Joint Research Management Office Standard Operating Procedure for:			
Annual Sponsor Oversight and Progress Reporting			
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Background:

Progress Reports (PR) are essential for maintaining oversight of approved studies, as required by sponsors and regulatory bodies.

It is a condition of Confidentiality Advisory Group (CAG) approval to provide these progress reports and for Clinical Trial of an Investigational Medicinal Products and Advanced Therapy Investigational Medicinal Products, there is a legal regulatory requirement for sponsors to submit the Development Safety Update Reports (DSUR) annually. PRs for clinical investigations or specifically to NHS Research Ethics Committees (REC) and Health Research Authority (HRA) are not required.

Purpose and scope:

This Standard Operating Procedure (SOP) describes the procedure for the preparation and submission of the sponsor oversight questionnaire and the required regulatory body progress report for all Barts Health NHS Trust (Barts Health) and Queen Mary University of London (Queen Mary) sponsored studies.

The SOP does not cover those studies covered by Queen Mary Ethics of Research Committee approval or externally sponsored studies hosted by Barts Health or Queen Mary.

This SOP applies to all Chief Investigators (CI), investigators, study teams and Joint Research Management Office (JRMO) staff involved in the set up and conduct of studies sponsored by Queen Mary and Barts Health.

For safety reporting refer to *SOP 26a Site level Pharmacovigilance for MHRA regulated studies*, *SOP 26b Site level Pharmacovigilance for Interventional and Research studies*, *SOP 26c Pharmacovigilance (Process for the Sponsor and CI)*,
SOP 26d Site level Pharmacovigilance for Clinical Investigations of Medical Devices.

Abbreviations:	
Barts Health	Barts Health NHS Trust
CAG	Confidentiality Advisory Group
CI	Chief Investigator
DSUR	Development Safety Update Report
HRA	Health Research Authority
JRMO	Joint Research Management Office
MHRA	Medicines and Healthcare products Regulatory Agency
PR	Progress Reports
Queen Mary	Queen Mary University of London
REC	Research Ethics Committee
SOG	Sponsor Oversight Group
SOP	Standard Operating Procedure
SOQ	Sponsor Oversight Questionnaire

SOP Text:

All PR due dates and applicable study type

	Responsibility	Activity
	JRMO staff	**Note requirements for each study type and due dates**

	CAG Due on the anniversary of the CAG approval date	**DSUR** Due on the Development International Birth Date*	**Sponsor Oversight Questionnaire (SOQ)** Due on the anniversary of the Confirmation of Sponsorship date
MHRA regulated Sponsored study	Yes (if applicable)	Yes	No
Interventional or Research sponsored study	Yes (if applicable)	No	Yes

*(The date of first clinical trial authorisation worldwide) and provide annual DSUR submissions until all open clinical trials are completed and their study reports submitted.

Failure to submit any of these progress reports to the JRMO will be classified as a non-compliance and should be reported to the Quality Assurance Manager following *SOP 31 Non-Compliance.*

	JRMO Staff	**Set up reminders** Set up reminders in the appropriate systems/reports for any due progress report(s), first reminder at least 30 days prior to the due date.
SOQ		
	JRMO staff	**Remind CI of the SOQ requirements** For all Interventional and Research studies of all risk levels, a SOQ *(See Associate document 1)* should be sent to the CI two months prior to the due date. Prepopulate the relevant study specific data fields from EDGE and send this draft SOQ to the CI.
	CI	**The sponsor oversight questionnaire should be submitted to the JRMO for review.** Please review and complete the SOQ. Submit the draft completed questionnaire (research.governance@qmul.ac.uk). Study extensions will need to be submitted via the normal amendment process *(SOP 17a, b and c Amendment Series).*
	Governance section staff or delegate	**Verify the data within the SOQ against JRMO records** Review SOQ (*Associated Document 2 Progress Report Guidance for JRMO reviewers*) and ensure EDGE reflects the data provided and seek clarifications wherever needed. Complete the appropriate EDGE Workflow. Once all checks have been completed, notify the CI of the completion of the JRMO review.
CAG Annual review		
	CI	**The draft CAG PR (if applicable) should be submitted to the JRMO for review.** At this stage, the CI should consider if it would be possible to reduce the amount of confidential patient information that they are processing. Please refer to HRA guidance (https://www.hra.nhs.uk/about-us/committees-and-services/confidentiality-advisory-group/guidance-confidentiality-advisory-group-applicants/) on reducing the disclosure of confidential patient information prior to submitting your annual review report. Please submit the draft CAG PR to the JRMO (research.governance@qmul.ac.uk) at the 12-month anniversary of the initial CAG Approval. Study extensions will need to be submitted via the normal amendment process *(SOP 17a, b and c Amendment Series).*

	Governance section staff or delegate	**Verify the data within the CAG PR form against JRMO records** Review CAG PR (*Associated Document 2 Progress Report Guidance for JRMO reviewers*) and ensure EDGE reflects the data provided and seek clarifications wherever needed. Complete the appropriate EDGE Workflow. Once all checks have been completed, notify the CI of the completion of the JRMO review.
7	CI	**Submit CAG report to the CAG team** Please submit the JRMO approved CAG PR to the Confidentiality Advice Team by email (cag@hra.nhs.uk) four weeks before the approval expires (i.e., no later than 11 months following the final approval date). The JRMO (research.governance@qmul.ac.uk) should be copied in when submitting or forwarded the appropriate correspondence to REC Any queries or substantial changes to the original CAG form should be escalated to the Caldicott Guardian to confirm information is in line with current practice.
DSUR Reporting		
	Assigned Clinical Trial Monitor	**Set up reminders for DSUR due dates** Reminders should be set up prior to report due date as per *SOP 26c AD2 ReDA instructions to log safety events* and *Associated Document 3 DSUR Template Emails.* *If there are delays in DSUR submission it may be necessary to escalate to the Sponsor Oversight Group (SOG) for assessment of delay.*
	CI or delegate	**A draft progress report should be submitted to the JRMO for review prior to submission to the MHRA** Please submit the draft DSUR to the JRMO (research.governance@qmul.ac.uk) with an aim of 1 week prior to submission deadline month (anniversary of the initial favourable opinion plus 60 days) to give the JRMO time to review and approve the draft. The CI should use the DSUR template and DSUR cover letter template (*Associated document 4 and 5*) where details of Reference Safety Information annual checks can be declared and confirmed.
	GCP & Governance manager or delegate	**Once the draft report has been received by the JRMO, the JRMO will then verify the data against JRMO records** Update any records i.e., EDGE to reflect the data provided and seek clarifications wherever needed. Review DSUR as per EDGE workflow, liaising with the CI and the study team as necessary. This review should include ensuring that current templates are used, that all sections are complete, and that all information is correct (to the sponsor's knowledge).

		Once review and EDGE workflow are completed, notify CI to submit the report to the regulatory body.
	CI	**Submit to the MHRA once the JRMO confirmation is received.** A DSUR report should be submitted to the MHRA no later than 60 calendar days from the clinical trial authorisation anniversary date. DSUR and appropriate safety report or cover letter should also be submitted to the approving REC for information. The JRMO (research.governance@qmul.ac.uk) should be copied in when submitting and in all correspondence with REC and MHRA including and acknowledgements or submission receipts.
	Assigned Clinical Trial Monitor	**Ensure reminders are set up and actioned (this includes appropriate escalation)** Individual event reminders must not be switched off until final version and submission evidence is received. Ensure draft copies of annual reports, GCP & Governance Manager's approval, final version and evidence of submission are saved as per *SOP 27 JRMO Internal Filing* Ensure SOG papers accurately reflect DSUR report status.
	GCP and Governance team	**Summary Monitoring Visit Reports** For regulated sponsored studies, information will be obtained from Summary Monitoring Visit Report submitted every 6 months. GCP Managers will review and log information as per EDGE workflows.

Change control

Section 1	New report requirement table based on study type
Throughout	Implementation of the sponsor oversight questionnaire

List of associated documents

Associated Document 1	Sponsor Oversight Annual Questionnaire
Associated Document 2	Progress Report Guidance for JRMO reviewers
Associated Document 3	DSUR Template Emails
Associated Document 4	DSUR Template
Associated Document 5	DSUR cover letter template