Monitoring of Active Studies

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1 Introduction

1.1 The Academic & Clinical Central Office for Research & Development (ACCORD) is a joint office comprising clinical research management staff from NHS Lothian (NHSL) and the University of Edinburgh (UoE).

1.2 The purpose of trial monitoring is to verify that:

(a) The rights and well-being of participants are protected.

(b) The reported trial data are accurate, complete, and verifiable from source records.

(c) The conduct of the trial is in compliance with the currently approved protocol/amendment(s), with Good Clinical Practice (GCP), and with the applicable regulatory requirement(s).

1.3 Monitoring may include site monitoring (performed on-site and/or remotely) and centralised monitoring, depending on the monitoring strategy as documented in the Monitoring Plan and the design of the trial. Monitoring activities and findings are documented in the MV report, which is filed in the Trial Master File (TMF) and/or Sponsor File. The monitor will support the location in resolving all findings until resolution.

2 Purpose

2.1 To document the procedure for monitoring selected active studies, including on-site and remote monitoring, for studies sponsored by NHSL and/or the UoE, and triggered monitoring of studies hosted by NHSL.

3 Scope

3.1 This SOP applies to the Senior Clinical Trials Monitor, Clinical Trials Monitor, or any other individual, who will conduct and document monitoring activities on behalf of the sponsor(s).

4 Responsibilities

4.1 The Clinical Trials Monitor, or designee, is responsible for conducting on-site MVs (including reporting and follow up) and remote monitoring as required by the combined risk assessment and documented in the study specific monitoring plan.

4.2 The Senior Clinical Trials Monitor is responsible for assigning a member of the team to conduct the monitoring visit and for reviewing the monitoring visit report. Review of the monitoring visit report can be performed by another member of the monitoring team as required.

5 Procedure

5.1 Before the Monitoring Visit

5.1.1 The Clinical Trials Monitor, or designee, will liaise with the Principal Investigator (PI), or location contact, to arrange a MV for each location as defined in the monitoring plan. Email confirmation will be filed in the Trial Master File (TMF)/Sponsor file held by ACCORD.

5.1.2 The Clinical Trials Monitor, or designee, will outline the requirements for the MV. It will be made clear to the PI, or location contact, that site files, data acquisition tools (e.g. case report forms) and source records are to be made available for the MV. Where applicable it will be agreed which participant medical records will be required. Where applicable, access to electronic participant medical records in compliance with local procedure will be requested.

5.1.3 The site MV may include visits to any supporting departments (e.g. pharmacy/laboratory/archive facility), which will be arranged prior to the MV where possible.

5.1.4 The Clinical Trials Monitor, or designee, will review the current approved protocol and relevant essential study records in preparation for the MV.

5.1.5 The monitoring and Source Data Verification (SDV) plans will be reviewed as preparation for the MV and any issues identified, with regard to following the monitoring and SDV plans, will be escalated to the Senior Clinical Trials Monitor.

5.1.6 The preceding Site Initiation Visit (SIV) or MV report and relevant follow-up letter and any contact reports documenting communication since the last MV will be reviewed for any outstanding actions that need to be addressed. This will be used to set objectives for the MV in conjunction with the monitoring and SDV plan.

5.1.7 Where required by the monitoring plan, the TMF or Sponsor File will be reviewed against the appropriate Essential Records Checklist (CR001-T01, CR001-T02 or CR001-T03) for any records needed to complete the relevant study file. Missing records will be sourced before or during the MV to complete the file.

5.2 During the Monitoring Visit

5.2.1 The Clinical Trials Monitor, or designee, will meet with the PI, or location contact, at the start of the MV to discuss any concerns from either party and to briefly outline the plan for the MV.

5.2.2 The Clinical Trials Monitor, or designee, will use any new information from this discussion to prioritise actions for the MV.

5.2.3 The SDV and monitoring plan will be followed and all activities documented. The number of MVs planned will allow for the SDV plan to be completed.

5.2.4 Performing a Monitoring Visit template (CM002-T05) may be used as a guide and prompt for activities to be conducted at the location. If completed during a MV, CM002-T05 will be filed alongside the corresponding MV report. The MV report template (CM002-T01) will be used during on-site MV unless otherwise agreed with the Senior Clinical Trials Monitor. For any activities not completed during the MV, this will be reflected in the MV report as actions for the next MV.

5.2.5 The Clinical Trials Monitor, or designee, will highlight any errors in Case Report Form (or other data acquisition tool) completion. Errors in CRFs or source records must be corrected by a suitably delegated trial team member.

5.2.6 The Clinical Trials Monitor, or designee, will assess if training or refresher training is required at any stage during the study. Any training needs will be highlighted to the PI. Training needs could include but are not limited to SOP training, protocol training

or GCP training. Where appropriate, the Clinical Trials Monitor, or designee, will arrange for training to be conducted and documented.

5.2.7 Suitability of facilities will be considered at each MV and in the event of an issue being raised by the trials team with regard to appropriate facilities being available for trial conduct. If facilities cease to be available during the study, the Clinical Trials Monitor, or designee, will report the issue to the sponsors' representative(s) and Quality Assurance staff.

5.2.8 Where required by the monitoring and/or SDV plan, the Clinical Trials Monitor, or designee, will review the TMF and/or ISF at the study location against the appropriate Records Checklist (CR001-T01, CR001-T02 or CR001-T03) for any records needed to complete the relevant study files. Missing records will be highlighted to the study team for inclusion in the TMF and/or ISF.

5.2.9 The Clinical Trials Monitor, or designee, will meet with the PI or location contact at the end of the MV to discuss any findings and any actions. If there are any serious issues uncovered at the MV, these must be raised with the PI and Senior Clinical Trials Monitor as soon as possible. If the PI is not available in person, then follow-up will be carried out via a phone call or e-mail. Any phone or e-mail contact must be documented in the MV report or evidence of communication filed.

5.2.10 The Clinical Trials Monitor will enter the necessary details of the MV into the MV Log (CM002-T04). The PI, or designee, will countersign the entry.

5.3 After the Monitoring Visit

5.3.1 Subsequent to the visit, the MV report (CM002-T01) and follow-up letter (CM002-T06) will be prepared by the Clinical Trials Monitor, or designee, who conducted the visit. The report will be completed with factual information only. No personal opinions or comments will be documented in the report.

5.3.2 The MV report will be subject to review by the Senior Clinical Trials Monitor, or designee, in accordance with the monitoring plan, before the Clinical Trials Monitor provides the follow up letter to the study location. Review must be completed by an individual who did not complete the MV report.

5.3.3 The MV follow-up letter will be sent to the PI, copying in any relevant study team members. If any issues relate to supporting departments, these departments will also

be copied in. In the follow-up letter it will be made clear which actions are intended for the study team.

5.3.4 Target times for completion of MV report, completion of review and sending follow up letter to PI are outlined in the monitoring plan. Where target times were not met, justification will be documented in a file note.

5.3.5 The MV report will be made available to the sponsors' representative(s). Copies of the MV report and follow-up letter will be stored securely in the TMF and/or Sponsor File.

5.3.6 Any significant findings identified at a MV will be highlighted to the sponsors' representative(s) as soon as possible and discussed at the Sponsorship Meeting. Significant findings at a trial location will prompt consideration of a further triggered monitoring visit or triggered audit.

5.3.7 Actions identified during the MV will be followed up to resolution using the Monitoring visit actions log (CM002-T03). This can be sent to and completed by the study team or completed by the ACCORD monitor. Correspondence around completion of actions will be filed with CM002-T03 in the TMF and/or Sponsor file.

5.4 Contact Reports

5.4.1 When communication with locations between MVs reveals information relevant to the outcome of the trial or relating to participant safety, or any other issue which requires additional documentation, this information will be documented in a Contact Report. Contact Report Forms (CM002-T02) will be prepared and signed by the Clinical Trials Monitor, or designee, reviewed by the Senior Clinical Trials Monitor or designee where required, and filed in the TMF and/or Sponsor File.

5.5 Remote Monitoring Visits

5.5.1 Methods for remote monitoring will be described in the Monitoring Plan and SDV plan. The SDV plan will also describe the means by which completion of remote monitoring activities are documented. The timeline for production of the relevant documentation will be the same as onsite monitoring visits unless otherwise stated in the SDV plan. Evidence of remote monitoring will be filed in the TMF and/or Sponsor file.

5.6 Triggered Monitoring Visits

5.6.1 Significant findings at a trial location will prompt consideration of a further triggered monitoring visit or triggered audit. Any additional study specific triggers for a

monitoring visit will be captured in the monitoring plan. The appropriateness of a triggered monitoring visit will be discussed by the Senior Clinical Trials Monitor, or designee, representatives of the sponsor(s) and where appropriate the relevant contact within the Research and Development (R&D) office that granted management approval for the trial location. This communication and the decision reached will be documented using an appropriate method in the TMF and/or Sponsor File and Investigator Site File (ISF), if applicable.

5.6.2 Studies that have not undergone the combined risk assessment process or where, following combined risk assessment, monitoring was not deemed necessary, may be subject to triggered monitoring where issues relating to participant safety and well-being, validity of study data or compliance with relevant regulations are identified by any means. The decision to carry out a triggered monitoring visit will be made through discussion between the sponsor(s) and Senior Clinical Trials Monitor. These discussions will be documented appropriately in the TMF and ISF, where applicable.

5.6.3 Studies hosted by NHS Lothian Health Board may be subject to triggered monitoring where issues relating to participant safety and well-being, validity of study data or compliance with relevant regulations are identified by any means. The decision to carry out a triggered monitoring visit will be made through discussion between the sponsor(s) and Senior Clinical Trials Monitor. These discussions will be documented appropriately in the TMF and ISF, where applicable.

6 References and Related Documents

- CM002-T01 Monitoring Visit Report
- CM002-T02 Contact Report
- CM002-T03 Monitoring Visit Actions Log
- CM002-T04 Monitoring Visit Log
- CM002-T05 Performing a Monitoring Visit
- CM002-T06 Monitoring Visit Follow Up Letter
- CR001-T01 Records Checklist (CTIMP)
- CR001-T02 Records Checklist (non-CTIMP)
- CR001-T03 Records Checklist (Medical Device)
- ICH-GCP E6(R3) Guidelines

7 Document History

Version Number	Effective Date	Reason for Change
1.0	14 SEP 2011	New procedure.
2.0	05 FEB 2016	New SOP template and updated SOP title. Introduction of contact report template and update to monitoring visit report template. Change to documentation of remote monitoring.
3.0	20 MAR 2017	Relocation of the Monitoring Visit Log from CR007 to CM002. New Monitoring Visit Log renamed CM002-T04.
4.0	15 AUG 2018	Change of author. Inclusion of a new template, CM002-T05 (Performing a Monitoring Visit). Clarification on the completion of CM002-T03 (Monitoring Visit Actions Log), and the production of relevant documentation related to Remote Monitoring Visits. Minor changes to CM002-T01 and CM002-T03.
5.0	28 OCT 2020	Inclusion of a new template: CM002-T06 Monitoring Visit Follow Up Letter. Update to state that email confirmation of monitoring visit to be filed in the Trial Master File/Sponsor File as applicable.
6.0	03 FEB 2025	SOP and associated documents (CM002-T01 to T06) moved to new ACCORD document templates
7.0	28 APR 2026	Updated to align with the amended Clinical Trial Regulations and ICH GCP E6 (R3). Use of CM002-T05 made optional. Clarification that if monitoring plan timelines are not met, this will be documented in a file note.

8 Approvals

Sign	Date
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