

Joint Research Management Office Standard Operating Procedure for:

Location Level Pharmacovigilance and safety reporting for sponsored CTIMPs and ATIMPs

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Purpose and Scope

This standard operating procedure (SOP) outlines the Local Investigator's responsibilities to ensure management and oversight of pharmacovigilance of Barts Health NHS Trust (Barts Health) and Queen Mary University of London (Queen Mary) sponsored clinical trials of investigational medicinal products (CTIMPs) and advanced therapy investigational medicinal products (ATIMPs).

[See SOP 26d for guidance on Safety Reporting for Clinical Investigations of Medical Devices.](#)

This SOP will identify and standardise the process for recording and managing reportable safety events. This SOP also describes the procedure for updating reference safety information (RSI), and the management of pregnancy.

For all studies sponsored by external organisations i.e. NHS Trusts other than Barts Health, universities other than Queen Mary, or commercial companies, the principles of this SOP apply but the sponsor's pharmacovigilance procedure must be followed.

Responsibilities:

For multi-location studies, the Coordinating Investigator (CI) has overall responsibility for pharmacovigilance and safety reporting for all the locations. The CI delegates responsibility for pharmacovigilance to the Local Investigator of each location. The Local Investigator is responsible for informing the CI of all Serious Adverse Events (SAE)/Suspected Unexpected Serious Adverse Reactions (SUSAR) that occur at their location in accordance with the guidance below. Where the CI is also a location Investigator (for example in single-centre studies), they are responsible for their location's pharmacovigilance.

The CI or where CI is a non-medic, an appropriate medically qualified individual is delegated by the sponsor to be the pharmacovigilance medical assessor.

Unless formally delegated, the sponsor is responsible for ensuring that all relevant information about UK relevant SUSARs are reported to the UK competent authority, the Medicines and Healthcare products Regulatory Agency (MHRA). The MHRA's definition of 'UK-relevant' includes:

- SUSARs originating in the UK
- SUSARs originating outside the UK where the sponsor has an ongoing study in the UK involving the same medicinal product.

Abbreviations:	
AE	Adverse Event
AESI	Adverse Event of Special Interest
ATIMP	Advanced Therapy of Investigational Medicinal Product
Barts Health	Barts Health NHS Trust
CI	Coordinating Investigator
CRF	Case Report Form
CTIMP	Clinical Trial of an Investigational Medicinal Product
IMP	Investigational Medicinal Product
JRMO	Joint Research Management Office
MedDRA	Medical Dictionary for Regulatory Activities
MHRA	Medicines and Healthcare products Regulatory Agency
nIMP	Non-IMP
Queen Mary	Queen Mary, University of London
RSI	Reference Safety Information
SAE	Serious Adverse Event
SAR	Serious Adverse Reaction
SOP	Standard Operating Procedure
SUSAR	Suspected Unexpected Serious Adverse Reaction
USM	Urgent Safety Measure
Definitions:	
See Associated Document 1 Pharmacovigilance Definitions.	

SOP Text:		
	Responsibility	Activity
Location set-up		
1.	Location Investigator	Confirm that all procedures are in place in order to record, assess and send SAE reports to the coordinating team. Please see SOP 46 Associated Document 3 SIV report for further details for location set-up requirements.
Recording and reporting of events for Barts Health & Queen Mary sponsored studies		
2.	Local Investigator	Record Adverse Events (AE) in participants' notes and assess whether AEs are serious (i.e. SAEs) and whether they need to be reported to the sponsor. AEs, including SAEs, should be recorded by the investigator from the point of informed consent until the end of the study unless otherwise specified for in the protocol. In studies where obtaining consent is delayed (such as those in emergency medicine scenarios), safety reporting should commence from the enrolment of the participant, which should be explicitly defined in the protocol. Avoid reporting individual symptoms as separate events. When multiple symptoms arise from a single medical issue, record the underlying cause as one AE rather than listing each symptom separately. "Death" should not be reported as an event term; it is an outcome that results from an underlying AE. The local Investigator or the medically qualified delegate for the study location must assess the AE to establish if it must be classified as a SAE. This assessment must occur within a timely manner to allow the event to be reported within 24 hours if necessary. The assessment should consider whether the event met the serious criteria at the time of the event and not at the time of the review. For definition of an SAE see Associated Document 1 Pharmacovigilance Definitions. If the AE is defined as SERIOUS as per the criteria in Associated Document 1, proceed to section 3. If the AE is not defined as SERIOUS, the AE is recorded in the source data and case report form (CRF), and the participant is followed up by the research team until resolution. The AE must be documented in the participant's medical notes. For some studies the Investigational Medicinal Product (IMP) manufacturer/funder may have identified Adverse Events of Special Interest (AESI). An AESI (serious or non-serious) is one of scientific and medical concern specific to the IMP or study, for which ongoing monitoring and rapid communication by the investigator to the sponsor/IMP manufacturer is required and detailed in the protocol. Please see section 7 for more details.

3.	Local Investigator	Assess whether an SAE is related to the study's IMP or non-IMP (nIMP) to establish if it is a Serious Adverse Reaction (SAR). Prior to submitting the SAE, the Local Investigator or a medically qualified delegate responsible for the treatment of the participant at location must assess <u>relatedness</u> of the event to each of the study IMPs and nIMPs as separate assessments.
4.	Local Investigator	Report All SAE/SAR/possible SUSARs to the sponsor or delegate as defined in the protocol within 24-hours. Details of the SAE/SARs must be recorded in the participant's source data, and the participant must be followed up by the research team to the resolution of the event. The Local Investigator must report all SAEs/SARs to the sponsor immediately except for those that the protocol or investigator brochure identified as not requiring immediate reporting. Immediate reporting is defined as 'within a very short period of time' and under no circumstances should this exceed 24 hours following knowledge of the SAE. The Barts Health/Queen Mary SAE form (see Associated Document 2) must be used unless a formal written waiver is issued and logged by the Joint Research Management Office (JRMO) Good Clinical Practice (GCP) team. A separate SAE form should be completed for each event that requires reporting. Once available information has been completed, the SAE form must be signed by the Investigator or appropriate delegated medically qualified person at the location. A signed copy of the form should be emailed to: research.safety@qmul.ac.uk. The Medical Assessor in consultation with the Sponsor and CI will determine expectedness and any onward and regulatory reporting requirements in the case of a SUSAR as per SOP26c Pharmacovigilance Reporting (Sponsor and CI) The sponsor will acknowledge receipt of reports in writing to the Investigator or coordinating team (depending on submitting party and agreements). If an acknowledgement of receipt is not received, reporter must contact the sponsor and request written acknowledgment. All follow-up or missing information (including the downgrade of SUSAR to an SAE) should be submitted to the Sponsor on a revised SAE form as soon as it becomes available.
5.	Local Investigator	Agree the MedDRA term for the SAE. If the SAE is not reported with a Medical Dictionary for Regulatory Activities (MedDRA) event term, the sponsor will code the event using a MedDRA term and inform the location of the coding, who should record the event locally with the same MedDRA term. If the Local Investigator disagrees with this coding, then they must provide an alternative MedDRA term to ensure consistency with sponsor records.

6.	Local Investigator	Inform the sponsor about AESIs. If the event is not classed as serious, but is specified as an AESI in the protocol, the Local Investigator must inform the sponsor within same timelines as a SAE.
Pregnancy within an CTIMP/ATIMP		
7.	Local Investigator	Local Investigator notifies sponsor of all pregnancies and follows them up to conclusion. Within 24 hours of becoming aware of a participant or partner pregnancy, the Local Investigator at location is responsible for notifying the sponsor (as per protocol) using the sponsor's pregnancy form. The Local Investigator is responsible for collecting all information and following up the pregnancy to outcome and according to the protocol's specified follow-up period (See Associated Document 3)
8.	GCP team	Obtain independent medical advice for any pregnancy reports received. When receiving a pregnancy report, the GCP team will request medical advice from a suitable expert e.g. a consultant obstetrician as agreed with the JRMO Clinical Director (see SOP 26c Pharmacovigilance (Process for the Sponsor and CI))
Urgent Safety Measures		
9.	Local Investigator	Implement USM If the need or notification of an Urgent Safety Measure (USM) arises, implement it immediately. Do not await regulatory or ethics approval. Please see SOP 17a Amendments for sponsored studies (including halting): Process for researchers for guidance on the sponsor's process for managing USM.
For externally sponsored (hosted) studies		
10.	Local Investigator	Use external sponsor's forms and SOPs, report relevant incidents via Queen Mary and Barts Health systems. Report SAEs and SUSARs as per external sponsor's procedures using the external sponsor's forms. Ensure that the research team is trained and complies with the study specific pharmacovigilance reporting requirements. The JRMO does not require submission of safety reports for externally sponsored CTIMPs unless it meets Barts Health or Queen Mary incident reporting standards. Please see Barts Health trust intranet for the Adverse Incident Policy for details and DATIX reporting requirements.

Change control

This section outlines changes from version **14.0** to version **15.0**

Section changed	Summary and description of changes
Throughout	General administrative changes
Page 1	Merger of scope and purpose
Section 1	Reference to SIV for Location Set-Up
Section 4	Merger of instructions for reporting SAE/SAR/possible SUSARs to the sponsor/delegate

List of associated documents

Document ref.	Document name
Associated document 1	Pharmacovigilance definitions
Associated document 2	Bart Health/Queen Mary SAE form
Associated document 3	Pregnancy reporting form