SOP number	**56.003**	Version	**5.0**
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			
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 study-specific 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 sites 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 a study-specific PM.

3. Procedures

3.1 Communication

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

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

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

3.2 Local Trial Team Updates

The PM will request the following documents when there are new members of the trial site team:

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

If an electronic case report form (eCRF) is being used in the trial the PM will request access from the Data Centre (DC) for new trial 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 site team before the end of the study the participating site should notify the PM and update Form 56.002D: Site Delegation Log to reflect this. The data centre should be also be notified for eCRF access to be revoked.

3.3 Ongoing Site Training

Where trial 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 site teams. This would include for any new members of the participating site teams, for any amendments to the trial, 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 site team on Form 56.002F and filed within the PI site file.

3.4 Amendments

Proposed amendments will be discussed and agreed at the TMG meetings. The Sponsor will determine whether an amendment is substantial or non-substantial as per SOP 51.021. The impact of the amendment on the upcoming trial milestone will be assessed and discussed by the TMG. If applicable, the TMG will propose a strategy on how to progress and approve the amendment with minimal impact on the upcoming trial milestone.

Once confirmation has been received from Sponsor on amendment classification, the PM will complete the appropriate IRAS amendment tool and organise signatories. The UK Process for Handling Study Amendments details the categorisation and timelines for amendments.

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

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 amendments via the TMG meetings.

An electronic amendment tracker will be maintained detailing distribution of amendments to stakeholders, site teams and local R&D. The PM will confirm with the site teams that the amendment has been approved locally and implemented (or otherwise if local R&D amendment approval is refused).

Where an amendment requires changes to the eCRF, the PM will notify the sites as above (using Form 56.003D) that the amendment should be processed by the local R&I contact but sites must not implement the amendment until instructed to do so by the PM when the eCRF is ready.
A provisional implementation date for amendments 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. The PM can then instruct sites to implement the amendment via email, 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 trial protocol. The PM, as part of the site set-up, will ensure sites 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 presented during the TMG meetings by the study monitor. Upon receipt of a protocol deviation report from site, 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 trial 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.

PM's working within the Project Management Unit (PMU) will hold regular PMU team meetings, reporting trial 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.

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 trial and will undertake regular Quality Checks verifying that pertinent documentation and correspondence is filed. This quality check will be documented using Form 51.016K in accordance with SOP 51.016.

3.9 Site Monitoring (if applicable)

Sponsor Governance Monitoring Team will monitor trial sites as agreed in the Monitoring Plan (Form 53.004A). The PM will be notified of any monitoring actions and will assist the trial site 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 site(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 site agreement the PM will instruct site teams as to when to raise invoices for site payments.

3.11 Trial Oversight and Stakeholder Reporting

PM will facilitate and aid the completion of the necessary reports required throughout the lifetime of the trial. These include progress reports to the funder, annual 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 Project Manager 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 56.003D - Amendment Email Template
- GUI 56.003A - Escalation Process for Actions Impacting Project Delivery and Study Integrity
- SOP 51.008 - Handling of Non-compliance with Good Clinical Practice (GCP) and /or trial protocol in clinical research sponsored, con-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
- SOP 53.001 - Handling Urgent Safety Measures for Clinical Trials for Investigational Medicinal Products
- 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
- Form 51.010E - R&I Study Strategic Plan
- Form 51.016A - Sponsor TMF Index
- Form 51.016K - TMF Index Pages
- Form 53.004A - Monitoring Plan for a Clinical Trial of an Investigational Medicinal Product
- Form 56.002B - Status Update
- Form 56.002D - Site Delegation Log
- Form 56.002F - Site Clinical Trial Training Log
- Form 56.002M - Source Data Plan

5. Related documents

None

6. Document History

Version	Date	Description
1.0	17/10/2016	First release
2.0	14/05/2018	Addition of GUI 56.003A and Forms 56.003A
3.0	30/09/2019	Changes made to clarify process on trial team updates, amendments and funding milestones.
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
5.0	28/06/2024	Changes to reflect updates to Sponsor processes