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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

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

1 Purpose

The purpose of this SOP is to:

- Describe the responsibilities of the Sponsor and Investigators with regards to monitoring clinical trials sponsored by Hull University Teaching Hospitals NHS Trust (HUTH).
- Describe the procedures that will be used to prepare, conduct, report and follow-up a monitoring visit.

2 Who should use this SOP

- This SOP should be used by:
  - All research staff involved with HUTH-sponsored CTIMPs – Chief/Principal Investigators, co-investigators, research nurses, clinical trial assistants, clinical support workers, project managers, clinical trial co-ordinators, data managers, administrators etc.
  - Clinical trials pharmacy staff – technicians and pharmacists.
  - All HUTH R&D staff who manage the sponsorship of HUTH-sponsored CIMPs.
  - Research staff involved with HUTH-sponsored non-CTIMPs may find this SOP a useful guide, although the SOP will need to be adapted for the non-CTIMP trial.
  - Research staff involved with clinical trials sponsored by an external organisation where the sponsor has no SOP for GCP monitoring. HUTH R&D SOPs are defaulted to in this case.

3 Background

- It is a legal requirement for the Sponsor to monitor clinical trials that involve medicinal products according to the UK Clinical Trial Regulations and Good Clinical Practice for clinical research (ICH GCP).

- ICH E6(R1) defines Monitoring as 'the act of overseeing the progress of a clinical trial, and of ensuring that it is conducted, recorded, and reported in accordance with the protocol, Standard Operating Procedures (SOPs), Good Clinical Practice (GCP), and the applicable regulatory requirements(s).

- Compliance with these standards ensures that:
  - The rights, safety and well-being of trial subjects are protected.
  - Good quality worthwhile research is performed.
  - The data from the trial is the best quality most reliable data.
  - The clinical trial is conducted according to its current approved protocol.

- MHRA GCP inspectors regularly inspect Sponsors of CTIMPs in order to check that these standards are being adhered to.

4 Monitoring procedures

4.1 Which clinical trials are monitored?

All clinical trials with investigational medicinal products (IMPs) for which the Trust is acting as Sponsor will be monitored by the R&D Department monitor or a suitable delegate.
Clinical trials that do not involve medicinal products (non-CTIMPs) may be monitored if they are considered to be higher risk for example a non-CTIMP involving a non-CE marked medical device or a non-CTIMP involving surgical procedures.

4.2 How are HUTH-sponsored trials identified?

Investigators who have a research idea are encouraged to approach R&D at the earliest opportunity to request Sponsorship and for advice on how to set-up a clinical trial (see R&D GCP SOP 05 Sponsorship HUTH CTIMPs).
The R&D QA manager and monitor will review the protocol and sponsorship request form and guide investigators through the set-up process. The R&D monitor will prepare the monitoring plan for the trial in collaboration with the QA manager and R&D manager.

5. Risk-adapted monitoring

A sponsor risk assessment entitled 'Risk-adapted Approach to the Management and Monitoring of CTIMPs' will be completed to decide the level of monitoring that is required for the study.

There are different types of monitoring and a combination of these may be used depending on risks associated with a particular study.

All studies irrespective of the outcome of the risk assessment will have an on-site site initiation monitoring visit and a monitoring visit after 3 – 5 participants have been recruited.

5.1 Central monitoring

For low risk studies central monitoring will be employed where possible.
Central monitoring will be carried out by the R&D QA team and may include, but not be limited to, the following:

Review of:

- Adverse events
- Recruitment rate and withdrawals
- Patient ID list (single HUTH site only)
- Consent forms
- Protocol deviations
- Delegation logs
- Eligibility checklists
- CVs, GCP certificates and Honorary Contracts.
- Study medication accountability logs (if pharmacy involved)
- Self-site monitoring carrying out annual checks, ISF document review/versions
- Data spreadsheet/database

R&D QA may ask investigators to carry out self-monitoring and this will include, but not be limited to, the following:

- Annual checks
- ISF document review and version control checks
- Patient status checks (screened, recruited, withdrawn, completed)

- Adverse event review
- Study closeout

Completed monitoring forms would be returned to R&D QA for review and further action if required e.g. an on-site monitoring visit or further training etc.

Central monitoring procedures relating to data should be documented in the Data Management Plan. For multi-site studies this will depend upon R&D QA having remote access to study data. For single-site studies the spreadsheet will be requested by R&D QA at intervals to check the audit trail and that data is being entered in a timely manner.

5.2 On-site monitoring

For higher risk studies on-site monitoring will be employed.
On-site monitoring will include, but will not be limited to, the following:
For sites:

- Reviewing the presence and filing of all essential documents in the ISF (using List of Contents as a checklist).
- At study start ensuring that the Data Management Plan, Reference Safety Information file note, labs file note and trial equipment file note have been prepared with investigators.
- Checking through the action list from the previous monitoring visit (if one).
- Ensuring that ISF and patient data CRFs are kept organized in a secure place.
- Checking that CRFs accurately reflect the study protocol.
- Checking the CRF data is complete.
- Reviewing the study procedure for obtaining informed consent with investigators.
- Checking that patient consent forms (ICFs) and patient information sheets (PIS) are the correct version, are being fully signed, initialed and dated prior to starting the study and distributed correctly.
- Checking accurate and timely reporting of adverse events (non-serious and serious).
- Reviewing the safety reporting procedure with investigators.
- Reviewing that all essential documents (including safety information) are being kept up-to-date during the study.
    - Checking that trial amendments are implemented after receipt of implementation email. See R&D GCP SOP 08 Amendments.
- Checking that study up-dates including safety information and annual reports are being sent to the MHRA, REC and R&D as appropriate.
- Checking that the stop-alert study stickers are on the inside front cover of patients' paper casenotes.
- Checking the eligibility of patients to enter the trial using patients' source data.
- Checking that patient data in CRFs reflects source data wherever possible (source data verification).
- Checking that study visits are recorded in patients' casenotes.

Minimum details to record are:

- *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,
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.*

For pharmacy:

- 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 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 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.

5.4 Monitoring of TMF

For multi-site HUTH-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

In recent years, remote monitoring has become more frequently favourable as the burden of travel to trial sites is removed and many site files are stored as electronic forms (therefore accessible remotely). 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. It should be stated in the monitoring plan where remote monitoring is to take place and the software/technique to be performed.
Remote monitoring should still comprehensively review all critical aspects of the trial and not be limited by the separation from the trial team.

6. Monitoring Plan

It is important to prepare a monitoring plan before the study starts and to include the completed Risk Assessment (Sponsor Risk-Adapted Approach to the Management and Monitoring of CTIMPs) as part the document.
Utilizing this risk assessment the sponsor can construct the monitoring plan to be consistent with critical aspects of the trial, identifying where non-compliance or deviations in the trial could occur. Monitoring efforts should be focused on those areas of highest risk for generating errors that matters, and the sponsor's oversight approach should be designed to proactively address issues rather than to be reactive to them.

Identifying all source data elements that are required to be captured and the location of that data element is a crucial first step for ensuring compliance with GCP and regulatory expectations and therefore should be in mind when preparing the monitoring plan.
Protocols should pre-specify when eCRFs are to be used for direct capture of source data; a common inspection finding is investigators recording serious adverse events (SAEs) directly into the eCRF for expedited reporting to the sponsor when this is not pre-specified in the protocol.

The monitoring plan will document the type of monitoring to be carried out.
If the study is to be centrally monitored the plan should specify what R&D QA will request for review and how often and if the investigator will be expected to carry out site self-monitoring checks.

If the study is to be on-site monitored the plan should specify the expected frequency of monitoring visits and the amount of source data verification required.
The monitoring plan should be reviewed when a substantial amendment is made, if there are any concerns regarding GCP compliance or any change in research staff that may affect the original risk assessment of the study. These changes may result in an increase in monitoring.

6.1 Frequency of on-site monitoring visits

Monitoring visits will be performed at the research department in which the clinical trial is being run and at the pharmacy department in which the study medication is stored and dispensed. The pharmacy department monitoring visit may be on the same day that the research department is monitored or may be on a separate day. In this SOP, the research department will be referred to as the site.

Monitoring visits occur before the study starts, during the study and at study completion.

The following describes the schedule of visits:

Site initiation monitoring visit
A site initiation monitoring visit ensures that all essential study documents are in place and research staff have been trained in study procedures before the study starts.

Monitoring visits when recruitment has begun

The first monitoring visit will occur after 3 – 5 patients have been recruited. The frequency of visits thereafter will be risk assessed at each visit and will be dependent on investigator GCP compliance.

Study closeout visit

A study closure visit will be carried out to ensure study documents and data are complete and prepared for archiving.

6.2 Organizing monitoring visits

The monitor will notify the Chief/Principal Investigator (CI/PI) by email that their clinical study will be monitored. The CI/PI will be asked for contact details of a member of the study research team with whom a monitoring visit can be arranged unless the visit can be arranged with the CI/PI directly. A mutually convenient visit day will then be confirmed (keeping the CI/PI on copy) and the objectives, length of visit and documents required specified. A pharmacy visit (if applicable) will also be arranged for either the same day or near to this time, keeping the CI/PI/research team informed.
An electronic copy of all email correspondence to organize monitoring visits should be saved in the study eTMF – Sponsor Oversight folder – Monitoring sub-folder. The format for saving emails is YYYY-MM-DD followed by a short title.

The following documents will be required at site/pharmacy for a standard monitoring visit:

- The Investigator Site File comprising all essential documents (defined in Section 8 ICH GCP).
- The study data collected in documents called case report forms (CRFs) or data collection forms (DCFs) so that each subject has a separate CRF or set of DCFs.
- The study patients' casenotes. These often need to be ordered by the research staff in advance to ensure availability at the monitoring visit. The monitor will request in advance which patients' casenotes will be required for the visit.
- The Pharmacy Site File, the study medication and returned medication for a pharmacy monitoring visit.
- Access (be this temporary or via a member of the trial team) to any electronic systems should be requested prior to monitoring visit to allow time for suitable training or access rights to be granted.
- It could be requested that a copy of the site eQMS (or similar quality system) is sent to the sponsor prior to the visit to ensure sponsor records and trial documentation correspond and any discrepancies can be investigated during the monitoring visit.

6.3 Preparing for monitoring visits

Site initiation visit
The monitor will set up the Investigator Site File (ISF) before the site initiation or site initiation visit. All the study details will be entered into the header of the following documents and then the documents will be printed off to file in the ISF.

- Investigator Site File (ISF) forms
- ISF – List of Contents
- Study Contact Sheet
- Study Patient List
- Study Training and Delegation Log
- Sample Log (if relevant)
- MHRA requirements for Reference Safety Information for CTIMPs file note

The ISF list of contents is available from Y:\Research\GCP SOPs & forms\Contents lists of study files. All the other GCP forms are on Y:\Research\GCP SOPs & forms\GCP forms.

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

- Labels for plastic wallets in patients casenotes 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).

Labels are available from Y:\Research\GCP SOPs & forms\Stationery.

Extras to take to visits:

- Casenotes sheet (prepare with investigator - Y:\Research\GCP SOPs & forms\GCP forms)
- Blank monitoring visit report and extra paper for notes.
- SDV (source data verification) forms (Y:\Research\GCP SOPs & forms\GCP forms)
- Monitoring File, set up using the Monitoring File List of contents (Y:\Research\GCP SOPs & forms\GCP forms)
- Plastic wallets (approx. 10)
- Diary and stationery (black pens, post-it notes, paperclips, hole-punch, stapler).

Casenotes sheets, SDV forms and stop-alert study stickers will need to be prepared for site Initiation.

- **Casenotes sheets** are prepared with investigators so that the relevant information about the study patient visits is recorded by investigators in the patients' casenotes. The casenotes sheets therefore need to be available before the first patient is entered.
- **SDV forms** list the study information checked in the casenotes against the CRFs and ISF by the monitor. See R&D GCP SOP 03 CRF for documenting study visits in casenotes and source data verification.
- **Stop-alert study stickers** are for the inside front cover of casenotes 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 casenotes
  - The date the patient entered and completed the trial.

Follow-on monitoring visits

The monitor needs to take to the visit the following:

- Blank monitoring visit report and extra paper for notes.
- Monitoring File containing previous visit's action list etc.
- Plastic wallets, diary and stationery as above.

Also if not already filed in the ISF:

- Copy of the most up-to-date ISF list of contents.
- Any up-dated documents

Pharmacy visits

For those pharmacy visits that are separate from the monitoring visit day, the monitor needs to take:

- Blank pharmacy monitoring visit report and extra notepaper
- Monitoring file with actions from previous pharmacy visit.
- Plastic wallets, diary and stationery as above.

6.4 Conducting monitoring visits

For most of the visit the monitor will need space and time on their own in order to check through the Investigator Site File, case report forms and source documents. A member of the study research team will need to be available on that day in order to answer any queries that the monitor may raise. This may take up to 1 – 2 hours towards the end of the monitoring visit. The CI/PI or other doctor responsible for the study should also be available on the visit day to discuss study progress and any issues. Likewise for pharmacy visits, the monitor will need a quiet place to review the Pharmacy Site File and study medication, and will need CT pharmacy staff on hand to answer queries.

The monitor will conduct a visit using the report form as a checklist. Blank monitoring visit report forms for site initiation, during-study and closeout monitoring visits at site and

pharmacy departments are available at Y:\Research\GCP SOPs & forms\Monitoring visit report forms. The monitor acts as the main line of communication between the sponsor and the investigator, therefore the completion of these forms with as much information as possible enables the sponsor to paint an accurate picture of the trials progression and compliance to the protocol and GCP.

6.5 Reporting monitoring visits and actions to follow-up from visits

A monitoring visit report should be completed within 5 working days after each visit. The report should be signed off by the monitor and reviewed by the R&D QA Manager/R&D Manager within 5 working days of report. Any changes to the study should be checked and the study risk assessment reviewed and amended if necessary. The signed report should be filed in the paper Monitoring File and a copy scanned and saved in the study eTMF, which is on the Y drive on the Trust's server with restricted access and password protected.

The report will contain a list of outstanding actions that the monitor will need to resolve and a list of outstanding actions that the investigators will need to resolve.

The investigator's actions list will be sent to the responsible doctor and relevant research staff as soon as the report is completed. Actions will have been discussed with site staff during the visit. The actions list specifies the timelines in which actions should be addressed.

6.6 Escalating actions

If actions are not satisfactorily resolved, a meeting between the monitor, QA manager, CI/PI or responsible doctor and research staff will be organized to resolve these issues. If actions are still not resolved the monitor will escalate these concerns to the R&D Manager and R&D Director for appropriate action.

6.7 Use of findings

If common problems are identified during the monitoring of Trust-sponsored clinical trials, these findings will then be used to improve the monitoring service available to researchers with the aim of improving the performance of studies in line with the requirements of GCP and the UK regulations.

7 Responsibilities of Investigators/Research Staff

Research staff has the following responsibilities with regards to GCP monitoring of HUTH-sponsored CTIMPs:

- To permit monitoring and auditing by the sponsor, and inspection by the appropriate regulatory authority(ies) (ICH E6(R1).
- To ensure that all study documentation and data are available for the purposes of monitoring and that the appropriate consent has been provided by the participant.
- To ensure that the site co-operates with the monitoring plan put in place by the Sponsor to demonstrate compliance with the UK Clinical Trial Regulations and ICH GCP.
- To liaise with the study monitor to arrange monitoring visits.
- To arrange a quiet desk for the monitor on visit days.
- To ensure at least one member of the research team who is directly involved with the study attends a site initiation monitoring visit and ensures that all subsequent actions are being addressed to the Sponsor's satisfaction.
- To ensure no patients are recruited before the Sponsor has issued green light.

- To make sure that the Investigator Site File (ISF) and patient data in CRFs are always kept organized in a secure place.
- To ensure filing in the ISF is up-to-date and available on monitoring visit days.
- To ensure patient data in CRFs are up-to-date and available on visit days.
- To ensure patient study visits are being recorded in patient casenotes/medical records and entries are up-to-date on visit days.
- To ensure reporting and documenting of all adverse events (serious or non-serious) are consistent with the protocol and are up-to-date.
- To make available on visit days the study participants' casenotes requested by the monitor.
- For at least one member of the research team who is directly involved with the study to be available to answer monitoring queries towards the end of the monitoring visit. This may take up to 1 - 2 hours possibly longer. The CI/PI or other responsible doctor will also need to be on hand to discuss study progress and any concerns.
- To ensure actions sent to investigators following a monitoring visit are resolved according to the timelines indicated on the actions list. If actions are not satisfactorily resolved, a meeting between the monitor, QA manager, CI/PI or responsible doctor and research staff will be organized to resolve these issues. If actions are still not resolved the monitor will escalate these concerns to the R&D Manager and R&D Director for appropriate action.
- To facilitate the monitor at the closeout visit to arrange archiving of the TMF and CRFs at study end according to the R&D GCP SOP 14 Archiving. .

8 Responsibilities of CT pharmacy staff

CT pharmacy staff has the following responsibilities with regards to GCP monitoring of HUTH-sponsored CTIMPs:

- To liaise with the monitor to arrange monitoring visits and to be available during a visit to answer any queries.
- To arrange a quiet desk for the monitor on visit days.
- To ensure that the Pharmacy Site File (PSF) and study medication are kept organized in a secure place and the medication is stored at the required temperature.
- To ensure that the documents in the PSF are filed according to the List of Contents for PSFs and that documents and filing are up-to-date for visit days.
- To keep all study documents in the PSF.
- To address actions from monitoring visits in a timely manner. If actions are not satisfactorily resolved, a meeting between the monitor, QA manager and CT pharmacy staff member will be organized to resolve these issues. If actions are still not resolved the monitor will escalate these concerns to the R&D Manager and R&D Director for appropriate action.
- To facilitate the monitor to archive the PSF at study end according to the R&D GCP SOP 14 Archiving.

9 Responsibilities of R&D monitor

The R&D monitor has the following responsibilities as regards monitoring trials:

- To organize, prepare, conduct, report and follow-up actions from monitoring visits according to the monitoring procedure described in point 6 above.
- To record dates of monitoring visits performed for all trials in a spreadsheet.
- To keep an up-to-date summary spreadsheet of monitoring status for all studies monitored.

- To train and facilitate investigators to understand the requirements for conducting CTIMPs according to ICH GCP and the UK regulations. In particular to train, advise and facilitate investigators in the:
  - Informed consent procedure according to theR&D GCP SOP 06 Informed Consent .
  - Safety reporting procedures according to the R&D GCP SOP 07 Safety Reporting
  - Amendment notification procedure according to the R&D GCP SOP 08 Amendments.
  - Urgent safety measures procedure according to the R&D GCP SOP 09 Urgent Safety Measures.
  - Completion of annual reports according to the R&D GCP SOP 10 Annual Reporting.
  - Completion of the end of trial notification according to the R&D GCP SOP 12 End of Trial.
- To ensure monitor's and investigator's actions from monitoring visits are resolved in a timely manner.
- To prepare and maintain the Monitoring File (MF) according to the List of Contents for MFs within the R&D department.
- To prepare and maintain the Trial Master File, this may be paper or electronic.
- To prepare and help maintain the Investigator Site File according to the List of Contents for ISFs.
- To process the serious event reports as they arrive at the R&D department according to Working Instruction 02 for processing SAE report forms. This is saved on the Y drive in \\hri_data3\clinicalgov\Research\GCP SOPs & forms\SOPs & WIs\2.0 R&D Working instructions.
- To conduct laboratory monitoring visits as relevant using the laboratory monitoring visit report form. The following must be checked as priority:
  - That all methods of analysis have been documented, version controlled, validated and validation documented, approved and signed.
- To facilitate the QA Manager to forward SUSAR reports to the MHRA and main REC within the required time frame.
- To facilitate the QA Manager to improve and keep up-to-date the GCP SOPs and documentation.
- To facilitate the QA Manager and R&D Manager to submit serious breaches according to the R&D GCP SOP 17 Serious Breach.
- To ensure that any concerns about GCP compliance, changes to the research team, changes to study processes are discussed with the R&D QA Manager and R&D Manager and an ongoing risk assessment is made after each monitoring visit.
- Verifying for the investigational product(s):
  - That the storage times and conditions are acceptable, and that supplies are sufficient throughout the trial
  - That the investigational product(s) are supplied only to subjects who are eligible to receive it and at the protocol specified dose(s).
  - That subjects are provided with necessary instruction on properly using, handling, storing and returning the investigational products(s).
  - That the receipt, use and return of the investigational product(s) at the trial sites are controlled and documented adequately.
  - That the disposition of unused investigational product(s) at the trial sites complies with applicable regulatory requirement(s) and is in accordance with the sponsor.

10 Implementation

- Implementation of this SOP will conform to the process outlined in R&D GCP SOP 01 Management of SOPs.