non STEMI Cluster hospital 99☐ Others, Specify_____

Medication on Discharge	
Was the Patient prescribed any medication on discharge? If Yes, provide the details below:	1☐ Yes 0☐ No

Sl No.	Medication Name

Adverse Events			
Adverse event experienced?:	1☐ Yes 0☐ No		
If Yes, provide the below details:			
Sl #	**Adverse Event**	**Response**	**Comments**
1	Stroke	1☐ Yes 0☐ No	
2	Cardiogenic Shock	1☐ Yes 0☐ No	
3	Access site Hemorrhage	1☐ Yes 0☐ No	
4	Major Bleed#	1☐ Yes 0☐ No	
5	Minor Bleed#	1☐ Yes 0☐ No	
6	Death ☐ Cardiac ☐ Non Cardiac	1☐ Yes 0☐ No	
7	SymptomaticIschemia	1☐ Yes 0☐ No	
8	Others Specify_____	1☐ Yes 0☐ No	

#Derived based on TIMI Score Scale

Referral Hospital				
Type of hospital referred :	1☐ STEMI Cluster hospital	2☐ Non STEMI Cluster hospital		
If STEMI Cluster please specify:	1☐ Class A	2☐ Class B		
Details of Referral Hospital:	Name: Address:			
Date and Time of notification to Referral Hospital	____/_____/_____ DD MMM YYYY	____:_____ HH MM	☐ Not available	
Mode of Transportaion to Referral Hospital:	1☐ Private	3☐ Ambulance	4☐ EMRI	5☐ Not known
If EMRI or Ambulance, provide the below details:				
Call Time:	____:_____ HH MM	☐ Not available		
Arrival Time:	____:_____ HH MM	☐ Not available		
Transport Start Time:	____:_____ HH MM	☐ Not available		
Management at Referral Hospital				
1☐ PCI				
2☐ Medical Management				
3☐ Unknown				
99☐ Others, Specify_____				

ADDITIONAL INFORMATION		
Medical/Surgical History		
Does the subject have any other clinically significant medical /surgical history? If Yes, provide the details below:	1☐ Yes 0☐ No	
Symptom/Diagnosis/ Procedure#	**Response**	**Medication (If Applicable)**
Diabetes Mellitus	1☐ Yes 0☐ No	
Hypertension	1☐ Yes 0☐ No	
Peripheral Vascular Disease	1☐ Yes 0☐ No	
Stroke	1☐ Yes 0☐ No	
Dyslipidemia	1☐ Yes 0☐ No	
Allergies	1☐ Yes 0☐ No	
Bronchial Asthma	1☐ Yes 0☐ No	
CAD (including Angina and MI)	1☐ Yes 0☐ No	
Others, Specify_____	1☐ Yes 0☐ No	
_____		

If the response to Medical History is checked as CAD, please provide previous management details:		
Previous Management	**Date**	**Details**
☐ Medical Management	___ / _____ / _____ DD MMM YYYY	
☐ PCI	___ / _____ / _____ DD MMM YYYY	
☐ CABG	___ / _____ / _____ DD MMM YYYY	
☐ Others Specify: _____	___ / _____ / _____ DD MMM YYYY	

Investigator Comments (if any)
_____ _____

Investigator Declaration
I cetify that I have reviewed all of the data contained within these case report forms and that it accurately reflects the course of this patient on this study. I understand that changes may be made to this data as a result of the data review process. Investigator Name : _____ Investigator Signature : _____ ____/_____/_____ DD MMM YYYY

Protocol No: LA-RSH/103/2012

Site ID: | | | - | | | - | D |

Patient ID:_____

Follow up (1 Month)		
Was the subject followed up:	1☐ Yes 0☐ No	
If followed up, please specify:	1☐Hospital 2☐Telephonic Follow up 3☐Lost to Follow up	
Date of follow up:	____/_____/_____ DD MMM YYYY	
Medical Condition	**Response**	
Asymptomatic	1☐ Yes 0☐ No	
Stroke	1☐ Yes 0☐ No	
Death ☐ Cardiac ☐ Non Cardiac	1☐ Yes 0☐ No	
If the Patient is Dead, please provide the details:	____/_____/_____ DD MMM YYYY	_____:_____ HH MM
Re-infarction	1☐ Yes 0☐ No	
If yes, please provide the details:	____/_____/_____ DD MMM YYYY	_____:_____ HH MM
SymptomaticIschemia	1☐ Yes 0☐ No	
Cardiac failure	1☐ Yes 0☐ No	
Repeat Intervention	1☐ Yes 0☐ No	
If yes, please provide details		
☐ CABG	____/_____/_____ DD MMM YYYY	_____:_____ HH MM
☐ PCI	____/_____/_____ DD MMM YYYY	_____:_____ HH MM
Comments (if any)		
_____ _____		

Protocol No: LA-RSH/103/2012

Site ID: | | | - | | | - | D |

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Follow up (6 Month)		
Was the subject followed up:	1☐ Yes 0☐ No	
If followed up, please specify:	1☐Hospital 2☐Telephonic Follow up 3☐Lost to Follow up	
Date of follow up:	____/_____/_____ DD MMM YYYY	
Medical Condition	**Response**	
Asymptomatic	1☐ Yes 0☐ No	
Stroke	1☐ Yes 0☐ No	
Death ☐ Cardiac ☐ Non Cardiac	1☐ Yes 0☐ No	
If the Patient is Dead, please provide the details:	____/_____/_____ DD MMM YYYY	_____:_____ HH MM
Re-infarction	1☐ Yes 0☐ No	
If yes, please provide the details:	____/_____/_____ DD MMM YYYY	_____:_____ HH MM
SymptomaticIschemia	1☐ Yes 0☐ No	
Cardiac failure	1☐ Yes 0☐ No	
Repeat Intervention	1☐ Yes 0☐ No	
If yes, please provide details		
☐ CABG	____/_____/_____ DD MMM YYYY	_____:_____ HH MM
☐ PCI	____/_____/_____ DD MMM YYYY	_____:_____ HH MM
Comments (if any)		
_____ _____		

Follow up (1 Year)		
Was the subject followed up:	1☐ Yes 0☐ No	
If followed up, please specify:	1☐Hospital 2☐Telephonic Follow up 3☐Lost to Follow up	
Date of follow up:	____/_____/_____ DD MMM YYYY	
Medical Condition	**Response**	
Asymptomatic	1☐ Yes 0☐ No	
Stroke	1☐ Yes 0☐ No	
Death ☐ Cardiac ☐ Non Cardiac	1☐ Yes 0☐ No	
If the Patient is Dead, please provide the details:	____/_____/_____ DD MMM YYYY	_____:_____ HH MM
Re-infarction	1☐ Yes 0☐ No	
If yes, please provide the details:	____/_____/_____ DD MMM YYYY	_____:_____ HH MM
SymptomaticIschemia	1☐ Yes 0☐ No	
Cardiac failure	1☐ Yes 0☐ No	
Repeat Intervention	1☐ Yes 0☐ No	
If yes, please provide details		
☐ CABG	____/_____/_____ DD MMM YYYY	_____:_____ HH MM
☐ PCI	____/_____/_____ DD MMM YYYY	_____:_____ HH MM
Comments (if any)		
_____ _____		