SOP number	**56.003**	Version	**6.0**
Title	**Project Management: Managing an Active Trial**		

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SOP category	NHSGGC Project Management Unit

Staff category

Staff Category	**R**	**A**	**C**	**I**
GCRF Clinical Research Manager		X		
Project Managers	X			
R&I Clinical Trial Monitors			X	
Sponsor Research Coordinator			X	
Sponsor Pharmacy			X	

1. Scope

This procedure applies to active research studies managed via the Project Management Unit (PMU) staff or Project Managers (PM) external to PMU. This SOP does not cover oncology studies coordinated by Glasgow Oncology Clinical Trials Unit. Any activity involved in the set-up of the study / prior to Sponsor Regulatory Green Light (RGL) and locations becoming active is covered in SOP 56.002.

2. Purpose

To describe the PM procedures to manage studies Sponsored by NHSGGC or Co-Sponsored with University of Glasgow (GU), and project managed by either PMU or an external PM.

3. Procedures

3.1 Communication

The PM will act as a communication conduit between all relevant stakeholders including the participating research location teams for the management of the study from set-up to close-out. The forms described in SOP 56.002 will be prepared by the PM and then maintained by the local team throughout the duration of the study.

The PM will maintain a list of contact details for each participating location, including the Principal Investigator (PI), lead nurse, pharmacists (if applicable), local Research & Innovation (R&I) and any other relevant staff members. These will be shared with Sponsor representatives as needed.

If additional participating location(s) are needed the PM will notify Sponsor of the request via the Trial Management Group (TMG) which includes representatives from monitoring and pharmacy (where relevant to the type of study) teams. If agreed, the PM will coordinate the set-up of any additional participating locations following SOP 56.002 Trial Set-up, notifying Research Ethics Committee (REC) of additional location(s) through the formal modification process (section 3.4).

3.2 Local Trial Team Updates

The PM will request the following documents when there are new members of the local study team:

- Form 56.002D: Participating Location Delegation Log
- Form 56.002F: Location Clinical Trial Training Log
- CV and GCP Certificates (if applicable)

If an electronic case report form (eCRF) is being used in the study the PM will request access from the Data Centre (DC) for new team members. If the DC is the Robertson Centre for Biostatistics (RCB), Form 02.025A will be used for requesting access, and the RCB must be consulted as to requirements for recording eCRF training.

Where staff are removed from the local team before the end of the study the participating location will notify the PM and update Form 56.002D: Participating Location Delegation Log to reflect this. The data centre must be also be notified for eCRF access to be revoked.

3.3 Ongoing Training

Where study related training needs are identified, the PM (in conjunction with other members of the TMG) will provide appropriate training materials or coordinate training sessions for the participating location teams. This would include for any new members of the study teams, for any modifications to the study, as described in section 3.4 or as a result of Non-Compliances or Serious Breaches. All study specific training will be recorded by the local team on Form 56.002F and filed within the ISF.

3.4 Modifications (Previously Amendments)

Proposed modifications to the study will be discussed and agreed at the TMG meetings. The Sponsor Research Co-ordinator will determine the classification of the modification as per SOP 51.021. The impact of the modification on the upcoming milestones will be assessed and discussed by the TMG. If applicable, the TMG will propose a strategy on how to progress and approve the modification with minimal impact on the upcoming trial milestone.

Once confirmation has been received from Sponsor on modification classification, the PM will complete the appropriate IRAS amendment tool and send to the Sponsor Co-ordinator to be locked for submission. The UK Process for Handling Study Modifications details the categorisation and timelines for these.

When REC and regulatory approvals (if applicable) are in place, the PM will ensure that all participating location teams are notified (using Email template form 56.003D), and provided with modification details, supporting documentation including a modification history log and relevant approvals. It is the local study team's responsibility to ensure that they have confirmation of local approval to implement the modification.

All trial stakeholders (Pharmacovigilance (PV), Data Centre (DC), Trial Monitoring Team and Pharmacy) will be notified and involved in discussions in relation to any substantial modifications via the TMG meetings.

An electronic modification tracker (Form 56.003B) will be maintained detailing distribution of modifications to stakeholders, location teams and local R&I/R&D departments. The PM will confirm with the location teams that the modification has been approved locally and implemented (or otherwise if local R&I approval is refused).

Where a modification requires changes to the eCRF, the PM will notify the participating locations as above (using Form 56.003D) that the modification must be processed by the local R&D contact but that location must not implement the modification until instructed to do so.

A provisional implementation date for modifications requiring changes to the eCRF will be agreed by the TMG. The DC will make the changes to the agreed timeline and inform the TMG when the changes are active. To ensure that eCRF changes can be implemented in good time, the DC must be involved in discussion about the modification and proposed implementation date as early as possible, i.e. prior to approval. Once changes have been made, the PM can then instruct participating locations by email to implement the modification, subject to local approvals being in place.

3.5 Urgent Safety Measures

The Sponsor/CI or the local PI may take appropriate urgent safety measures in order to protect research participants against any immediate hazard to their health or safety. The PM will ensure the approving REC is notified that such measures have been taken, the justification and plan for further action as per SOP 53.001.

3.6 Protocol Deviations/Non-compliances

Protocol deviations will be managed as described in SOP 51.008 Handling of Non-compliances with Good Clinical Practice (GCP) and/or the study protocol. The PM, as part of the location set-up, will ensure local teams are aware of the procedure for reporting protocol deviations, using Form 51.008A/Form 51.008C depending on the categorisation of the deviation. Protocol deviation listings are provided prior to the TMG meetings and the CI and Statistician are responsible for evaluating the impact of deviations on trial safety and outcomes. TMG minutes will reflect this. Upon receipt of a protocol deviation report, the PM will send to the Trial Monitoring Team, if required the PM will facilitate any corrective and preventative measures.

3.7 Committees/Meetings

As instructed the PM will act as a coordinator for study committees as described in the R&I Study strategic plan (Form 51.010E). There may be a requirement to escalate actions from these committees to the NHSGGC Sponsor Oversight Committee, if this is required GUI 56.003A / Form 56.003A will be followed.

PMs working within the Project Management Unit (PMU) will hold regular PMU team meetings, reporting progress using the Trial Status Update (Form 56.002B). This will allow milestones/timelines and any difficulties to be monitored and discussed with senior team members as required.

For First in Human (FIH), or studies involving unlicensed ATIMP/GMOs, additional committee meetings post-RGL are required to manage the risks associated with these types of studies. Frequency and types of committees needed will be determined at study set up.

3.8 Trial Master File (TMF) Maintenance

The PM will maintain relevant sections of the TMF following Form 51.016A throughout the duration of the study and will undertake regular Quality Checks verifying that pertinent documentation and correspondence is filed. For regulated trials this quality check will be documented using Form 51.016K in accordance with SOP 51.016.

3.9 Monitoring (if applicable)

Sponsor Governance Monitoring Team will monitor participating locations as agreed in the Monitoring Plan (Form 53.010A). The PM will be notified of any monitoring actions and will assist the local study teams to complete these if needed.

If there is a change to the original Source Data Plan (Form 56.002M) during the lifespan of the study then the Study Monitor will obtain a revised source data plan from the affected location(s) and inform relevant trial stakeholders of the change(s). A copy of the revised source data plan will be held in the monitoring section of the TMF (section 12.3, Form 51.016A).

3.10 Study Invoice Management

As detailed in the agreement with the participating location the PM will instruct local study teams as to when to raise invoices for payments.

3.11 Oversight and Stakeholder Reporting

PM will facilitate and aid the completion of the necessary reports required throughout the lifetime of the study. These include progress reports to the funder, progress reports to the Ethics Committee and any others as needed. PM will notify the DC of TSC/DMC meeting dates that will require reports to be made available. The DSUR will be submitted to MHRA, if applicable, by the Pharmacovigilance (PV) team. In addition, the PM will update the Sponsor CTIMP Oversight Committee of trial progress and issues on an ongoing basis.

4. Referenced documents

- Form 56.003A - Sponsor Oversight Committee Escalation
- Form 56.003B - Modification Tracker
- Form 56.003D - Modification Email Template
- GUI 56.003A - Escalation Process for Actions Impacting Project Delivery and Study Integrity
- SOP 51.008 - Handling Non-Compliance with Good Clinical Practice (GCP) and/or the trial protocol in clinical research Sponsored, Co-Sponsored or Hosted by NHS Greater Glasgow and Clyde
- SOP 51.016 - Preparation and Maintenance of a Trial Master File
- SOP 51.021 - Sponsor Review and Approval of Amendments for Research Sponsored by NHSGGC or Co-Sponsored by NHSGGC and the University of Glasgow
- SOP 53.001 - Handling Urgent Safety Measures for Clinical Trials for Investigational Medicinal Products and non-CA marked Medical Devices
- SOP 56.002 - Project Management Trial set-up
- Form 02.025A - RCB User access request form
- Form 51.008A - Protocol Deviation Reporting Form
- Form 51.008C - Protocol Deviation Log CTIMPS
- Form 51.010E - R&I Study Strategic Plan
- Form 51.016A - Sponsor TMF Index
- Form 51.016K - TMF Index Pages
- Form 53.010A - Monitoring Plan for a Clinical Trial of an Investigational Medicinal Product/Medical Device Investigation
- Form 56.002B - Status Update
- Form 56.002D – Participating Location Delegation Log
- Form 56.002F - Location Clinical Trial Training Log
- Form 56.002M - Source Data Plan

5. Related documents

- None

6. Document History

Version	Date	Description	Retrospective Implementation
1.0	17/10/2016	First release	No
2.0	14/05/2018	Addition of GUI 56.003A and Forms 56.003A	No
3.0	30/09/2019	Changes made to clarify process on trial team updates, amendments and funding milestones.	No
4.0	23/01/2020	Changes made to include trial status updates part of SMG agenda and minutes Quality check of CI Site File included	No
5.0	28/06/2024	Changes to reflect updates to Sponsor processes	No
6.0	14/05/2026	Terminology changes as per updated regulations Addition in relation to FIH/GMP studies	No