DIVISION OF RESEARCH AND INNOVATION

Joint Research and Development Office

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Title: **MONITORING OF CLINICAL TRIALS OF AN INVESTIGATIONAL MEDICINAL PRODUCT BY GOSH (SPONSOR)**	
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1. Scope

This SOP covers the procedure to be used by the Joint R&D Office when monitoring non-commercial Clinical Trials of an Investigational Medicinal Product (CTIMP) sponsored by GOSH. The procedure covers all stages of the clinical trial.

GCP is a set of internationally recognised ethical and scientific quality requirements which must be observed when designing, conducting, recording and reporting clinical trials that involve the participation of human subjects.

Monitoring forms an integral part of GCP. Compliance with GCP provides assurance that the rights, safety and well-being of trial subjects are protected, and that the results of the clinical trials are credible. Monitoring has also been emphasised in the Commission Directive 2005/28/EC better known as the GCP Directive[4].

There is also a requirement for monitoring research projects under the UK Policy framework for Health and Social Care research.

2. Purpose

The purpose of this SOP is to provide guidance to the monitor in routine monitoring procedures conducted for GOSH Sponsored and/or Managed CTIMPs.

This SOP applies in the following situations:

- Monitoring single-centre clinical trials carried out at GOSH and/or ICH-UCL.

- Monitoring other sites of a single centre or multi-centre clinical trial Sponsored by GOSH/UCL. Monitoring responsibilities for individual sites within a multi-centre clinical trial Sponsored by GOSH/UCL will be addressed in detail in site agreements and monitoring plan which are outside the remit of this SOP.

- When monitoring clinical trials hosted at GOSH/UCL and where the Sponsor of the clinical trial has delegated the responsibility of monitoring to GOSH/UCL as specified in the Clinical Trial Agreement for that clinical trial.

3. Definitions/Abbreviations

Monitoring is defined by International Conference on Harmonisation for Good Clinical Practice (ICH GCP) 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 Requirement(s)1.

The above definition for monitoring is in the context of a monitoring visit at a clinical trial site. However, for the purpose of this SOP, monitoring also includes activities carried out remotely, over the telephone or electronic mail.

4. Responsibilities

At GOSH the activities related to Sponsoring a clinical trial have been delegated to the Joint R&D Office. Monitoring will be delegated to suitably qualified and trained members of the Joint R&D Office. Whilst performing the activities related to monitoring, the responsible personnel will be referred as 'The Monitor(s)'. Where necessary, the Joint R&D Office may need to appoint external monitor in case where GOSH is leading the trial jointly with other organisation or managing the trial on behalf of other organisation however this will be captured separately in an appropriate agreement.

Monitors in the Joint R&D Office will have scientific and/or clinical knowledge as well as previous experience of coordinating/managing clinical trials. They will also be appropriately trained and their qualifications and training records will be documented as per the requirement in R&D office.

4.1 The Monitor is responsible for:

- Becoming familiar with all Sponsor SOPs, GCP principles, and the applicable regulatory requirement(s) associated with their role.

- Becoming thoroughly familiar with the clinical trial Protocol, the trial documentation and the Investigational Medicinal Product (IMP) prior to monitoring activity.

- Communication between the Sponsor and the trial team.

- Ensuring the trial team is maintaining essential documentation

- Clinical trial is conducted and documented according to the approved protocol. The Investigator should follow all approved trial documentation and all subsequently approved amendment(s).

- Verify that the Investigator and research team have adequate qualifications and resources throughout the trial period and facilities including laboratories and equipment for safe and proper conduct of the clinical trial.

- Ensure that the Investigator has informed all the Clinical Trial team members about the clinical trial and their clinical trial-related duties.

- Verify that the Investigator and the Investigator's clinical trial staff are performing the specified clinical trial functions, in accordance with the protocol and any other written agreement between the Sponsor and the Investigator/Clinical Trial Site.

- Communicate deviations from the Protocol, SOPs, GCP, and the applicable regulatory requirements to the Investigator and taking appropriate action designed to prevent recurrence of the detected deviations.

- Verify, for the IMP(s):

  a) That storage times and conditions are acceptable, in accordance with the IMP manual, and that supplies are sufficient throughout the clinical trial
  b) That the IMP(s) are supplied only to subjects who are eligible to receive it and at the protocol specified dose(s).
  c) That each trial patient is provided with necessary instruction on properly using, handling, storing, and returning the IMP(s).
  d) That the receipt, use, and return of the IMP(s) at the clinical trial sites are controlled and documented adequately.
  e) That the disposition of unused IMP(s) at the clinical trial sites complies with applicable regulatory requirement(s) and is in accordance with the Sponsor's instructions
  f) The Investigator has relevant and updated information on the IMP such as the current Investigator's Brochure, the IMP dossier or Summary of Product Characteristics (SmPC), all documents, and all clinical trial supplies needed to conduct the clinical trial in compliance with regulatory and GCP guidelines.

- Verify that written informed consent was obtained from trial subjects prior to trial involvement and related activities

- Verify that the Investigator is enrolling only eligible subjects.

- Reporting the subject recruitment rate

- Verify that source documents and other clinical trial records are accurate, complete, kept up-to-date and maintained.

- Verify that the Investigator provides all the required data for monitoring purposes and that data is accurate, complete, timely, and legible, dated, and identify the clinical trial.

- Check the accuracy and completeness of the Case Report Form (CRF) entries, source documents and other clinical trial-related records against each other.

    a) Data required by the protocol should be accurately captured in the CRFs and are consistent with source documents
    b) Any dose and/or therapy modifications should be well documented for each of the clinical trial participants.
    c) Adverse events, concomitant medications and comorbidities are reported in accordance with the protocol in the CRFs.
    d) Determine whether all Adverse Events/ Reactions (AE/Rs) are appropriately reported within the time periods required by the Sponsor's SOP for Pharmacovigilance, GCP, the Protocol, the Research Ethics Committee, and the applicable regulatory requirement(s).
    e) Missed visits and tests that are not conducted, and examinations that are not performed are clearly reported as such in the CRF and medical notes/source documentation
    f) All withdrawals and dropouts of enrolled subjects from the clinical trial are reported and explained in screening and enrolment log.
    g) Inform the Investigator/Research team of any CRF entry error, omission, or illegibility. The Monitor should ensure that appropriate corrections, additions, or deletions are made, dated, explained (if necessary), and initialled by the Investigator or a delegated member of the research team.

- Ensure they never change entries on any of the documents reviewed. All documents must be checked for version control, pagination and must relate to the final approved version of the Protocol

The above activities are for guidance purposes and activities undertaken will depend on the design and risk level of the trial in place. In addition to some of the activities listed above, the procedure outlined below for monitoring will also include some of the requirements recommended by the UK Policy framework for health and social care and requirements necessary for compliance with the UK Regulations.

5. Procedure

The Monitor will use the procedure outlined in this section as guidance for monitoring clinical trials. There are four main areas to consider where monitoring activities will take place:

5.1 Trial Registration

The Clinical Trials Manager will inform the Monitor of a new CTIMP. The Monitor may also be informed of a new CTIMP through 'Registration of Projects'. Following GOSH sponsorship approval (process described in 'Sponsorship approval for GOSH sponsored Clinical Trials SOP' or where it has been agreed that GOSH will manage the trial, the Monitor should then update the monitoring tracker which is located at R& D department shared drive with details of the trial. Please note that this tracker has two excel sheets. One excel sheet tracks monitoring undertaken & the other keeps track of annual reporting such as DSUR and APR.

Trial Set Up

Typically, non-commercial clinical trials Sponsored by GOSH are investigator-led clinical trials. The trial is designed, and the protocol written by the Chief/Principal Investigator in collaboration with the Sponsor's R&D Office and other relevant departments such as Pharmacy, Gene Therapy Team etc. Upon requesting approvals from relevant regulatory bodies such as MHRA, REC and HRA, the Clinical Trials Manager & the Monitor will generally be involved in preparation, quality control required documents

Where the Sponsor/Joint R&D office may not be in possession of all required documents. The Monitor should obtain copies of these documents for the Sponsor's record.

All service departments related to the trial must be consulted during the trial set-up process, especially if they have been delegated the exclusive responsibility of collecting some of the essential documents for the clinical trial.

During trial set up, the Monitor(s) is to do as follows:

1. Assist the CI along with Clinical Trials Manager with protocol development
2. Assist the CI in developing all essential trial documentation
3. Develop Monitoring Plan based on the Risk Assessment of the study
4. Ensure that all the relevant approvals are in place
5. Check all service departments that are to be involved in the conduct of the trial
6. Update the trial information on ReDA
7. Perform a Trial Initiation Visit

The risk assessment conducted as per GOSH sponsorship SOP will include assessment of risks to consider when monitoring. These sections of the risk

assessment should be used to support developing the monitoring plan which will cover the monitoring schedule, key data be captured, the frequency of monitoring and so forth. The protocol should be reviewed upon development of the monitoring plan

5.2.1 Monitoring Plan

Monitoring Plan is the approved document that describes the monitoring requirements for each study. This will include information on site visits, data to be reviewed and action plans.

A trial specific Monitoring Plan should be created using (Monitoring Plan Template) for each new trial, which will detail the extent of monitoring to be done. The completed risk assessment shall be used to determine the intensity and the focus of the monitoring activity. This will be agreed with the Chief Investigator of the trial.
This will depend on the phase of the study, whether the drug is licensed, and any other safety concerns should be considered when developing the monitoring plan.
In order to develop the monitoring plan, the following shall be considered:

- Objective, purpose and design of the trial
- Study endpoints
- Number of patients, frequency of trial visits, and the anticipated rate of recruitment at the site
- Number of sites
- Investigational medicinal product (e.g. licensed vs. unlicensed, licensed indication vs. unlicensed indication, known safety profile)
- Complexity of the trial and the trial documentation
- Quality of data being produced and therefore ongoing training requirements
- The stage of the trial e.g. recruitment phase, follow up, nearing completion
- Investigator's and site's experience and past performance
- Rate of occurrence of adverse events including Serious Adverse Events
- Any other risks identified during the risk assessment

The Monitoring Plan should have details on the following areas:

- Frequency of monitoring visits for source data verification (SDV)
- Breakdown of the frequency of monitoring of the TMF,ISF and Pharmacy
- Identify critical data, based on study endpoints.
- Type of monitoring; On-site ad/or Remote
- Areas to be covered at the initial visit and subsequent visits
- Number/percentage of subjects to be reviewed at each visit
- Definition of source data and extent of SDV
- The data which will be checked as part of the monitoring visit
- Handling of protocol deviations
- Verification of drug accountability records (if applicable)
- Escalation of findings

The risk assessment is a live process which should be revisited throughout the course of the trial. Events such as recruitment rate, persistent findings during past

monitoring, amendments and urgent safety measures which may increase or decrease the risk of a study, Therefore, the monitoring plan should function as a live document and be updated in accordance with the risk assessment.

5.2.2 Types of monitoring

Methods of monitoring must be considered when drafting the monitoring plan. There are two main types to consider; remote and on-site monitoring.

On-site monitoring: This is the traditional route of monitoring. This involves having on-site access to perform monitoring visit activities specified in the monitoring plan for that trial. This method of monitoring supports more immediate discussions with a member of the research teams about findings, clarifications etc.

Remote monitoring: Remote monitoring involves monitoring the trial from a remote location, outside of the research team offices. This may involve SDV through monitoring electronic data capture and electronic patient records. It can be used for assessing compliance at sites where on-site monitoring may not be feasible or on-site monitoring may be omitted. Any data which cannot be verified remotely must be verified on-site. For monitors who are not Trust employee, EMR can be accessed via secured GOSHLink which can be obtained by contacting study team.

5.2.3 Trial Initiation Visit

Once all essential documents are in place and the Trial Master File (TMF) or the Investigator Site File (ISF) has been set-up, the Monitor will conduct a Trial Initiation Visit using the template (Trial Initiation Report Template). During the visit, the Investigator can discuss any issues that may have arisen during the Trial Set-up period. If there are no issues to discuss, the Monitor can begin checking through the documentation.

The Monitor(s) will arrange to meet with the CI at the trial site by telephone or by e-mail.

At the trial initiation visit the Monitor(s) will discuss all aspects of the trial management with the Investigator team with an emphasis on Pharmacovigilance. The initiation report will be signed off within 2 weeks of the visit and recruitment can commence provided R&D 'Notice of No Objection' or confirmation of arrange capacity and capability is in place. R&D Notice of No Objection will coincide with the Trial Initiation Visit and will be issued after all the regulatory and ethical approvals are in place. A green light checklist will also be completed. The site can only commence recruitment after green light has been given by the sponsor (R&D) via email to the recruitment team. Recruitment will not begin until R&D confirms the green light release.

Finally, the Monitor will need to remind the CI of their obligation to inform the Sponsor when the clinical trial officially begins. This date is considered to be the date when the first consent form is signed.

5.3 Trial Management

All CTIMPs will be monitored to ensure compliance with the principles and conditions of current GCP.

The extent and nature of monitoring activities will be determined mainly by the CTIMP risk assessment conducted to determine Sponsorship. During the conduct of the trial there are further considerations to be taken into account such as recruitment rates and the numbers of Serious Adverse Events (SAEs) and Suspected and Unexpected Serious Adverse Reactions (SUSARs).

5.3.1 Recruitment rates

The Monitor will collect quarterly recruitment numbers and record this data on GSH Sponsored-Managed CTIMPs Monitoring Tracker in the Monitoring folder available on R&D's shared drive.

5.3.2 Routine versus triggered monitoring

In cases of triggered monitoring, routine monitoring will be postponed. Triggered monitoring may occur under the following circumstances:

- Report or suspicion of fraud
- Report or suspicion of misconduct
- Serious concerns related to safety issues
- Trials which have had a number of critical/major findings at a previous monitoring visit

Please note, that all planned dates for routine monitoring is saved on the GSH Sponsored-Managed CTIMPs Monitoring Tracker.

5.3.3 Monitoring visit arrangement

To arrange a monitoring visit, the Monitor will send an e-mail, ideally 2-3 weeks prior to intended dates to inform the Principal Investigator (PI) and/ clinical trial team members of suitable dates for a the monitoring visit. This is to ensure the trial team are given sufficient time to prepare for the monitoring visit. The Monitor will also need to send an e-mail to the GOSH Pharmacy Department (if Pharmacy has been involved) to arrange a mutually convenient time for the pharmacy monitoring visit

The Monitor should request an updated list of enrolled trial patients. Generally, SDV will be conducted on a random selection of up to five patients in addition to records of patients with reported SAE/R s and/or SUSARS. The trial team should be informed of the subjects selected by e-mail.

However this is highly dependent on the monitoring plan and the nature of the trial. In instances where 100% monitoring is required in a phase I study, prior to dose escalation as per DMC charter specifications, monitoring of all patients should be prioritised. The DMC charter should specify this, hence should be referred to upon completion of the monitoring plan. The monitoring plan will state what 100% SDV would entail for that respective trial.

5.3.4 Monitoring Visit Preparation

The Monitor should become well acquainted with the protocol and specific monitoring requirements i.e. monitoring plan associated with the trial being monitored, prior to the planned monitoring. The last monitoring report/finding log should be reviewed to ensure that all previous raised actions are addressed and resolved in the subsequent monitoring visit.

5.3.5 Monitoring Visit

At the start of the monitoring visit, the Investigator can discuss any issues that may have arisen since the previous monitoring visit.

Using the relevant Monitoring Report Template (Site Monitoring Report Template and Monitoring Report Pharmacy Template), the Monitor will check through the trial documentation. The Monitoring Report will serve as guidance for the review and will also serve to record general findings and comments. The monitor will also use the Detailed Findings Log to further expatiate on findings related to data management, trial coordination (e.g. operational activities to research team) and trial management, which cannot be adequately captured on the Monitoring Report Template. The finding log is a continuous document where findings are recorded and actioned.

The Monitor may need to persist for information to be provided which is required to ensure compliance. They will also need to ask for copies of any other documents as and when deemed necessary.

At the end of the session, the Monitor will need to summarise the findings and inform the trial team that a Monitoring Report will be written up, and if required, a Detailed Findings Report.

5.3.6 Draft Monitoring Report and Detailed Findings Log.

A Monitoring Report should be drafted and should address all monitoring findings. If all findings cannot be addressed adequately through the Monitoring Report alone, then a Detailed Findings Log should be completed also.

Any emails or communication with regards to the findings after the visit will be filed in the site file.

Ideally, the Monitoring Report and Detailed Findings Log will be written up within 4 weeks of the visit. However, any Critical and Major findings highlighted by the monitor will need to be communicated with the Clinical Trials Manager/ Head of Governance, Clinical Trials and Contracts.

The Clinical Trials Manager/ Head of Governance, Clinical Trials and Contracts will then assess and confirm if the finding can be validated as Critical or Major. The monitor will then need to inform the research team/PI/CI immediately after the monitoring visit. If this is not possible, the research team/PI/CI should be inform through an email. This would be in order to prevent continued poor practice as soon as possible. The Critical and Major findings should still be stated in the draft Detailed Findings Report.

The draft Monitoring Report will be reviewed by the Clinical Trials Manager or Head of Governance, Clinical Trials and Contracts. The Detailed Monitoring Findings Report will be reviewed by the Clinical Trials Manager. The reports will be then sent to the Investigator and the corresponding trial team.

The Monitor will also need to write a Monitoring Report for Pharmacy (if the monitor is performing pharmacy visit) and proceed as per the Monitoring Report process mentioned previously. A Detailed Pharmacy Monitoring Findings Log should also be completed, if the Monitoring Report for Pharmacy cannot capture all findings appropriately. This will also be reviewed by the Clinical Trials Manager.

The Detailed Findings Log will be a detailed explanation of findings that have been discovered during the course of a monitoring report. These findings will be classified as one of the following MHRA Inspection Findings Grading System:

1. Critical: A critical finding can fall into one or more of these points specified. It is a significant and unjustified departures from applicable regulatory requirements or guidance that:
    - Has jeopardised/potentially jeopardises safety and well-being of trial patients
    - Caused reporting and recording of unreliable data
    - Number of Major non-compliances across areas responsibility indicating a systematic quality assurance failure
    - Insufficient or untimely corrective action has taken place regarding a previous Major finding
    - Breach in Regulation 31A – where access to the TMF, upon request is inaccessible or unavailable. It is also when content of the TMF is incomplete and unable to constitute for basic inspection, so that compliance cannot be verified.

2. Major: a non-critical finding but is a significant and unjustifiable departure from regulatory requirements or GCP guidance. It may have potential to become

critical if not addressed. It is also applicable where there is a departure from such practices are evident within a single area of responsibility.

3. Other: Not critical not Major, but is a departure from regulatory requirements, GCP guidance or procedural i.e. trust SOP requirements.

4. Observational: This may be observations in operational activities within the research team. These are not findings but can become findings if not addressed or amended.

The findings will be given codes, 1- 4, as described above. These codes will be incorporated into the Detailed Findings Report.

5.3.7 Final Monitoring Report

The Monitor will need to ensure that the Investigator/trial team provides any comments within two weeks of sending the draft Monitoring Report via e-mail. Once all comments have been received, the Monitoring Report will be finalised and sent to the Investigator team for signing. The signed report should be sent back within a week by the investigator trial team. Once the signed report has been returned to the Sponsor, it will be duly signed and dated by the Monitor, the Head of Governance, Clinical Trials and Contracts. All the signatories must ideally be completed within 2 weeks of the final report sent. The monitor will then distribute the final report to the relevant members of the trials team and the investigator.

It is important that all findings raised on the Detailed Findings report are resolved or clarified for the respective visit.

The signed Monitoring Report must be filed in the monitoring section of the sponsor's trial database ReDA and TMF.

5.3.8 Monitoring Visit Follow-up

After the monitoring visit, the completed and fully signed monitoring report will be stored as an electronic file on ReDA (R&D Database) under the named trial folder.

The Monitor will update the date of the monitoring visit and any non-compliance which needs attention on the monitoring tracker.

The Monitor must follow-up on all preventive and corrective actions specified in the final monitoring report and detailed findings log after the given timelines have elapsed. The timelines given to resolve the outstanding actions would be 4 weeks in total. Any urgent issues will be given priority and corrective/preventive actions

may need to be put in place as soon as possible based on the risk of the issue. Please refer to Managing CAPAs SOP.

5.3.9 File notes

File Notes are documents that are used to prove that omissions and errors identified in the trial documentation have been recognised. If any omissions or errors are identified where a File Note would be suitable, the Monitor will advise the Investigator to write one. The Monitor may however on some occasions write a File Note on behalf of the Investigator. In these instances, the Monitor will request that the Investigator files away the File Note in the relevant location.

A CAPA may need to be put in place if applicable. This would be specified in the Monitoring Report

5.3.10 Escalation Process

Serious non compliances and reoccurring unresolved critical and major findings should be escalated to the Clinical Trials Manager/Head of Governance, contracts and clinical trials /Deputy Director of R&I for taking any further action. The process of escalation should be in accordance with the Management of Serious Breaches occurred in Clinical Trials of Investigational Medicinal Products SOP.

5.3.11 Trial oversight committees

The sponsor may specify particular oversight arrangements and recommend an independent committee. The appropriate structures will vary according to the size, complexity and risks associated with the trial.

5.3.11.1 Independent Data Monitoring Committee (IDMC)

A data monitoring committee may be set up to review the safety data and conduct of clinical trial. The role of the committee is to review the accruing trial data and to assess whether there are any safety issues, ethical issues, the progress of a clinical trial, including the safety data and the critical efficacy endpoints at intervals and recommend to the Sponsor whether to continue, modify, or stop a trial (ICH GCP 5.5.2).

The DMC should be the only body that has access to unblinded data.

5.3.11.2 Trial Steering Committee (TSC)

The role of a TSC is to provide overall supervision of the trial and ensure that it is being conducted in accordance with the principles of GCP and the relevant regulations. It should provide advice to the investigators on all aspects of the trial.

The TSC will usually have members who are independent of the investigators, e.g. an independent chairperson.

5.3.11.3 Trial Management Group

The composition of the trial management group varies from a single person i.e. CI, to multiple members of team who oversee day to day conduct and management of trial. They should ensure the protocol is adhered to and take appropriate action to safeguard participants and the quality of the trial itself.

All documentations produced by oversight committees will include key decisions made during the trial and should be filed in the TMF.

Trial teams must send meeting minutes from committee's to the R&D for review. The R&D should review the meeting minutes and confirm that there are no immediate actions arising from this meeting with regards to sponsor oversight.

5.4 Trial Close Out

Once the trial has ended, either when recruitment is complete (the last patient has been recruited and all patient visits have been complete) or because of early termination, the PI/CI and research team must inform R&D and the monitor must contact the trial team to make arrangements to monitor the final stages of the trial. This is to ensure that all outstanding issues have been addressed and that a close-out visit can be arranged in a timely manner.

The purpose of this monitoring visit is to ensure that all trial documentation is complete (including CRFs) and that all SAE/Rs have been reported appropriately.

This session also serves the purpose of reminding the PI of his/her obligation to write a final study report which will need to be submitted to the Joint R&D Office, the MHRA and the Research Ethics Committee (REC) who have approved the study. The study results must also be submitted on public database where the trial is registered.

The Pharmacy Department will also need to be monitored as part of the close-down procedure. The monitor should also confirm with the pharmacy team if there are any remaining unused trial supplies, and if applicable pharmacy should confirm once they are destroyed.

Following the End of Trial Monitoring Visit, the Monitor will need to write a final Monitoring Report using the End of Trial Monitoring Report template (End of Trial Monitoring Report Template) and if required, may also complete a Detailed Pharmacy Findings log.

All outstanding issues will need to be resolved before the close-out of the clinical trial and before the trial documents are archived. Electronic databases should also be locked once all outstanding data/queries are resolved after the close out visit.

Conclusive points to address during the close out visit

- Review all regulatory files for accuracy and completeness.
- Resolve all outstanding sponsor queries.
- Reconcile all investigational study product accountability and shipment records.
- Evaluate requirements for data storage
- Update public database status and report results

5.4.1 Monitoring of Blinded Trials

Precautions should be taken at each step of the monitoring in order to avoid any bias in the study. The monitor should only be allocated the IMP aspects by protecting the blindness and consideration should be taken how the visits and communication will be documented, reviewed and approved without causing any bias in the trial.

6. Related Documents *

Document Name
Sponsorship approval for GOSH sponsored clinical trials SOP'
Managing CAPAs
Management of Serious Breaches occurred in Clinical Trials of Investigational Medicinal Products SOP.
Monitoring Plan Template
Trial Initiation Report Template
Monitoring Report Template
Monitoring Report Pharmacy Template
End of Trial Monitoring Report Template
Monitoring Detailed Findings Log
Detailed Pharmacy Findings Log
File Note Template
GSH Sponsored-Managed CTIMPs Monitoring Tracker
GSH Sponsored-Managed CTIMPs Annual Reporting Tracker

***Reports, templates and logs can be found on the R&D shared drive/Q-Pulse. SOPs can be found on Q-pulse and the GOSH website.**

7. References

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Appendices (If applicable)

Not applicable. Please refer to Section 6 Related documents. All documents are available electronically.