SOP number	**56.002**	Version	**5.0**
Title	**Project Management Trial Set-up**		

Prepared by Signature	Lynsey Gillespie Date
Approved by Signature	Lynn Prentice Date
Released by Signature	Julie Brittenden Date

SOP category	56 NHS GG&C Sponsor Project Management Unit

Staff category

Staff Category	**R**	**A**	**C**	**I**
Project Management Unit	X			
Heart Failure Project Manager	X			
Robertson Centre for Biostatistics (RCB) Project Manager	X			
GCRF Manager		X		
Head of Clinical Trials for Heart Failure Group (University of Glasgow)		X		
Director of Operations RCB		X		
Sponsor Research Coordinator				X
Chief Investigator				X
R&I Systems Manager				X
Senior R&I Manager				X
R&I Pharmacy				X
Lead Clinical Trials Pharmacist				X

1. Scope

This procedure applies to Project Management Unit (PMU) staff and study specific Project Managers (PM). Accountability of this SOP differs as detailed in the RACI. This SOP does not cover studies coordinated by Cancer Research UK Clinical Trials Unit, Glasgow.

2. Purpose

To describe the trial set-up process for all studies sponsored by NHSGGC or co-sponsored with University of Glasgow (UoG), and project managed by either PMU or a study specific PM.

3. Procedures

3.1. Notification of a Clinical Trial

The R&I Coordinator will notify the Project Manager (PM) once trial funding has been successful.

The Research Coordinator and PM will meet with the Chief Investigator (CI) to discuss the R&I study strategic plan (SOP 51.010/ Form 51.010E) and PM activities will be delegated at that stage.

3.2. Trial Management Group

The Trial Management Group (TMG) will be convened and the scope / responsibilities agreed in the TMG charter (using the MRC template TMG charter) following the first meeting.

TMG meetings will follow a set agenda (Form 56.002O) and must have formal minutes as a record of each meeting.
For studies which are managed by PMU, the PM will complete a regular Trial Status Update (Form 56.002B) with general trial and milestone information. This form will be reviewed and discussed within the PMU meetings/with PM line management as the trial progresses to identify any issues that should be fed back to the wider Trial Management Group, or potentially escalated to the Sponsor Oversight Committee (SOC) if required.

3.3. Integrated Research Application System (IRAS)

The PM will support the Chief Investigator (CI) with developing the trial combined review IRAS form, which will be used to submit to the Research Ethics Committees (REC) and the Medicines and Healthcare products Regulatory Agency (MHRA). The PM is also responsible for ensuring that the IRAS form and any relevant trial documentation is provided to the national research coordinating centre (NRSPCC in Scotland, HRA in England & Wales, and Research Gateway in Northern Ireland) so they can initiate regulatory approval processes in local participating sites R&I departments. The PM will track progress of each application, and provide regular updates to the TMG.

3.4. Trial Master File Set-up

The PM is responsible for the set-up and maintenance of the Project management sections (Form 51.016A) of the Trial Master File (TMF) throughout the duration of the trial.

For a CTIMP the PM is responsible for ensuring the paper file is stored in a safe and secure environment and must be made available when required for audit, monitoring and inspection purposes.

For a non-CTIMP all study documentation will be saved electronically in the study e-Folder.

3.5. Pharmacy Participating Site File Set-up (if applicable)

All pharmacy documents will be provided by R&I Pharmacy and the PM will prepare the Pharmacy Participating Site File following section 10 of Form 51.016A. The first pharmacy file will be reviewed by R&I Pharmacy for accuracy before the PM will send to the participating site (s).

3.6. Investigator Site File (ISF) set-up

The PM will prepare the local PI Site File following the Principal Investigator Site File Index (Form 51.016C or non-CTIMP equivalent) for each of the participating sites.

All site set up documentation will be filed in the PI Site File as part of the Green For Go process (SOP56.001).

The PM will populate the following standardised documents (as applicable to the study) with the general information about the trial. The local participating site team will then update the local information going forward and maintain this throughout the duration of the trial:

- Form 56.002C: Screening Log Template
- Form 56.002D: Site Delegation Log template
- Form 56.002E: Communication Plan Template
- Form 56.002F: Site Clinical Trial Training Log Template
- Form 56.002G: Enrolment and Patient ID Log Template
- Form 56.002M: Source Data Plan Template

The first site file will be reviewed for completeness by NHS GG&C Trial Monitors as per the monitoring plan, if applicable. The PM will complete or delegate any actions to site staff from the Actions Resolution Document Form 53.004C.

The PM will forward Source Data Plan (Form 56.002M) to the site for completion as part of the Green for Go process. The study monitor will follow up with the site team to agree and sign off on the SDP.

3.7. Laboratory Master Research File (if applicable)

A Laboratory Master Research File is held by the QA Manager at each NHS GG&C laboratory.
A CTIMP study must be included in the Laboratory Master Research File if it uses NHS GG&C labs for central analysis and it falls under category 2 or 3, as defined below. Note categorisation of the lab tests must be completed in collaboration with the CI and Sponsor coordinator using SOP 51.028 / Categorisation of Lab tests FORM 51.028A.

Category	Description	To be included in Lab Master File?
1	Standard of care sampling, standard analysis	No
2	Standard of care sampling, non-standard analysis	Yes
3	Non-standard of care sampling, non-standard analysis	Yes

If applicable, the trial paperwork detailed in Laboratory Master Research File Index (Form 56.002L) must be provided to the local lab contact for filing in their laboratory master research file. In the event a Master Research File is not available the PM must create one using Form 56.002L. The file will be monitored for completeness by NHS GG&C Trial Monitors. The Master Research File will then be maintained by nominated member of lab staff.

4. Referenced documents

- Form 51.016A: Trial Master File Index
- Form 51.016C: Principal Investigator Site File Index
- SOP 51.010 / Form 56.010E: R&I Project Strategy Form

- SOP 51.028 – NHS Laboratory Samples for Trials involving an Investigative Medicinal Compound (CTIMP) Sponsored by NHS GG&C or Co-sponsored by NHS GG&C and the University of Glasgow or hosted by NHS GG&C
- Form 51.028A – Categorising Laboratory Tests undertaken within in CTIMPs Sponsored by NHS GG&C or Co-sponsored by NHS GG&C and University of Glasgow
- Form 53.004C – NHS GG&C Monitoring Actions Resolution Document
- SOP 56.001 – Site Set Up – Green for Go Process
- Form 56.002B – Trial Status Update Template
- Form 56.002C – Screening Log Template
- Form 56.002D – Site Delegation Log Template
- Form 56.002E – Communication Plan Template
- Form 56.002F – Clinical Trial Training Log Template
- Form 56.002G – Enrolment and Patient ID Log Template
- Form 56.002L – Laboratory Master Research File Index
- Form 56.002M – Source Data Plan Template
- Form 56.002O – TMG Agenda Template

5. Related documents

- SOP 51.016 – Preparation and Maintenance of a Trial Master File
- SOP 51.020 – Sponsor Regulatory Green Light
- SOP 53.004 – Monitoring Clinical Research – Site Monitoring Visit
- SOP 53.005 – GCP Audit of Research Studies and Systems Supporting Research

6. Document history

Version	Date	Description
1.0	17/10/2016	First release
2.0	09/03/2018	Details on Laboratory Master Research File added including Form 56.002L
3.0	27/09/2019	Changes made to clarify process on trial status update, project plan including adding Form 56.002N; pharmacy participating Site file Set Up and PI participating Site File Set Up including adding Form 56.002M.
4.0	23/01/2020	Changes made to include trial status updates part of SIG/ SMG agenda and minutes
5.0	18/08/2023	Update to SOP template v2.0 Addition of RACI matrix Formatting and wording updates Change to staff category to include external PMs