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Humber Health Partnership

GCP Monitoring SOP

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This page details the version history SOP and the main changes made for each new version.

Version Log		
Version number and date	**Author**	**Details of significant changes**
Version 1, 04.02.13	J H Pacynko	First SOP approved by R&D Committee on 01.02.13.
Version 2, 01.02.18	S Moffat	The following new sections have been added: • Risk adapted monitoring • Central monitoring • Laboratory monitoring • Monitoring plan The TMF will now be held at R&D instead of the investigator site. The site will be provided with an Investigator Site File. Mention of auditing of TMF for multi-site trials run by a CTU is added.
Version 3, 01.06.2022	G. Constable	**Changes are shown by wording in red.** 3 Background Added definition taken from ICH guidelines Removal of reference to HEY, changed to HUTH. Added sections to Monitoring Plan taken from MHRA/FDA article https://doi.org/10.1002/CPT.2386 in-line with current best practices. 5.2 Inclusion of Targeted Monitoring section 5.3 Lab GCP monitoring visit added prior to the start of the trial. 5.4 To change Sponsor TMF audits of CTUs (for multi-site trials) to Sponsor TMF monitoring visits. 5.5 Remote monitoring in-line with current trends in monitoring 6.2 Organizing monitoring visit added statements to reflect current practice 6.4 Conducting monitoring visit Amended to include ICH definitions 6.5 To specify the timelines for completion and review of monitoring visit reports. 7. Responsibility of investigators/Research staff Amended to included ICH definitions 9. Responsibility of R&D Monitor Amended to include ICH definitions
Version 4, 27.04.2026	L Cox	Changes are shown in red wording. SOP fully updated to align with ICH E6(R3), incorporating modernised GCP principles.

Docusign Envelope ID: E2F60965-D1CE-816E-831A-50005B374B4A

		• Added Quality by Design (QbD) and Critical-to-Quality (CtQ) concepts throughout the SOP. • Updated definition and scope of monitoring to reflect R3's emphasis on proportionate, risk-based Sponsor oversight. • Expanded requirements for central, remote, statistical, on-site, targeted, laboratory, and TMF monitoring. • Strengthened expectations for digital system oversight, including audit trails, data integrity, validation, and secure access. • Updated Monitoring Plan section to include adaptive oversight, CtQ identification, SDV rationale, and digital governance. • Added responsibilities for investigators, pharmacy, and monitors relating to data integrity (ALCOA+), digital systems, and CtQ processes. • Updated escalation pathways, CAPA expectations, and Sponsor oversight language. • Revised all sections for clarity, consistency, and alignment with current MHRA expectations and best practice. • Update from HUTH to HPP incorporating both HUTH and NLaG.

Docusign Envelope ID: E2F60965-D1CE-816E-831A-50005B374B4A

Section no.	Contents	Page no.
1	Purpose	5
2	Who should use this SOP	5
3	Background	6
4	Monitoring Procedures	7
	4.1 Which clinical trials are monitored	7
	4.2 How are HHP-sponsored trials identified	7
5	Risk-adapted monitoring	7
	5.1 Central monitoring	8
	5.2 On-site monitoring	8
	5.3 Laboratory monitoring	9
	5.4 Monitoring of TMF	10
	5.5 Remote Monitoring	10
6	Monitoring Plan	10
	6.1 Frequency of on-site monitoring visits	11
	6.2 Organising monitoring visits	12
	6.3 Preparing for monitoring visits	12
	6.4 Conducting monitoring visits	13
	6.5 Reporting monitoring visits and Follow-Up Actions	13
	6.6 Escalatory actions	14
	6.7 Use of findings	14
7	Responsibilities of Investigators/Research staff	14
8	Responsibilities of CT pharmacy staff	15
9	Responsibilities of HHPR&D monitor	16
10	Implementation	17

Please note for definitions of acronyms refer to Appendix 1 of Management of SOPs. Refer to Appendix 2 of Management of SOPs for the standards to which clinical trials that investigate the safety and/or efficacy of a medicinal product are conducted.

All the HHP R&D GCP SOPs are available at:
https://www.hey.nhs.uk/research/researchers/gcp-sops-for-hey-sponsored-ctimps/

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1 Purpose

The purpose of this SOP is to describe the Sponsor's oversight responsibilities and the procedures for monitoring clinical trials sponsored by Humber Health Partnership (HHP). This includes:

- Monitoring is one of the principal quality control activities and it must be ensured that monitoring activities are proportionate, risk based and aligned with the principles of ICH GCP, UK Clinical Trial Regulations, and Good Clinical Practice (GCP).
- Ensuring that monitoring supports the protection of participants' rights, safety, dignity, and wellbeing.
- Ensuring that data generated is reliable, complete, and of sufficient quality to support the trial's objectives.
- Describing the procedures for preparing, conducting, reporting, and following up monitoring visits.
- Embedding Quality by Design (QbD) and Critical to Quality (CtQ) principles into monitoring activities to ensure oversight focuses on aspects of the trial that matter most to participant safety and data integrity.

2 Who should use this SOP

This SOP applies to:

- All research staff involved in HHP sponsored CTIMPs, including Chief/Principal Investigators, co-investigators, research nurses, clinical trial assistants, clinical support workers, project managers, trial coordinators, data managers, and administrators.
- Clinical Trials Pharmacy staff involved in the storage, dispensing, accountability, or oversight of investigational medicinal products.
- All HHP R&D staff responsible for Sponsor oversight, quality assurance, monitoring, and governance of HHP sponsored CTIMPs.
- Research staff involved in HHP sponsored non CTIMPs where risk-based monitoring is required.
- Research staff conducting externally sponsored studies only where the external Sponsor does not provide a monitoring SOP, in which case HHP SOPs apply by default.

This SOP should be read alongside:

- R&D GCP SOP 05 (Sponsorship)
- R&D GCP SOP 03 (CRF and Source Data Verification)
- R&D GCP SOP 08 (Modifications)
- R&D GCP SOP 14 (Archiving)
- The Sponsor's Risk Adapted Approach to the Management and Monitoring of CTIMPs
- ICH E6(R3) and UK Clinical Trial Regulations

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3 Background

It is a legal requirement for the Sponsor of CTIMPs to ensure that clinical trials are monitored in accordance with UK Clinical Trial Regulations and Good Clinical Practice.

ICH E6(R3) defines monitoring as:

"The Sponsor's oversight activities that evaluate whether trial related activities are being conducted, and data are being generated, documented, and reported in accordance with the protocol, GCP, and applicable regulatory requirements."

ICH E6(R3) emphasises:

Docusign Envelope ID: E2F60965-D1CE-816E-831A-50005B374B4A

3.1 Quality by Design (QbD)

Monitoring must support a trial design that proactively minimises risks to participants and data integrity. Monitoring should focus on preventing errors that could meaningfully impact participant safety or the reliability of results.

3.2 Critical to Quality (CtQ) Factors

Monitoring should prioritise oversight of trial processes, data, and procedures that are essential to:

- Protecting participants
- Ensuring reliable and interpretable results
- Maintaining data integrity
- Ensuring appropriate management of investigational products
- Ensuring adequate documentation and traceability

3.3 Proportionate, Risk-Based Oversight

Monitoring approaches should be tailored to the specific risks of each study, taking into account:

- The complexity of the intervention
- The vulnerability of the population
- The criticality of data elements
- The experience of the site
- The digital systems used
- The potential impact of errors

3.4 Data Governance and Digital Systems

ICH E6(R3) introduces strengthened expectations for:

- Data integrity
- Audit trails
- Validation of digital systems
- Vendor oversight
- Secure handling of electronic data
- Remote and central monitoring using digital platforms

3.5 Regulatory Oversight

MHRA GCP inspectors routinely assess Sponsor oversight systems, including monitoring plans, monitoring reports, risk assessments, and evidence of proportionate oversight.
Monitoring ensures that:

- Participants' rights, safety, dignity, and well-being are protected.
- The trial is conducted in accordance with the approved protocol.
- Data are accurate, complete, and verifiable.
- Risks are identified early and mitigated effectively.
  The Sponsor maintains adequate oversight of delegated activities.

4 Monitoring procedures

Monitoring is a core Sponsor oversight activity and must be proportionate to the risks, complexity, and Critical-to-Quality (CtQ) factors of each study. Monitoring may include a combination of central, remote, on-site, and targeted approaches, selected based on the Sponsor's risk assessment and documented in the Monitoring Plan.

Monitoring procedures must ensure that:

- Participant rights, safety, dignity, and well-being are protected.
- Data critical to the reliability of trial results are accurate, complete, and verifiable.

Docusign Envelope ID: E2F60965-D1CE-816E-831A-50005B374B4A

- Trial conduct is consistent with the approved protocol, GCP, and regulatory requirements.
- Digital systems and data flows are appropriately governed, validated, and secure.
- Delegated activities are appropriately overseen by the Sponsor.

4.1 Which clinical trials are monitored?

All HHP-sponsored CTIMPs must be monitored in accordance with this SOP and the Sponsor's risk-adapted monitoring approach.

Monitoring is also required for:

- Non-CTIMPs assessed as higher risk (e.g., non-CE-marked devices, invasive procedures).
- Any study where the Sponsor determines that oversight is required to ensure participant safety or data integrity.

Monitoring intensity and methods must be proportionate to:

- The complexity of the intervention
- The vulnerability of the population
- The criticality of data elements
- The experience of the site
- The digital systems used
- The potential impact of errors on participant safety or trial outcomes

4.2 How are HHP-sponsored trials identified?

Investigators must contact R&D at the earliest opportunity to request Sponsorship and obtain guidance on trial design, feasibility, and regulatory requirements.

The R&D QA Manager and R&D Monitor will:

- Review the protocol and Sponsorship request
- Assess risks and identify CtQ factors
- Determine the appropriate monitoring approach

Prepare the Monitoring Plan in collaboration with the Investigator and R&D QA Manager. The Monitoring Plan must be finalised before recruitment begins

5. Risk-adapted monitoring

Monitoring must be proportionate and risk-based. The Sponsor will complete a Risk-Adapted Approach to the Management and Monitoring of CTIMPs, which identifies:

- Critical-to-Quality (CtQ) factors
- Key risks to participant safety and data integrity
- Appropriate monitoring methods
- The frequency and intensity of oversight
- Digital systems requiring validation or governance checks
- Vendor oversight requirements

All studies, regardless of risk level, will receive:

- A site initiation monitoring visit
- A monitoring visit after the first 3–5 participants

Monitoring methods may include:

- Central monitoring
- On-site monitoring
- Remote monitoring
- Targeted monitoring
- Laboratory monitoring
- TMF monitoring

The Monitoring Plan must document the rationale for the chosen approach.

5.1 Central monitoring

Docusign Envelope ID: E2F60965-D1CE-816E-831A-50005B374B4A

Central monitoring is appropriate for low-risk studies or where digital systems allow efficient oversight. It may include review of:

- Adverse events and safety reporting
- Recruitment, withdrawals, and participant status
- Consent documentation
- Protocol deviations
- Delegation logs
- Eligibility checklists
- CVs, GCP certificates, and contracts
- Study medication accountability (if applicable)
- ISF document completeness and version control
- Data entry timeliness and audit trails
- Data trends, outliers, or inconsistencies

Central monitoring may also include statistical monitoring, such as:

- Trend analysis
- Outlier detection
- Data completeness checks
- Cross-site comparisons (for multi-site trials)

Investigators may be asked to complete self-monitoring activities, including:

- Annual ISF checks
- Adverse event reviews
- Participant status checks
- Document version control
- Closeout readiness checks

Central monitoring procedures must be documented in the Data Management Plan.

5.2 On-site monitoring

On-site monitoring is required for higher-risk studies or where CtQ factors cannot be adequately assessed remotely.

On-site monitoring includes, but is not limited to:

Essential Documents

- Verification that all essential documents are present, complete, and current.
- Confirmation that the ISF is organised, secure, and accessible.

Study Start-Up

- Verification that the Data Management Plan, Reference Safety Information, and laboratory/equipment file notes are in place.

Informed Consent

- Review of consent processes and documentation.
- Verification that correct versions of PIS/ICF are used and properly completed.

Safety Reporting

- Review of AE/SAE documentation and reporting timelines.
- Verification that safety information is up-to-date and communicated appropriately.

Protocol Compliance

- Review of protocol adherence and implementation of amendments.
- Verification that study updates and reports have been submitted to MHRA, REC, and R&D.

Source Data Verification (SDV)

- Verification that CRF data match source data for CtQ elements.
- Review of casenote documentation, including visit dates, assessments, AEs, medications, and relevant clinical information.
    - *Clearly written date, brief study title/acronym and visit number.*
    - *Date patient given patient information sheet (PIS). Date of consent. Date of screening.*
    - *Version number of PIS and ICF.*
    - *Medical history, concomitant diseases and medication including study medication, and any changes in concomitant diseases and medication at subsequent visits.*
    - *Anything which is relevant to the ongoing care of the subject;*
    - *relevant results and study medic's assessment of these results,*

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- *brief description of any AEs with start & stop times/dates and any significant test results or a medical summary of events if more appropriate.*
- *Any other relevant details.*

Pharmacy Oversight:

- Review of prescriptions, accountability logs, storage conditions, and unblinding procedures.
- Verification that essential documents are maintained in the Pharmacy Site File.

A combination of central and on-site monitoring may be used for medium risk studies.

- Checking prescriptions against study medication accountability forms.
- Checking temperature storage requirements of study medication.
- Checking the randomization procedure and unblinding if applicable.
- Checking that essential documents are present and being kept up-to-date in the Pharmacy Site File.

A combination of central and on-site monitoring may be carried out for medium to low risk studies.

Targeted monitoring:

If monitoring identifies areas of concern or non-compliance, targeted monitoring will be implemented. This may include:

- Increased frequency of visits
- Focused review of specific processes or data
- Additional training or corrective actions

The risk assessment must be updated accordingly.

If monitoring has highlighted certain areas of GCP non-compliance, then more frequent on-site visits will be focused on those areas until a satisfactory outcome has been reached. The risk assessment will be updated accordingly. Issues will be escalated as required.

5.3 Laboratory monitoring

For studies involving laboratory analysis that contributes to primary or secondary endpoints, the Sponsor must ensure:

- Completion and review of a regulatory vendor questionnaire
- Verification of laboratory capability, quality systems, and data integrity controls
- An on-site laboratory monitoring visit before sample transfer
- A follow-up visit after 3–5 participants (or earlier if required)

Laboratory monitoring is required **regardless of study risk level.**

For studies that involve taking samples for analysis which is conducted in support of primary or secondary endpoint data and objectives or where the analysis is critical to the conduct of the trial, the following monitoring of the laboratory carrying out the storage and analysis of samples will be carried out:

- A Regulatory vendor questionnaire will be sent to the laboratory undertaking the analysis. The questionnaire is to be completed by the laboratory manager/supervisor.
- The completed questionnaire must be reviewed by R&D QA before the laboratory agreement is signed.
- An onsite laboratory monitoring visit, prior to the start of the trial and ideally after 3 – 5 patients have been recruited to the study, using the laboratory monitoring report form as a checklist. At the latest a lab monitoring visit will be performed before any samples have been transferred from the hospital research department to the lab.

The above lab monitoring will be carried out irrespective of the outcome of the risk assessment of the study.

Docusign Envelope ID: E2F60965-D1CE-816E-831A-50005B374B4A

5.4 Monitoring of TMF

For multi-site CTIMPs where a CTU maintains the TMF:

- The Sponsor will risk-assess whether central or on-site TMF monitoring is required.
- The Monitoring Plan must document the type and frequency of TMF oversight.
- TMF monitoring must assess completeness, version control, audit trails, and data integrity.

For multi-site HHP-sponsored CTIMPs, where a CTU has been delegated the task of creating, maintaining and archiving the TMF, then whether to perform central monitoring or monitoring visit of the TMF will be risk assessed by the Sponsor. The decision on the type and frequency of monitoring will be documented in the Risk Assessment.

5.5 Remote Monitoring

Remote monitoring may be used where appropriate and must be documented in the Monitoring Plan.

Remote monitoring requires:

- Secure access to electronic systems - The monitor can access trial documentation, either through access granted by the trial team or by virtually showing the monitor individual files when required, and review as necessary.
- Verification of data integrity and audit trails
- Clear description of the software or method used
- Assurance that remote review covers all CtQ elements
  Remote monitoring must not compromise participant confidentiality or data security and should still comprehensively review all critical aspects of the trial and not be limited by the separation from the trial team.

6. Monitoring Plan

A Monitoring Plan must be prepared before the study starts and must be based on the Sponsor's completed Risk-Adapted Approach to the Management and Monitoring of HHP- Sponsored trials. The Monitoring Plan must clearly describe how the Sponsor will oversee the trial in a way that is proportionate, risk-based.

The Monitoring Plan must:

- Identify Critical-to-Quality (CtQ) factors and describe how monitoring will protect these.
- Describe the monitoring strategy, including central, remote, on-site, targeted, laboratory, and TMF monitoring as applicable.
- Include monitoring of important trial activities performed outside site (central lab, external imaging etc.) its frequency and documentation- Critical for any single centre CTIMP where HHTU is not involved.
- Define the frequency, intensity, and scope of monitoring activities.
- Describe how digital systems, data flows, and audit trails will be reviewed.
- Specify which data elements require source data verification (SDV) and the rationale.
- Describe how protocol deviations, safety events, and data trends will be identified and escalated.
- Define how monitoring findings will be documented, reviewed, and followed up.
- Describe how the Monitoring Plan will be adapted if risks change during the trial.

The Monitoring Plan must be reviewed:

- When a substantial modification is implemented
- When new risks emerge
- When staffing or site capability changes
- When monitoring identifies significant issues
- At least annually for long-running studies

Any changes must be documented and version-controlled.

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6.1 Frequency of on-site monitoring visits

Monitoring visits will occur at:

Site Initiation

To confirm that:

- Essential documents are in place
- Staff are trained
- Systems and processes are ready
- CtQ factors are understood
- Data collection and consent processes are appropriate

Early Recruitment Visit

After the first **3–5 participants** have been recruited, to verify:

- Consent processes
- Eligibility assessments
- Safety reporting
- Data accuracy for CtQ elements
- Site readiness for continued recruitment

Ongoing Monitoring

Frequency will be determined by:

- Risk level
- Site performance
- Data quality
- Protocol compliance
- Safety profile
- Digital system reliability
- Investigator experience

Closeout Visit

To ensure:

- All data are complete
- All essential documents are present
- All outstanding actions are resolved
- TMF and ISF are ready for archiving

Pharmacy monitoring visits may occur on the same day or separately.

6.2 Organizing monitoring visits

The monitor will notify the CI/PI by email that a monitoring visit is required. The CI/PI will provide contact details for the appropriate research team member to arrange the visit.

The monitor will confirm:

- Date and time of the visit
- Objectives and scope
- Documents required
- Patients' casenotes needed
- Pharmacy visit arrangements (if applicable)
- Any digital system access required

All correspondence must be saved in the eTMF (Sponsor Oversight → Monitoring).

The following must be available at the visit:

- Investigator Site File (ISF)
- Case Report Forms (CRFs) or Data Collection Forms (DCFs)
- Participant casenotes
- Access logs or audit trails

Docusign Envelope ID: E2F60965-D1CE-816E-831A-50005B374B4A

- Delegation logs and Training records
- Pharmacy Site File and study medication (if applicable)
- Access to electronic systems (EHR, eCRF, eTMF, eQMS, etc.)

If required, the site may be asked to provide:

- A copy of the site's eQMS structure

6.3 Preparing for monitoring visits

Site Initiation Visit Preparation

The monitor will set up the Investigator Site File (ISF) before the site initiation or site initiation visit.

The monitor will prepare:

ISF List of Contents

- Study Contact Sheet
- Study Patient List
- Training and Delegation Log
- Sample Log (if applicable)
- Reference Safety Information file note
- Case notes sheet - are prepared with investigators so that the relevant information about the study patient visits is recorded by investigators in the patients' case notes. The case notes sheets therefore need to be available before the first patient is entered. Prepare with investigator.
- SDV forms
- Stop-alert stickers - are for the inside front cover of case notes and specify;
    - The patient is involved in a clinical trial
    - The contact telephone number of the CI/PI
    - The allowed date of destruction of the case notes
    - The date the patient entered and completed the trial.
    - Monitoring File

All documents must be pre-populated with study identifiers.

In addition, the following stickers/labels need to be taken:

- Labels for plastic wallets in patients case notes for copies of ICF, PIS, GP letter.
- Stop-alert study stickers for inside front cover of medical records (these should be completed with allowed date of destruction).

Extras to take to visits:

- Blank monitoring visit report and extra paper for notes.
- SDV (source data verification) forms - list the study information checked in the case notes against the CRFs and ISF by the monitor. See R&D GCP SOP 03 CRF for documenting study visits in case notes and source data verification
- Plastic wallets (approx. 10)
- Diary and stationery (black pens, post it notes, paperclips, hole-punch, stapler).
- Case notes sheets, SDV forms and stop-alert study stickers will need to be prepared for site Initiation.

Follow-On Visits

The monitor must bring:

- Previous monitoring reports and action lists
- Updated ISF List of Contents
- Blank monitoring report forms
- SDV forms
- Stationery and plastic wallets

Pharmacy Visits

The monitor must bring:

- Pharmacy monitoring report form

Docusign Envelope ID: E2F60965-D1CE-816E-831A-50005B374B4A

- Previous pharmacy action lists
- Monitoring File

6.4 Conducting Monitoring Visits

The monitor will:

- Work independently for most of the visit to review documents and data
- Use the monitoring report form as a checklist
- Verify CtQ data elements
- Review consent, eligibility, safety reporting, and protocol adherence
- Review digital system access, audit trails, and data integrity
- Meet with research staff to discuss findings
- Meet with the CI/PI or responsible doctor to discuss study progress

Pharmacy visits will include review of:

- Accountability logs
- Storage conditions
- Temperature records
- Prescriptions
- Unblinding procedures
- Pharmacy Site File

The monitor acts as the primary communication link between the Sponsor and the site.

6.5 Reporting Monitoring Visits and Follow-Up Actions

A monitoring report must be completed within **5 working days** of the visit.
The report must:

- Be signed by the monitor
- Be reviewed by the R&D QA Manager and R&D Manager (if the Risk Assessment Level has changed) within **5 working days**
- Include a clear list of actions for both the monitor and the site
- Specify timelines for completion
- Document any changes to the risk assessment
- Be filed in the Monitoring File and eTMF

The investigator's action list must be sent promptly to the CI/PI and relevant staff.

6.6 Escalatory Actions

If actions are not resolved within agreed timelines:

1. A meeting will be arranged between the monitor, QA Manager, CI/PI, and research staff.
2. If issues persist, concerns will be escalated to the R&D Manager and R&D Director.
3. The Sponsor may implement additional oversight, including:
    - Increased monitoring
    - Temporary recruitment suspension
    - Additional training
    - Corrective and preventive actions (CAPA)

Serious or persistent non-compliance may require reporting to MHRA or REC.

6.7 Use of Findings

Monitoring findings will be used to:

- Improve Sponsor oversight processes
- Identify common issues across studies
- Inform training and guidance for research teams
- Strengthen risk assessments and Monitoring Plans
- Support continuous improvement in GCP compliance

Findings may be anonymised and shared across the Trust to support learning.

Docusign Envelope ID: E2F60965-D1CE-816E-831A-50005B374B4A

7 Responsibilities of Investigators/Research Staff

Investigators and research staff must support Sponsor oversight and ensure that GCP monitoring can be conducted effectively for any HHP-Sponsored Trials that have been risk-assessed as requiring any type of R&D QA Monitoring.

Responsibilities include:

7.1 Access and Cooperation

- Permit monitoring, GCP auditing, and regulatory inspections.
- Ensure that all essential documents, data, and systems are accessible to the monitor.
- Ensure that participant consent includes permission for access to medical records for monitoring purposes.

7.2 Compliance with the Monitoring Plan

- Cooperate with the Monitoring Plan and ensure that all monitoring requirements are met.
- Ensure that no participants are recruited until the Sponsor has issued **Green Light**.
- Ensure that all staff delegated to trial duties are trained, competent, and documented on the Delegation Log.

7.3 Documentation and Data Integrity

- Maintain the Investigator Site File (ISF) in an organised, complete, and up-to-date state.
- Ensure that CRFs and source data are accurate, contemporaneous, attributable, legible, and verifiable.
- Ensure that participant visits are documented in casenotes/medical records, including:
- Visit date and study identifier
- Consent details
- Eligibility assessments
- Medical history and medications
- AEs/SAEs
- Relevant clinical assessments
- Investigator review and clinical judgement

7.4 Safety Reporting

- Ensure that all AEs and SAEs are documented and reported in accordance with the protocol and regulatory timelines.
- Ensure that safety information is reviewed and acted upon promptly.

7.5 Availability During Monitoring

- Ensure that at least one research team member directly involved in the study is available during monitoring visits to answer queries.
- Ensure that the CI/PI or responsible doctor is available to discuss study progress and any concerns.

7.6 Follow-Up of Actions

- Complete all actions assigned following a monitoring visit within the specified timelines.
- Participate in escalation meetings if actions are not resolved.
- Support corrective and preventive actions (CAPA) where required.

7.7 Closeout and Archiving

- Support the monitor during the closeout visit.

Docusign Envelope ID: E2F60965-D1CE-816E-831A-50005B374B4A

- Ensure that ISF, CRFs, and essential documents are complete and ready for archiving in accordance with R&D GCP SOP 14.

8 Responsibilities of CT pharmacy staff

CT Pharmacy staff play a critical role in ensuring the investigational medicinal product (IMP) integrity and compliance with HHP-Sponsored Trials

Responsibilities include:

8.1 Access and Cooperation

- Liaise with the monitor to arrange pharmacy monitoring visits.
- Ensure availability during visits to answer queries and provide access to required documentation.

8.2 IMP Management

- Maintain accurate and complete accountability logs for receipt, storage, dispensing, return, and destruction of IMP.
- Ensure IMP is stored under appropriate conditions and that temperature monitoring records are complete and reviewed.
- Ensure prescriptions are accurate and consistent with the protocol.
- Ensure unblinding procedures (if applicable) are documented and followed.

8.3 Documentation

- Maintain the Pharmacy Site File in an organised and up-to-date state.
- Ensure that all essential documents are present, including:
- Accountability logs
- Temperature logs
- Delegation and training records
- IMP handling SOPs
- Certificates of analysis (if applicable)

8.4 Follow-Up of Actions

- Complete all actions assigned following a pharmacy monitoring visit within agreed timelines.
- Participate in escalation processes if issues persist.

9 Responsibilities of HHP R&D monitor

The R&D Monitor is responsible for implementing the Sponsor's oversight strategy and ensuring that monitoring is conducted in accordance with ICH E6(R3), UK regulations, and this SOP.

9.1 Conduct of Monitoring

- Conduct monitoring in accordance with the Monitoring Plan and CtQ priorities.
- Use central, remote, on-site, targeted, laboratory, and TMF monitoring as appropriate.
- Verify data integrity, protocol compliance, and participant safety.

9.2 Documentation and Reporting

- Complete monitoring visit reports within **5 working days**.
- Ensure reports are reviewed by the R&D QA Manager/R&D Manager within **5 working days**.
- Document all findings, actions, and follow-up requirements clearly and objectively.
- File reports in the Monitoring File and eTMF.

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9.3 Communication and Escalation

- Communicate findings promptly to investigators and research staff.
- Escalate unresolved issues to the QA Manager, R&D Manager, and R&D Director as required.
- Support CAPA development and implementation.

9.4 Continuous Improvement

- Identify common issues across studies and contribute to improvements in Sponsor oversight processes.
- Provide feedback to R&D QA on emerging risks, training needs, and systemic issues.

9.5 Competence

- Maintain up-to-date training in GCP, risk-based monitoring, and digital system oversight.
- Ensure monitoring activities reflect current regulatory expectations and best practice.

10 Implementation

This SOP will be implemented through:

- Dissemination to all relevant research, pharmacy, and R&D staff.
- Training sessions for staff involved in HHP-sponsored CTIMPs.
- Integration into Sponsor oversight processes, including risk assessment, monitoring planning, and quality assurance.
- Ongoing review of monitoring findings to ensure continuous improvement.
- Compliance with this SOP is mandatory for all HHP-sponsored CTIMPs. Non-compliance may result in corrective actions, increased oversight, or escalation to the R&D Manager or R&D Director.