# Developing Monitoring and SDV Plans

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| Document No.: | CM004 v5.0 |
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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 Monitoring is one of the key mechanisms whereby the Sponsor can be assured that it is in compliance with the legislation and the trial protocol/procedures. A monitoring plan and source data verification (SDV) plan are required for each NHSL and/or UoE sponsored study selected for monitoring. The monitoring plan will define the strategies utilised to provide sponsor oversight. The SDV plan is required to define monitoring activities to be conducted by the Clinical Trials Monitor, or designee.

1.3 Monitoring and SDV plans will be developed for all trials that have been subject to the ACCORD combined risk assessment process and selected for monitoring. These plans will also be implemented for studies not subjected to combined risk assessment but where monitoring is required for sponsor oversight as decided during sponsor review.

## 2 Purpose

**2.1** To describe the process for formulating and documenting a monitoring plan and SDV plan for NHSL and/or UoE sponsored studies selected for monitoring.

## 3 Scope

**3.1** This Standard Operating Procedure (SOP) applies to the Senior Clinical Trials Monitor, Clinical Trials Monitor or any other individual, who will develop a monitoring and SDV plan on behalf of the sponsor(s).

## 4 Responsibilities

4.1 The Clinical Trials Monitor is responsible for formulating and documenting monitoring and SDV plans in accordance with this SOP and, where applicable, the combined risk assessment (GS002).

4.2 The Senior Clinical Trials Monitor is responsible for assigning a member of the monitoring team to complete the monitoring and SDV plans and for reviewing these on completion.

# 5 Procedure

## 5.1 Monitoring Plans for Combined Risk Assessed Studies

5.1.1 The level of monitoring required is determined by completing the combined risk assessment tool (GS002-T01). The risk assessment will identify any vulnerabilities in the trial that need to be mitigated by monitoring and management activities. The outcomes of this process are used to populate the monitoring plan (CM004-T01), detailing the specific monitoring activities in line with the mitigating actions identified in the risk assessment. Consideration is given for unblinded monitors and reviewers (if required). The monitoring plan template can be made bespoke for each study with the agreement of the Senior Clinical Trials Monitor, or designee.

5.1.2 The monitoring plan will contain a description of the methods of monitoring that will be applied to the trial. Monitoring can include:

- Onsite monitoring – Monitoring activities that are primarily undertaken during a physical visit to the investigator site by one or more monitoring personnel.
- Remote or central monitoring - Monitoring activities that are undertaken by the monitoring personnel in a location away from the investigator site

5.1.3 The Monitoring Strategy template and entries in the management strategy comments found in the combined risk assessment tool will be used to complete the monitoring strategy template section of the monitoring plan, which defines the level of monitoring required for each area of the trial.

5.1.4 A full description of the schedule of monitoring to be conducted will be defined. This will take into account requirements for different site risk levels (low, medium and high) according to GS013-T02 Feasibility Site Risk Indicator, where required. For example, high-risk sites may require greater monitoring oversight (e.g. onsite SIV instead of remote, additional telephone monitoring) than medium and low risk sites. Site risk level may also be used to determine which sites will receive an onsite visit during the course of the trial.

5.1.5 The required frequency of recruitment figure reporting will be recorded in the monitoring plan. Screening and recruitment rates will be reported to the ACCORD monitoring office according to the agreed frequency recorded in the monitoring plan.

5.1.6 The monitoring plan will confirm if any monitoring tasks are to be delegated from the ACCORD monitoring team. The monitoring plan will include documentation of appropriate delegation and confirmation from the designee that delegated monitoring tasks are understood and responsibility for their completion is accepted.

5.1.7 The monitoring and SDV plan will establish a clear escalation process for issues identified during delegated monitoring activities. Issues will be escalated to the Senior Clinical Trials Monitor, or designee, in the first instance.

## 5.2 Monitoring Plans for Other Studies

5.2.1 Studies which will not undergo combined risk assessment, but which have been deemed at sponsorship review to require monitoring will automatically be assigned a reduced monitoring level for all aspects of the trial unless justification for increasing this is provided by the Sponsor representative.

5.2.2 The monitoring plan will contain a description of the methods of monitoring that will be applied to the trial. Monitoring will be proportionate but designed to maintain oversight of the trial in line with the monitoring levels applied. Remote monitoring will be utilised where possible with onsite monitoring only undertaken where aspects of the monitoring plan cannot be verified remotely.

5.2.3 The monitoring plan will confirm if any monitoring tasks are to be delegated from the ACCORD monitoring team. The monitoring plan will include documentation of appropriate delegation and confirmation from the designee that delegated monitoring tasks are understood and responsibility for their completion is accepted.

5.2.4 The monitoring and SDV plan will establish a clear escalation process for issues identified during delegated monitoring activities. Issues will be escalated to the Senior Clinical Trials Monitor, or designee, in the first instance.

5.2.5 For trials where a monitoring plan does not exist, e.g. for trials which have not undergone combined risk assessment and have not been deemed as requiring monitoring at Sponsorship review, a triggered monitoring visit can be performed in response to identification of a suspected serious breach or other serious issue where more information is required by the Sponsor. These triggered visits can be

undertaken either remotely or onsite and will be written up according to SOP CM002. Visits will focus on the information required to investigate the issue identified. If the Sponsor deems ongoing monitoring is required as part of a preventative action for such an issue, a monitoring and SDV plan will be developed for the trial.

### 5.3 Completing the SDV Plan

5.3.1 The SDV plan (CM004-T02) will be completed in conjunction with the monitoring plan. The SDV plan will be populated with details derived from the combined risk assessment, the monitoring plan and discussion with the Chief Investigator (CI) and/or Trial Manager where required. Data requiring review will be confirmed and timeframes for data entry and resolution of issues will be described. The percentage of data requiring review defined in the SDV plan will be based on the level of monitoring allocated (refer to GS002-T01 Combined Risk Assessment Tool Report), the planned monitoring frequency and the number of participants in the study. The SDV plan can be made bespoke for each study with the agreement of the Senior Clinical Trials Monitor, or designee.

### 5.4 Updating Monitoring and SDV Plans

5.4.1 Monitoring and SDV plans will be reviewed, and a new version created at expiry date if the study is still ongoing (the monitoring plan expiry date is the end of study date). A review will also take place if there are changes to the trial, or the combined risk assessment, that are assessed by the Senior Clinical Trials Monitor, or designee, to require reappraisal and update of the monitoring plan.

### 5.5 Escalation Process

5.5.1 For remote monitoring, triggers will be used for escalating to onsite monitoring. These will be defined in the monitoring and/or SDV plan. For both remote and onsite monitoring, unresolved issues or serious non compliances will be escalated to the Senior Clinical Trials Monitor, or designee. If the issues cannot be resolved, they will be further escalated to the sponsor representatives and Quality Assurance.

## 6 References and related documents

- CM004-T01 Monitoring Plan
- CM004-T02 SDV Plan
- GS002 Combined Risk Assessment
- GS002-T01 Combined Risk Assessment Tool
- GS013 Site Feasibility
- GS013-T02 Feasibility Site Risk Indicator

- ICH GCP E6 (R2)

## 7 Document History

| Version Number | Effective Date | Reason for Change |
|---|---|---|
| 1.0 | 14 SEP 2011 | New procedure. Discontinued 20 Nov 2012. |
| 2.0 | 05 FEB 2016 | Reintroduction of discontinued procedure with updated SOP template and SOP title. Changed to reflect combined risk assessment integrated risk-based monitoring approach. Updated monitoring plan template and introduction of SDV plan template. |
| 3.0 | 15 AUG 2018 | Change of author. Additional information added in 5.1.1, 5.1.2 and 5.5.1. Minor administrative changes throughout. Minor changes to monitoring and SDV plan templates. |
| 4.0 | 15 SEP 2020 | Change of author.<br>Additional information added in 5.3.1 and 5.4.1.<br>Reference to GS013 Site Feasibility SOP added.<br>Update to References and Related Documents |
| 5.0 | 08 NOV 2024 | Updates to section 5.2 to further define oversight of studies which do not require combined risk assessment but are deemed by Sponsor Representative to require monitoring oversight.<br>CM004-T01 updated with minor admin changes.<br>SOP, CM004-T01 (updated to v4.0) and CM004-T02 (updated to v4.0) all moved to new template. |

# 8 Approvals

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| Elizabeth Craig<br>Elizabeth Craig (Oct 23, 2024 13:12 GMT+1)<br><br>APPROVED: Elizabeth Craig, Senior Clinical Trials Monitor, NHS Lothian, ACCORD | Oct 23, 2024 |
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# CM004 Developing Monitoring and SDV Plans v5.0

Final Audit Report 2024-10-24

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