SERIOUS ADVERSE EVENT REPORTING FORM

Initial Reporting: Once you have become aware of a SAE or SUSAR, please email this form to the BAMI Trial Office (BTO) [e-mail: **bami@qmul.ac.uk] within 24 hours of learning of the event. "SAE report" must be in the email's subject line.** The form should be signed by the PI/delegated doctor, scanned and e-mailed to the BTO. If that could not be achieved, a signed copy of the same form (without editing and additional information) must be sent to the BTO at the earliest opportunity by fax [+44 20 3465 6491]. Once this form is received by the BTO an acknowledgment email will be sent to your site during office hours. If you do not receive an acknowledgement on the following working day, please contact the BTO [Tel: +44 20 3765 8740].

Full title of the study	The effect of intracoronary reinfusion of bone marrow-derived mononuclear cells (MN-MNC) on all cause-mortality in acute myocardial infarction
Study Acronym	BAMI
Name of sponsor	Queen Mary University of London
Sponsor R&D Number	EudraCT Number: 2012-001495-11
MREC Number	13/LO/0315
Chief Investigator	Name: Prof Anthony Mathur Phone No: (+44) 20 3765 8715 Email address: a.mathur@qmul.ac.uk
Is this a double blind study?	No
Name of IMP	T2c001 (Bone marrow derived mononuclear cells (BM-MNCs))

The following sections should be completed by the SITE:

Report type: ☐ Initial ☒ Follow-up

Subject identification code:	Patient/initials (first, last): stephen, hawking	
Date of Birth: (Day/Month/Year) 23 /11 /1941	Patient's Age: 76	Sex: ☒ M ☐ F

Principal Investigator		
Name: piyush	Phone No: 7895432176	Email address:
Trial Co-ordinator at local site:		
Name: shark	Phone No:	Email address:
Reporting host institution		
Trust/ Institution name: shark Blood testing institute		Site number: 49
Date of site become aware of event: 22 /10 /2006	Onset date of SAE: 23 /10 /2006	Resolution date of SAE: 01 /02 /2007

Event description (eg. body site, symptoms):
Please use separate form for each event
patient is suffering from Spinal cord and nerve root disorders which is of type Sacral radiculopathy.

Type of SAE	Severity
☒ Results in Death ☒ Life threatening ☐ Hospitalisation or prolongation of hospitalisation ☐ Persistent or significant disability or incapacity ☐ Congenital anomaly or birth defect "Other" important medical event If "Other", please describe:	☐ Mild ☐ Moderate ☒ Severe

Bone marrow derived mononuclear cells re-infusion		
Was IMP (t2c001) infused? ☒ Yes ☐ No	Re-infusion Date: 27 /12 /2006	Re -Infusion Time: 15 : 00 24 hour clock

Causal relationship to IMP	Causal relationship to intervention
Is the SAE likely to be related to the IMP t2c001? ☒ Related ☐ Unrelated ☒Patient in control arm	Does the SAE have a causal relationship to the intervention? ☒ Bone Marrow Aspiration ☐ Cardiac Catheterisation ☐ Not related to invasive procedure ☒ No intervention taken
Is the SAE expected? (Expected reactions will be found in the Investigator Brochure and protocol) ☒ Expected ☐ Unexpected	Is the SAE due to the progression of an underlying illness? ☒ Yes ☐ No
Is the event classified as a SUSAR? (i.e. RELATED to the IMP and UNEXPECTED) ☒ Yes ☐ No If Yes, please give IMP batch number T2c001 Batch Number: 234642 *If regarded as SUSAR, please also fill in the CIOMS form attached to this form	Is the SAE related to the trial CONDUCT? ☒ Yes ☐ No
Names of non IMPs concomitant medicines: EXERMET-500mg	Names of concomitant diseases: Sacral radiculopathy

If SAE during index admission, action taken with study treatment	Did the PI withdraw the patient from the study?
☐ Infused ☐ Not Infused ☒ Infusion stopped ☐ Infusion interrupted ☐ Not applicable, please Give details:	☒ Yes ☐ No

Outcome of SAE	
☐ Resolved ☐ Resolved with sequelae *specify sequelae: ☐ Improved ☐ Persisting ☒ Worsened	☒ Fatal *Date of death: 14 /03 /2018 *Copy of post-mortem available? ☐ Yes ☒ No ☒ Unknown

Additional information requested by the CI's team for this project:	
Relevant Medical History :	**Relevant Lab Results / Imaging Results (e.g. ECG, blood test):**
	blood test: nueron scanning

Delegated person completing the form if not the PI		
Print name: stephen hawking	Phone No.: 8765432189	Email address:
Signature:	Job title: software engineer	Date:

Principle Investigator / Delegated person		
Print name: george	Phone No.:	Email address:
Signature:	Date:	

For BAMI Trial Office use only

Date form RECEIVED by BAMI Trial Office from Investigator Site: 13 /11 /2007 (*This date will be DAY 1 for SUSARs*)	Reviewed by: Date reviewed: 22 /12 /2007

Chief investigator reviewed Date: / / CI's signature:	Fully Agree with PI's assessment ☐ Yes ☒No If No, please specify worst PI assessment ever

For R&D Office use only

Date form RECEIVED by R&D team: / / Reviewed by: Date reviewed: / /	**For SUSAR only** Date Reported to MHRA: 12 /11 /2007