STANDARD OPERATING PROCEDURE FOR MONITORING CLINICAL TRIALS OF INVESTIGATIONAL MEDICINAL PRODUCTS (CTIMPs)

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1. PURPOSE

This document describes the procedure for monitoring Clinical Trials of Investigational Medicinal Products (CTIMPs) conducted under the UK Clinical Trials Regulations (as amended and implemented in 2026) and ICH Good Clinical Practice (GCP) (as adopted in the UK) and risk-adaptive monitoring.

Monitoring is the act of overseeing the progress of a clinical trial and ensuring that it is conducted, recorded and reported in accordance with the Protocol, Standard Operating Procedures (SOPs), GCP and the applicable regulatory requirements.

Monitoring activities must be proportionate to the risks posed by the trial, as determined through documented Sponsor risk assessment (RA), and focused on the protection of participants and the reliability of the trial data and ensuring data integrity, quality and traceability throughout the trial duration.

2. SCOPE

This SOP applies to all members of staff involved with the CTIMP in the monitoring of CTIMPs sponsored by NHS Tayside/University of Dundee. Monitoring duties may be delegated to a third party ensuring appropriate Sponsor oversight is maintained. This delegation must be documented in a formal agreement. A risk-based and proportionate approach to monitoring will be used. This SOP may be applied for Non CTIMPs where appropriate.

3. RESPONSIBILITIES

Research Governance: Conduct and document the Sponsor RA, review and approve the monitoring strategy and monitoring plan. Notify Clinical Trial Monitor of all approved modifications and subsequent approvals, and any changes made to the Sponsor risk assessment.

Research Governance or Sponsor representative: Review and approve the Monitoring Plan.

Lead Clinical Trials Monitor/delegate: Produce a risk-based Monitoring Plan according to the Sponsor RA.

4. PROCEDURE

4.1 Monitoring Visits

4.1.1 Monitoring is undertaken by a TASC Clinical Trials Monitor (CTM) or a delegate on behalf of the Sponsor.
4.1.2 Monitoring can be onsite or remote e.g. by telephone or MS Teams.
4.1.3 The Monitoring Visit Log must be completed at each monitoring visit.

4.2 Monitoring Plan

4.2.1 Following the RA, a Monitoring Plan (Doc Ref 039) will be produced.
4.2.2 A CTM will determine the monitoring visit schedule and requirements and detail these in the Monitoring Plan. The level of monitoring for individual trials should be determined by the Sponsor RA and critical to quality factors so that those meeting multiple risk criteria are monitored more frequently. The intensity of monitoring can be adjusted based on continuous RA throughout the study.
4.2.3 More frequent monitoring, including triggered visits, will be undertaken at the request of Sponsor.
4.2.4 The Monitoring Plan should document the types of monitoring visits required for the trial e.g., Site Initiation Visit (SIV), First Participant First Visit (FPFV), routine monitoring visit(s) during recruitment and follow-up, remote monitoring, and the Close-Out Monitoring Visit (COMV).
4.2.5 The Monitoring Plan will detail the level of Source Data Verification (SDV) and frequency, type and intensity of monitoring.
4.2.6 The Monitoring Plan should be filed in the Sponsor File, Trial Master File (TMF) Investigator Site File (ISF) and Pharmacy Site File (PSF).
4.2.7 The Monitoring Plan will be reassessed and modified, as per continuous RA, documenting the rationale for any risk adapted changes. Previous versions of the Monitoring Plan must be superseded and retained in the Sponsor File, TMF, ISF and PSF.

4.3 Prior to a Monitoring Visit

4.3.1 The CTM or delegate should familiarise themselves with the protocol, monitoring plan and essential study documents.
4.3.2 The CTM or delegate should arrange a date and time with a member of the research team for the monitoring visit. The Chief Investigator (CI)/ Principal Investigator (PI) may nominate an appropriate person e.g., a trial administrator or research nurse for the CTM to liaise with to arrange the monitoring visit.
4.3.3 Prior to the visit, the CTM or delegate should explain to the CI/PI (or other nominated individual) what will be covered in the visit, and which documents will be reviewed during the visit. It is the CI/PI's responsibility to ensure that these documents are available.

4.4 Site Initiation Visit

4.4.1 The SIV will occur prior to site activation and the recruitment of the first participant. The RA may detail that the SIV will be carried out by the trial team and will not require a monitoring visit.

4.4.2 The purpose of the SIV is to ensure that the research site staff are trained on the protocol and study procedures and the site has all approvals in place for the trial to begin. These visits can be at site or remote.

4.4.3 During the SIV, the following will be checked:

- Research staff know their responsibilities, are familiar with the protocol, study procedures, study-specific training requirements and all essential records.
- Investigator responsibilities.
- Research staff understand monitoring procedures.
- All approval documents are in place.
- Signature and delegation logs, CVs and GCP certificates and training logs are in place.
- Investigational Medicinal Product (IMP) accountability procedures.
- Monitoring Plan
- Serious Adverse Event (SAE) Reporting.
- Potential breach reporting.
- Review of the TMF/ISF and PSF.

4.5 First Participant First Visit and Interim Monitoring Visits

The scheduling of the Routine Monitoring Visit will take place according to the Monitoring Plan. These visits can be at site or remote. The purpose of these visits is to check that the trial is being conducted in accordance with the principles of GCP. The following may be checked proportionate to study risk:

- Recruitment
- Informed Consent Forms
- Eligibility sign-off by PI
- GP letter has been sent
- SDV of Case Report Forms (CRF) for selected participants
- Approvals for study modifications
- Safety reporting
- SDV of SAEs reported to Sponsor
- Check for breaches
- IMP accountability
- Sample storage
- Review of the TMF or ISF and PSF

4.6 Close Out Monitoring Visits

4.6.1 The COMV will take place when the last participant at that site has completed their last study visit. These visits can be at site or remote.

4.6.2 As a minimum, the following, will be checked:

- Informed Consent forms
- IMP accountability
- SAE reconciliation
- Safety Reporting
- Check for breaches
- Sample storage
- CVs and GCP certificates

4.6.3 The CTM will check that essential records are complete and filed in the TMF/ISF and PSF.

4.7 After the Monitoring Visit

4.7.1 The CTM or delegate should complete the monitoring report within agreed timelines. This report will document the visit and include any risk-related concerns and actions to be completed by the CI, PI or delegate. This will be reviewed by the Senior clinical trials monitor prior to report sign-off.

4.7.2 The Monitoring Visit Report should be signed by the CTM or delegate and sent to the personnel identified in the Monitoring Plan within two weeks of completion of the visit.

4.7.3 A copy of the signed monitoring report will be filed in the Sponsor File and TMF/ISF and PSF.

4.7.4 It is CI/PI responsibility to ensure resolution of actions within appropriate timelines. Repeated failure to comply within the agreed timelines will be reported to the CI and Sponsor.

4.7.5 The completed monitoring visit actions will be filed in the Sponsor File and TMF/ISF and PSF as applicable.

5. ABBREVIATIONS & DEFINITIONS

CI	Chief Investigator
COMV	Close Out Monitoring Visit
CRF	Case Report Form
CTIMP	Clinical Trial of Investigational Medicinal Product
CTM	Clinical Trial Monitor
FPFV	First Participant First Visit
GCP	Good Clinical Practice
IMP	Investigational Medicinal Product
ISF	Investigator Site File
PI	Principal Investigator
PSF	Pharmacy Site File
RA	Risk Assessment
SAE	Serious Adverse Event
SDV	Source Data Verification
SIV	Site Initiation Visit
SOP	Standard Operating Procedure
TASC	Tayside Medical Science Centre

TMF Trial Master File

6. ASSOCIATED DOCUMENTS & REFERENCES

Doc Ref 039: Monitoring Plan template

7. DOCUMENT HISTORY

History prior to 2021 is in the archived SOPs available from TASC Quality Assurance Dept.

Version Number:	Reviewed By (Job Title):	Effective Date:	Details of editions made:
10	Debbie Pankhurst (CTM) Heather Barclay (Pharmacovigilance Monitor)	03/12/2021	Scheduled review, text refreshed throughout, no changes to procedure made.
11	Marney Keiller (Senior Clinical Trials Monitor)	04/12/2023	Scheduled review, "review of monitoring plan" added as a Research Governance responsibility in section 3.
12	Marney Keiller (Senior Clinical Trials Monitor)	04/12/2025	Scheduled review, reduction in the time line for issue of report. Vocabulary changed in line with ICH-GCP R3 updated terms.
13	Marney Keiller (Senior Clinical Trials Monitor)	28/04/2026	Updated in accordance with the new Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025.

8. APPROVALS

Approved by:	Date:
Dr Steve McSwiggan, Senior R&D Manager NHS Tayside	30 Mar 2026
Dr Valerie Godfrey, TASC Quality Assurance Manager, on behalf of TASC Clinical Research Guidelines Committee	27 Mar 2026