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

Case Report Form (Baseline Data Collection)
Class A/B Hospital

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:_____

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

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_____

DIRECT ADMISSION	☐ Not Applicable		
Date and Time of Arrival at Hospital	____/_____/_____ DD MMM YYYY	____:_____ HH MM	☐ NA
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	☐ NA	
Date and Time of Symptom Onset:	____/_____/_____ DD MMM YYYY	____:_____ HH MM	☐ NA
Initial ECG Time:	____:_____ HH MM	☐ NA	
Time of STEMI confirmation:	____:_____ HH MM	☐ NA	
Location of infarction (as per ECG)			

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DIRECT EMRI TRANSFER	☐ Not Applicable		
Date and Time of Call to EMRI	____/_____/_____ DD MMM YYYY	____:_____ HH MM	☐ NA
Date and Time of EMRI despatch	____/_____/_____ DD MMM YYYY	____:_____ HH MM	☐ NA
Time of arrival at patient site:	____:_____ HH MM	☐ NA	
Time of departure from scene:	____:_____ HH MM	☐ NA	
Date and Time of Symptom Onset:	____/_____/_____ DD MMM YYYY	____:_____ HH MM	☐ NA
Date and Time of Arrival at Hospital	____/_____/_____ DD MMM YYYY	____:_____ HH MM	☐ NA
Location of ECG Recording:	3☐ Ambulance 1☐ Hospital 9☐ Not Applicable		
Initial ECG Time:	____:_____ HH MM	☐ NA	
Time of STEMI confirmation:	____:_____ HH MM	☐ NA	
Location of infarction(as per ECG)			

EMRI TRANSFER FROM C/D SPOKE		
Mention the spoke hospital patient has been transferred from:	3☐ Class C 4☐ Class D	
Is the patient accompanied with the Baseline CRF from the spoke hospital:	1☐ Yes 0☐ No	
If yes, has the form been attached to the Class A/B CRF:	1☐ Yes 0☐ No	
Time of arrival in Hospital A/B:	____:_____ HH MM	☐ NA

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NON STEMI CLUSTER ENTRY	☐ Not Applicable		
Time of arrival of patient at non STEMI cluster Hospital:	____/_____/_____ DD MMM YYYY	____:_____ HH MM	☐ NA
Date and Time of Symptom Onset:	____/_____/_____ DD MMM YYYY	____:_____ HH MM	☐ NA
Initial ECG Time:	____:_____ HH MM	☐ NA	
Time of STEMI confirmation:	____:_____ HH MM	☐ NA	
Location of infarction (as per ECG)			
Mode of Transportation:	1☐ Private 2☐ Public 3☐ Ambulance 4☐ EMRI 5☐ Not known		
EMRI/Ambulance call time: ____:_____ HH MM	EMRI/Ambulance arrival time: ____:_____ HH MM	☐ NA	
Time of start of patient transfer:	____:_____ HH MM	☐ NA	
Time of arrival in Hospital A/B:	____:_____ HH MM	☐ NA	

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)**

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Patient ID:_____

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 9☐ Not Applicable						
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				

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

PCI					
Cath Lab activation time:	____:____ HH MM			☐ NA	
Patient Arrival Time at Cath Lab	____:____ HH MM			☐ NA	
Date and Time of Vascular Access:	____/_____/_____ DD MMM YYYY			_____:_____ HH MM	
Date and Time of Start of Diagnostic Angiography:	____/_____/_____ DD MMM YYYY			_____:_____ HH MM	
Date and Time of End of Diagnostic Angiography:	____/_____/_____ DD MMM YYYY			_____:_____ HH MM	
Catheter Access:	1☐Radial			2☐Femoral	
Findings of Diagnostic Angiography:	1☐ Single Vessel Disease			2☐ Double Vessel	
	3☐ Triple Vessel Disease			4☐ Insignificant Disease	
Aspiration	1☐ Yes 0☐ No				
Date and Time of Balloon Inflation/Stent deployment:	____/_____/_____ DD MMM YYYY			_____:_____ HH MM	
Vessels	**Stenosis?**	**Severity**	**Culprit Vessel**	**No. of Stents**	**Type of Stent**
☐ Left Anterior Descending (LAD)	1☐ Yes 0☐ No	_____%	1☐ Yes 0☐ No		1☐ DES 2☐ BMS 3☐ M Gaurd
☐ Left Circumflex Artery (LCX)	1☐ Yes 0☐ No	_____%	1☐ Yes 0☐ No		1☐ DES 2☐ BMS 3☐ M Gaurd
☐ Right Coronary Artery (RCA)	1☐ Yes 0☐ No	_____%	1☐ Yes 0☐ No		1☐ DES 2☐ BMS 3☐ M Gaurd
☐ Others, Specify _____	1☐ Yes 0☐ No	_____%	1☐ Yes 0☐ No		1☐ DES 2☐ BMS 3☐ M Gaurd

Medication in Cath Lab					
Medication	Route of Administration	Actual Dosage Administered		Administration	
		Mg	U	DD/MMM/YYY	HH : MM
☐ Aspirin					
☐ Clopidogrel					
☐Prasugrel					
☐Unfractionated Heparin					
☐Low Molecular Weight Heparin, specify_____ _					
GP IIb/IIIa Inhibitors ☐Abciximab ☐Eptifibatide ☐Tirofiban ☐Others Specify:_____					
☐Bivaluridin					
☐Fondoparinaux					

Other Medication During Hospitalization				
Was any other medication administered to the patient during hospitalization in Hospital A/B?	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

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

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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)		
_____ _____		

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)		
_____ _____		