Joint Research Management Office Standard Operating Procedure for:			
Pharmacovigilance and Device Safety Reporting (Process for the Sponsor and Chief Investigator)			
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Purpose:
This standard operating procedure (SOP) outlines the actions and responsibilities of the Joint Research Management Office (JRMO) regarding safety reporting. This SOP will identify and standardise the process for receiving, logging, and acknowledging reportable safety events and pregnancies for studies sponsored by Barts Health NHS Trust (Barts Health) or Queen Mary University London (Queen Mary).
Scope:
This SOP is relevant to the JRMO staff and associated staff named within this SOP only. Please note:

The JRMO research database application (ReDA) is used to collect and record pharmacovigilance (PV) and safety events for sponsor oversight purposes only. This function is referred to as the PV desk in this SOP and includes monitoring of the PV safety email inbox. PV is managed by the JRMO during working hours only.

Medical assessment, trends, safety signals and data collection of events for statistical analysis are the responsibility of the Chief Investigator (CI).

Abbreviations:	
AE	Adverse Event
AESI	Adverse Event of Special Interest
APR	Annual Progress Report
ASADE	Anticipated Serious Adverse Device Effect
Barts Health	Barts Health NHS Trust
CI	Chief Investigator
CIP	Clinical Investigation Plan
CTIMP	Clinical Trial of an Investigational Medicinal Product
DSUR	Development Safety Update Reports
GCP	Good Clinical Practice
HRA	Health Research Authority
IB	Investigator's Brochure
IMP	Investigational Medicinal Product
JRMO	Joint Research Management Office
MedDRA	Medical Dictionary for Regulatory Activities
MHRA	Medicines and Healthcare products Regulatory Agency
NCC	National Coordinating Centre
NIMP	Non-Investigational Medicinal Product
PI	Principal Investigator
PV	Pharmacovigilance
QA	Quality Assurance
Queen Mary	Queen Mary University of London
REC	Research Ethics Committee
ReDA	Research Database Application
RSI	Reference Safety Information
SADE	Serious Adverse Device Effect
SAE	Serious Adverse Event
SAR	Serious Adverse Reaction
SmPC	Summary of Product Characteristics
SOG	Sponsor Oversight Group
SOP	Standard Operating Procedure
SUSAR	Suspected Unexpected Serious Adverse Reaction
USADE	Unanticipated Serious Adverse Device Effect
USM	Urgent Safety measures

Definitions:
See *SOP 26a Associated Document 1 Pharmacovigilance Definitions.*

Relevant SOPs:	
• SOP 26a	Site level Pharmacovigilance for MHRA regulated studies
• SOP 26b	Site level Pharmacovigilance for Interventional and Research studies
• SOP 26d	Site Level Safety Reporting for Clinical Investigations of Medical Devices

SOP Text:		
	Responsibility	**Activity**
Designing safety reporting procedures.		
1.	CI	**When designing the study, ensure that the protocol or Clinical Investigation Plan (CIP) contains comprehensive information on safety reporting.** Define process for periodic review of adverse events and [if applicable] device deficiencies. Ensure systems are in place to report Serious Adverse Events (SAE) and (if applicable) device deficiencies within 24-hours. The CI must ensure that there are systems in place for sites to report safety events and [if applicable] device deficiencies within 24 hours of becoming aware of the event Confirm the arrangements for managing pregnancies and describe them in the protocol or CIP . **For CTIMPS and ATIMPS:** When designing the study, ensure that the reference safety information (RSI) is clearly defined in the protocol/CIP and on the cover letter to the Medicines and Healthcare products Regulatory Agency (MHRA) when submitting the Clinical Trial Application. For guidance assessing and reviewing the RSI *see Associated Document 1: RSI guidance*. Agree review & update processes with the Good Clinical Practice (GCP) and Governance manager. Arrangements should include how the CI will access the most current RSI. CIs must ensure that the defined RSI is reviewed at least once a year. CIs who fail to regularly review the RSI will be escalated to the JRMO SOG. **For International studies:** New versions of the Investigator's Brochure (IB) or Summary of Product Characteristics (SmPC), which include a change to the RSI, must be approved by the sponsor before submission for regulatory approval, and, if the study is UK-relevant, must be submitted in parallel to the UK and non-UK competent authorities. This is to ensure that the same version of the RSI is relevant in all countries during the development safety update reports (DSUR) reporting period.

		See guidance in SOP 26d *Associated Document 1 Guidance on safety reporting for Clinical Investigation Plans*
2.	JRMO GCP & Governance Managers and Contract and Costing Teams	**Agree with the Investigational Medicinal Product (IMP) or device manufacturer the arrangements for Adverse Events (AE) and [if applicable] device deficiency assessments and reporting.** These arrangements should be agreed early in the development of the study (ideally at the funding agreement stage) and defined in the contract between the sponsor and the manufacturer. For Clinical investigations: The sponsor should delegate the manufacturer responsibility for assessing received Unanticipated Serious Adverse Device Effect (USADE) and device deficiency reports and for reporting them to the MHRA when required, unless otherwise agreed with the JRMO GCP & Governance manager.
3.	CI	**Prepare Safety Reporting Systems** The CI must ensure that there are systems in place at all sites to report Serious Adverse Events (SAE) and other reportable events to the sponsor within 24 hours of the site becoming aware of the event. The mechanism to report to the sponsor within 24-hours may be through a coordinating centre or the research team. The appropriate JRMO Reporting Form (*see* SOP 26a Associated Document 2 for Clinical Trial of an Investigational Medicinal Products (CTIMP) and Advanced Therapy Investigational Medicinal Products (ATIMP), and SOP 26d Associated Document 2 for Clinical Investigations) must be used when reporting SAEs or device deficiencies. As part of the study set up, the form may be modified for study specific requirements. Requests to amend the Barts Health/ Queen Mary forms with study specific additions must be made in writing to the JRMO; no fields may be removed/omitted from the form. If Adverse Event of Special Interests (AESI) are identified as needed and listed in the Protocol, ensure a study specific & appropriate AESI form is created. A template is attached to this SOP. If pregnancy reporting is required, the pregnancy reporting form *(SOP 26a associated document 3)* must be made available to the study team. All modifications to this form must be approved by the JRMO GCP & Governance Manager. The CI must ensure that sites receive a list of events s for each experimental device or IMP in order to make expectedness assessments. This system should include the CI (acting as sponsor medical assessor) review events in a within 72 hours of receiving the SAE.
4.	CI/ delegated Medical Assessor/ Sponsor Oversight Group (SOG)	**Ensure the CI fulfils their role as CI and medical assessor. The CI is delegated by the sponsor to be the PV/device safety medical assessor.** The CI must ensure sites are aware of the requirement to report safety events, AESI and pregnancies to the JRMO. If the CI fails to comply with PV/Safety reporting timelines or provide adequate CI oversight, as outlined in *SOP 26a*, this will be logged as a Non-Compliance as per *SOP 31 Non-Compliance*. Continuous non-compliances will be escalated in accordance with the escalation policy,

		commencing with the Research Governance Operations Manager and the SOG at the JRMO. Unless otherwise formally agreed and document through a written agreement by the sponsor and a delegated body, the sponsor is responsible for ensuring that all relevant information about 'UK-relevant' Suspected Unexpected Serious Adverse Reaction (SUSAR), and reportable device events are reported to the competent authority (MHRA).
5.	CI and GCP & Governance manager	**Ensure the JRMO is able to unblind events where applicable.** When a participant on a blinded study has a SUSAR or reportable device effect, the JRMO as sponsor must be able to unblind prior to submitting the event report to regulatory agencies. This process should be clearly documented in the protocol/CIP and detailed in a study specific unblinding SOP. In the case of a SUSAR arising from a comparator drug it must be reported to the sponsor, who is also obliged to report to the MHRA. Events associated with a placebo or sham procedure will usually not satisfy the criteria for an Adverse Reaction (AR) and therefore will not be subject to expedited reporting. However, where SUSARs or reportable device effects are associated with the placebo or sham procedure, the CI must report to the sponsor who will notify the competent authority.
6.	Research Governance Operations Manager	**Ensure a suitable database is available to log and manage safety events on behalf of Queen Mary and Barts Health sponsored studies.** At the time of writing that is the Infornetica REDA system.
7.	Senior GCP & Governance Manager/ delegate	**Assign a JRMO Clinical Trial Monitor to manage the PV desk for each study.** Ensure the Clinical Trial Monitor is appropriately trained prior to being assigned to the PV desk and adequately supported throughout. Ensure the PV desk is appropriately supported, managed, and covered at all times. Ensure allocated staff have access to the PV safety email inbox.
Processing Safety reports		
8.	Clinical Trial Monitor	**Check the PV desk for new correspondence at least once every working day, all new events should be acknowledged within 2 working days and fully logged within 5 working days.** The JRMO will process and log the following events for CTIMPs & ATIMPS: SAEs, SUSARs, AESI, and Pregnancies. The JRMO will process the following events for Clinical Investigations: SAEs, Serious Adverse Device Effects (SADE), Anticipated Serious Adverse Device Effect (ASADE), Unanticipated Serious Adverse Device Effects (USADE), AESI, reportable Device Deficiencies, and Pregnancies.

		The JRMO will process the following events for Interventional and Research studies: only related and unexpected events reportable to research ethics committee (REC), and reportable pregnancies. **Acknowledging the event** • Ensure submission email is accompanied by a SAE or device safety report form. • Ensure the attachment can be open and is legible • Confirm it is a valid report using the definition in this email • Identify and flag any SUSARs, SADEs, USADEs and device deficiencies that could have caused SADEs, immediately notify the allocated GCP & Governance Manager (or, if absent, either GCP & Governance manager or if both are absent the Quality Assurance (QA) Manager). • Email Study coordinator Principal Investigator (PI) and sender to confirm receipt. Save this email as evidence that the above has been completed **Fully logging the event** Ensure forms are comprehendible and complete. Email study coordinator for missing data. Log the event within ReDA's Post Approval tab using the above principles (see associated document 2). Check whether the event term is an appropriate Medical Dictionary for Regulatory Activities (MedDRA) preferred term. If it is not, then allocate an appropriate MedDRA preferred term. If the event is related, review RSI and confirm JRMO agreement that the event is unexpected or expected. All submitted forms must be saved into the "Indemnity" folder using the same format name used in ReDA: • Sub 'Study patient number/ID', SAE 'MedDRA term (Event name)', JRMO 'date SAE received by JRMO/dd-mm-yy' • Example: Sub R055_SAE Portal Vein Thrombosis_JRMO_21.01.2016 Upload all submitted forms onto the 'Safety' section on the 'Documents' tab in ReDA. Ensure SAE files are labelled correctly (see associated document 1). Issue formal acknowledgement of the event on the day the event has been assessed for validity. Secondary acknowledgement should be sent to the sender and Study Coordinator and CI, stating the name of the logged SAE and whether there is any missing information or signatures that have still to be received. Confirm whether the event has been assessed as expected or unexpected and ask the CI to respond if they disagree. If a new MedDRA term has been assigned to the event, state the term, and ask the CI to respond if they disagree.
9.	Clinical Trial Monitor	**Follow up events.** Follow up details will be logged in the existing ReDA entry where the initial report was logged.

		When significant new information is received as part of a follow up, the event should be reassessed to see if it now meets the criteria of a SUSAR or reportable device effect. Save all submitted forms into the "Indemnity" folder using the same format name used in ReDA and adding f-u (indicating follow-up): When notified of a pending end of trial, ensure all events are reconciled/closed. Repeat this process with all follow up information until all events are closed. **The date of the event and title remain unchanged - the data of follow up and details are added to the comments field.**
For CTIMPS & ATIMPS		
10.	GCP & Governance Manager or delegated Clinical trial monitor	**Process and log SUSARs as per UK regulatory guidance.** This is commonly performed by the Clinical Trial Monitor once trained and deemed competent by the GCP manager. Review all valid SUSARs as soon as possible. Establish Day 0 (as per definition above) and notify all involved (Including GCP & Governance manager if a delegate is performing this task). Ensure that both the PI's and CI's assessment of the SUSAR correspond. If not, discuss with the CI and, if needed, seek independent advice. Log the SUSAR within the Queen Mary and Barts Health e-SUSAR account as per current MHRA guidance and within UK regulatory and Health Research Authority (HRA) timelines (see MHRA main website for web address). Any SUSAR occurring in the UK which is fatal or life-threatening should be logged **within 7 days** after the sponsor becomes aware of the event. Non-fatal or non-life-threatening events should be submitted **within 15 days** after the sponsor becomes aware of the event. Any additional information should be submitted **within 8 days** of logging the first report. Reports of SUSARs in double-blind studies should be unblinded prior to submission. Procedures related to un-blinding for SUSAR report purposes can be found in study specific SOPs. Any interpretation of wording on SUSAR reports should be checked with CI prior to e-SUSAR submission. Once logged, download the submission PDF, and send it to the CI, Study Coordinator and the local JRMO Clinical Trial Monitor for logging at local level.
11.	CI	**If the SUSAR is arising from a nIMP and this has been assessed as likely to affect the safety of the study participants, this should be reported to the sponsor who will notify the MHRA.** If there is a reasonable possibility that the event is related to a nIMP but there is no reasonable possibility that the event is related to an IMP and is not considered to constitute a hazard to the safety of other study participants, this should be reported to the Sponsor who will, with the CI, assess whether to report the event to the competent authority, or whether standard safety reporting should be considered (yellow card scheme).

		In the case of a SUSAR which: • is suspected to be an interaction between Investigational Medicinal Product (IMP) and a nIMP, or • could be related to either an IMP or a nIMP but the PI/CI cannot determine which it is related to, the event must be reported to the sponsor who will notify the competent authority.
12.	CI	**CI notifies the sites and REC of SUSARs.** As sponsor, Bart Health/Queen Mary delegates to the CI responsibility for: • Informing the appropriate REC of SUSARs that have occurred in the UK • Notifying all sites (PIs) of SUSARs It is not a requirement to notify the UK REC of non-UK SUSARs. It is normally the responsibility of the National Coordinating Centres (NCCs) to report SUSARs to the relevant international RECs in their country of origin. The SAE must be reported to the REC if it relates to the following: • A new event, related to the conduct of the study or the development of the IMP that is likely to affect the safety of subjects. • An SAE associated with the study procedures, and which could modify the conduct of the study. • A significant hazard to the subject population such as lack of efficacy of an IMP. Expected Serious Adverse Reactions (SAR) do not need be reported to the main REC apart from in the following situations: • Single case reports of an expected serious adverse reaction with an unexpected outcome e.g., death • An increase in the rate of occurrence of an expected serious adverse reaction which is judged to be clinically important.
For Clinical Investigations		
13.	Device Manufacturer or GCP & Governance Manager	**Notify the MHRA of reportable safety events occurring on Clinical Investigations of Medical Devices.** The device manufacturer should normally be delegated responsibility for reporting events to the MHRA. The manufacturer may report the event according to their own procedures but must comply with the statutory reporting requirements and must forward a copy of the event report and all correspondence to the JRMO in a timely manner. Where the sponsor retains responsibility for event reporting to the MHRA, this will be completed by the JRMO GCP team. Events that must be reported to the MHRA are: • All SADEs including USADEs

		• All SAEs, whether initially considered to be device/procedure related or not, involving a device under clinical investigation within Great Britain. • All device deficiencies that could have led to a SADE if appropriate action had not been taken, intervention had not occurred, or circumstances had been less fortunate. Review all valid safety reports as soon as possible after receipt. Establish Day 0 and notify all involved. Ensure that both the PI's and CI's assessment of the event correspond. If not, discuss with the CI and, if needed, seek independent advice as per sections 7 and 8. Report the event as per current MHRA guidance without delay (see MHRA main website for web address). Any interpretation of working should be checked with the CI prior to submission of the report. Events in double-blind Clinical Investigations should be unblinded prior to submission. Procedures related to un-blinding safety reporting purposes can be found in study specific SOPs. Once submitted, save a copy of the report, and send it to the CI, Study Coordinator and the local JRMO Clinical Trial Monitor for logging at local level. Updates to reportable events must be managed in the same way and in the same timeline as new event reports. In multi-national studies, all events must be reported to the MHRA regardless of the country they occur in. The event may need to be reported to the competent authorities in other countries according to national laws. This activity may be delegated to the device manufacturer or to NCC in each country.
14.	CI	**Periodically review all recorded AEs and device deficiencies.** Review all adverse events recorded in the case report form and confirm agreement or disagreement with the site's assessment of seriousness, relatedness and whether the event is anticipated. Review all device deficiencies recorded in the case report form and confirm agreement or disagreement with the site's assessment of whether the device deficiency could have led to a SADE. Complete and document the periodic review in accordance with the CIP or other essential documents. The periodic review should take place at least quarterly. In the event that the CI disagrees with the site assessment, they should notify the JRMO (see section 15 for details). In some circumstances this activity may be delegated to the device manufacturer. If this is the case the contract will detail those delegations and which SOPs are being followed.
15.	Medical Assessor	**Assess received SAE and device deficiency reports** All received reports of SAEs and device deficiencies that could have caused SADEs must be reviewed within 72 to hours of receipt.

		The device manufacturer should normally be delegated the responsibility of being medical assessor and may do so according to their own procedures. The device manufacturer must communicate its assessment to the JRMO within 72 hours. Where the sponsor is responsible for assessing received reports, the CI or a suitable medical delegate will be the medical assessor. The medical assessor must review the event and confirm that they agree with the site's assessments concerning the event's seriousness, whether it is related to the device and whether it is an anticipated event. In the event that the medical assessor disagrees with the site, they should notify the JRMO. The JRMO may facilitate discussion between the two parties. However, in the absence of a consensus the event should be processed according to the most severe categorisation. This could lead to events being upgraded and reported to the MHRA. Reports must always represent both assessments.
16.	CI	**Notify the REC of all USADEs.** Unless delegated to the manufacturer, the JRMO will report USADEs to the MHRA per JRMO SOP 26c: *Site level Pharmacovigilance for MHRA regulated studies* . The CI is responsible for notifying the REC that approved the Clinical Investigation of all USADEs. Use the HRA Non-CTIMP safety report form available at https://www.hra.nhs.uk/documents/1087/safety-report-form-non-ctimp.docx. The report must be submitted to the REC within 15 days of the CI becoming aware of the event. Device deficiencies, ASADEs and other SAEs do not need to be notified to the REC.
17.	CI	**Notify all sites of all SAEs that have been reported to the sponsor (multi-centre Clinical Investigations only).** The process for notifying should be described in the CIP or in another essential document e.g., a study specific safety reporting procedure.
18.	CI	**Ensure all relevant committees are provided with all relevant safety information.** The process and timing for providing safety information should be described in the CIP or the committee's charter.
19.	Medical Assessor	**Assess SADEs and device deficiencies that could have led to SADEs to and determine whether the risk analysis needs to be updated and whether corrective and preventative action is required.** Where changes to the risk analysis or CIP are required, the sponsor should be notified immediately. A substantial amendment must be made to implement the change.
Medical assessment of reportable safety events		
20.	CI	**Assess all reportable events and pregnancies within 72 hours of receipt (note this included follow up reports).**

		Acting as the sponsor's medical assessor, the CI or appropriate delegate must review all SAEs within 72 hours. The CI must assess the event to determine that it does meet the definition of an SAE, and that the event and narrative are clear and provide sufficient information. The CI's assessment also includes an assessment of: • Seriousness: the final assessment is completed by the PI (or delegate). Should a difference of opinion arise the CI and PI must discuss the event, but the PI at site will make the final decision. • Relatedness: if the CI disagrees with the PI's assessment, the opinion and explanation of both the CI and PI should be provided on the report. However, the PI's assessment of relatedness will be used to define the event. • Expectedness: using the current version of the RSI. Expectedness decision must be made purely on the content of the RSI and should not take into account other factors should as study population or subject history. This applies to all IMPs and investigational devices used in the study. Where the site is asked to make this assessment, please note the final assessment is completed by the CI. This review should be document on the SAE form where possible or cam be clearly documented in an email. This assessment should be filed in the TMF and sponsor oversight files.
21.	GCP Team/Clinical Director for Research & Development	**Seek and arrange independent review in cases of dispute between the CI, a PI and /or JRMO GCP team when assessing an SAE.** Should such a dispute arise, the GCP team will contact the Clinical Director for Research & Development for clinical expertise and resolution. For seriousness and relatedness, the PI decision stands, and the PI should not be pressure to change his/her mind. A conversation can occur if there is disagreement. The Clinical Director is ultimately responsible for making a final decision on behalf of the sponsor.
22.	Clinical Trial Monitor	**Ensure the JRMO does not process non-reportable events.** The following events are normally not reportable as defined in this SOP - CTIMPS: Adverse Events which are not serious and are not AESI. Clinical Investigations: Adverse Events which are not serious and are not AESI. Device Deficiencies have been assessed as not having led to a SADE. Interventional and research sponsored studies: Any event other than unexpected serious adverse reactions. Hosted studies: All events. Upon receiving a non-reportable event, notify the reporter that the event is not reportable following JRMO procedures. Save the correspondence in indemnity.

23.	CI	**Clinical Investigations only: document periodic reviews of all AEs** In Clinical Investigations of Medical Devices, the CI must also document a periodic review of all adverse events and device deficiencies recorded in the study case report forms. This review should occur at least quarterly.
Medical assessment of pregnancies within the scope of this SOP		
24.	CI	**CI must include pregnancy reporting and follow-up procedures in the protocol/CIP.** The CI must ensure that the protocol/CIP clearly outlines the procedures that must be followed should a study participant or their spouse become pregnant whilst taking the IMP or using the investigational device during the study period. If pregnancy reporting is felt not to be required, this must be clearly justified in the protocol/ CIP. The sponsor's pregnancy form (see SOP 26a Associated Document 3) must be used when the CI is notified of a pregnancy. Study-specific additions to the pregnancy form may be requested in writing to the JRMO but no fields may be removed from the pregnancy form. The CI must ensure systems are in place at all sites to report pregnancies to the sponsor within 24-hours of becoming aware of the event of a pregnancy, and that all pregnancies are followed to outcome. The length of follow-up post birth must be assessed by the CI using information (IB/ SmPC) and described clearly in the protocol/CIP. Pregnancy follow-up can be through a coordinating centre or the central research team, as appropriate to the care of the participant.
25.	GCP Team	**Obtain independent medical advice for any pregnancy reports received** When receiving a pregnancy report, the GCP team will request medical review and advice on length of follow up needed from an appropriately qualified person as identified by the Clinical Director for Research & Development.
26.	Clinical Trial Monitor	**Log any pregnancy in ReDA** as per the instructions in associated document 3.
27.	Clinical Director for Research & Development	**Arrange for a member of the obstetric department to review any reports of pregnancies that are received by the JRMO.** Provide independent medical expertise to the GCP team. Expertise may include, but is not limited to, classifying 'normal' or 'abnormal' birth, length of follow up needed and whether the participant can remain on the study.
28.	GCP Team	**Ensure that the CI and study team are aware of and follows the advice.** Log all information and documentation within ReDA and study files.
Implement Urgent Safety Measures (USM) (Not applicable for Clinical Investigations)		

29.	Sponsor and CI	**Implement USM immediately, seek advice from the MHRA and sponsor before (if possible), inform the MHRA & REC within 3-days of the urgent safety measure with an amendment.** The sponsor and investigators may implement urgent safety measures to protect clinical trial participants from any immediate hazard to their health and safety; the measures must be taken immediately. See JRMO SOP 17a *Amendments for Halted Studies* for the USM Procedure.
Reconciliation, Ongoing oversight, and annual review		
30.	CI and JRMO	**Follow SOP 19 (Annual Progress Reports (APR)) to ensure regulatory obligations are met.** Ensure that appropriate assessment is preferred regarding safety and risk of study.
31.	CI	**Once the study is active, review the RSI at intervals agreed with GCP manager at set up at a minimum yearly in line with DSUR creation (CTIMPs) or APR (Clinical Investigations).** An SOP should be created to document and log this process.
32.	Clinical Trial Monitor	**Every other quarter and following every onsite monitoring event perform study specific reconciliation for all live MHRA regulated studies.** Every other quarter generate a study specific SAE Log on ReDA and compare it to the coordinating team's SAE Log sent with the quarterly monitoring report/ acquired during monitoring visits or requested from the study team. Perform reconciliation to ensure accuracy and that all documents appropriately stored. Confirm completion to trial coordinator and in Edge. Save both logs and all related correspondence in the "Indemnity" folder and file in the JRMO sponsor's files. As the Study nears its end- ensure the CI and study team are aware of the need to close all SAEs or confirm that the SAE is open ongoing at end of study.
33.	Clinical Trial Monitor	**Prepare reports for the SOG meeting** In preparation for the sponsor oversight group meeting, run report as requested by the GCP & Governance managers, likely to include but not limited to: The number of SAEs, SARs and SUSARs or SAEs, SADEs and USADEs for all sponsored MHRA-regulated studies within reporting period. Number of device deficiencies that could have led to SADEs in all sponsored Clinical Investigations of Medical Devices within the reporting period. To identify 'on time' and 'late' reported SAEs and other safety events. All late reported SAEs and SUSARs/ reportable device events for that quarter are to be highlighted and documented at the pre-sog meeting. Any evident trends will be discussed at this meeting and escalated to the JRMO QA manager as a non-compliance

		Provide figures to the Clinical Trial Facilitator to compile meeting papers.
34.	SOG members	**Review safety information as per group remit.** Action, as necessary.

Change control

This section outlines changes from version **2.0** to version **3.0**

Section changed	Summary and description of changes
Throughout	CI responsibilities added (moved from Sop 26a) to clarify and streamline.
Definitions section	Definition of Valid report updated/clarified
Throughout	Clinical investigation procedures added

List of associated documents

Document ref.	Document name
Associated Document 1	RSI Guidance
Associated Document 2	ReDA instructions to log safety events

List of templates

Document ref.	Document name
Template 1	Template AESI Form