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Title	**Monitoring Clinical Research - Site Compliance Visit**		

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SOP category	NHS GG&C Sponsor Governance

Staff category

Staff Category	**R**	**A**	**C**	**I**
Lead Clinical Trial Monitor		X		
Clinical Trials Monitors	X			
Research Governance Manager			X	
Project Managers			X	

1. Scope

This standard operating procedure applies to all members of the Research and Innovation Monitoring Team, working within the Glasgow Clinical Trials Unit (GCTU).

2. Purpose

The purpose of this SOP is to describe the procedures that will be used by the Clinical Trial Monitors (CTM) acting on behalf of the Sponsor(s) to conduct Site Compliance Visits for Clinical Trials of an Investigational Medicinal Product (CTIMPs), medical device trials (CIMD) and non-CTIMP studies Sponsored or Co-sponsored by NHS Greater Glasgow and Clyde (NHSGGC). If monitoring on behalf of a non-NHSGGC Sponsor, this Standard Operating Procedure may also be used, upon agreement with the Sponsor (Form 53.014A).

3. Procedures

3.1. Monitoring Plan

The monitoring plan as developed under SOP 53.010 will detail the requirements of SCV for the trial. The minimum requirements are listed in section 3.4.

3.2. Timing of the Site Compliance Visit (SCV)

The first SCV will take place after all regulatory approvals are in place but prior to the first site receiving Green for Go (SOP 56.001). The CTM will liaise with the site and/or Project Manager (PM) to decide when the most appropriate time would be to carry out the site compliance visit and what format this will take based on the trial management structure and team/site availability.

The Monitoring Risk Assessment (Form 53.010B) of the trial will confirm the SCV activity and this will be documented in the Monitoring Plan (Form 53.010A). This can change throughout the trial; as the risk assessment is revisited in response to any changes in trial design and delivery e.g. set up documents found unfiled/missing during a monitoring visit, substantial amendment to trial etc. The SCV activity will be a pragmatic and risk based approach and in larger trials with multiple sites i.e. > 15, will have a percentage of SCVs conducted, dependent on the risk of the trial and site and the activity already undertaken by the Project manager, which can be early in the trial or a combination of early and staggered throughout to ensure consistency. The Monitoring Plan will document the number of SCV to be conducted documenting the reasoning for the level, and the activity during the visit.

3.3. Arranging the Site Compliance Visit

The CTM will aim to arrange the visit with site staff and/or the Project Manager with enough notice to ensure that the Investigator Site File (ISF) is available, complete and ready for the study to start at site. Any potential issue(s) identified at the SCV which may cause a delay that may impact on the study start date must be communicated at the earliest opportunity and required actions expedited to minimise impact.

3.4. Conducting the Site Compliance Visit

The visit may be completed on-site, remotely via video call or remotely via email facilitated document review. If undertaking the visit remotely, the Q-Pulse checklist may be utilised to aid the CTM in obtaining the relevant information and trial-specific questions asked.

The CTM will prepare a site file checklist, a document which can be compiled highlighting the expected contents of the ISF, ahead of the visit and if appropriate. This can be sent to site staff beforehand for them to complete. The CTM will review the most recent version of the protocol, ensure the protocol is signed off by the PI and decide what checks will be required at site to ensure that they are ready to begin the trial, checks include for example (but not limited to):

- Trial specific processes that have been put in place i.e. sample storage, transfer, devices which needed data cleared prior to releasing for further patient use
- Devices, storage, accountability and location – who access the room, does the device go to another participant
- IMP storage and location (e.g. stored out with pharmacy) - liaise with Sponsor pharmacy
- Trial specific equipment – ECG, ECHOs, scales – present and calibrated
- Delegation log – ensure all staff are delegated appropriately, sufficient staff are available for the trial and the log is trial specific (ensure core activities are present)
- Protocol signature page
- Site staff training – Trial specific, protocol, GCP and CVs, have they all attended the SIV /signed that they have read and understood training slides provided by the Sponsor.
- Site file location and storage
- Data transfer processes e.g. will data been transferred at end of trial, from Safe Haven, and how will this process be documented
- PI availability and site staff cover
- Does Source Data Plan reflect actual location/logistics - will workbooks be utilised locally to collect some source data
- Safety/device deficiency reporting process - did the site staff attend the SIV and are they aware of what deficiencies are and how to report. Do they understand the specific regulatory process for onward reporting of all protocol deviations to Sponsor for onward reporting to the MHRA, if required.
- Non-compliance/protocol deviation reporting - has the site been trained, did they attend the SIV
- Archiving - Does the site have an Archiving SOP within its Quality Management System (QMS), who is responsible on the team for archiving?
- General site queries - does the site work within a QMS and who do they report major non-compliances to at site, who should be contacted if the site staff are not compliant with actions from monitoring findings.

The Q-Pulse checklist will be completed and information gathered in response to each of the required questions or checks. Any issues will be resolved via the Action Resolution document.

3.4.1. Visit Documentation

In advance of the visit, a Monitoring Visit Agenda (Form 53.004F) will be sent to the CI/PI and site/trial representatives by the Monitor recording the tasks to be undertaken at the visit. This will be sent by email, prior to the visit ensuring the site have enough time to prepare for the upcoming visit.

A report will be generated on Q-Pulse per Guideline 53.004A and relevant documents (Agenda, FU letter, ARD) uploaded for review by the Lead CTM/Research Governance Manager, or a member of the Governance team if LCTM or RGM not available, once the visit has been completed.

3.5. Follow Up

A follow up letter (Form 53.004H) will be used to inform the PI and site staff of any documents that need to be included or updated, or any other actions that are deemed necessary, which will be outlined in the Actions Resolution Document generated by Q-Pulse after the report writing process.

The actions must be completed, as per escalation of monitoring findings SOP 53.004, prior to opening of the site.

4. Referenced documents

- SOP 53.010 - Monitoring Clinical Research – Preparation and Management of a Monitoring Plan
- SOP 56.001 - Site Set Up - Green for Go Process
- Form 53.004F - Monitoring Visit Agenda Template
- Form 53.004H - Preliminary Follow Up Letter / Follow Up Letter
- Form 53.010A – Monitoring Plan for a Clinical Trial of an Investigational Medicinal Product
- Form 53.010B - NHSGGC Research Governance Monitoring Risk Assessment
- Guideline 53.004A - Q-Pulse Guidance for Monitoring Visit
- Form 53.014A – External Sponsor Monitoring Process Arrangement form
- SOP 53.004 - Monitoring Clinical Research – Site Monitoring visit

5. Related documents

- N/A

6. Document history

Version	Date	Description
1.0	29/10/2024	First Release

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