

## 1 PURPOSE

The purpose of this Standard Operating Procedure (SOP) is to describe the procedures for performing and documenting co-monitoring visits.

The purpose of the co-monitoring is to:

- Standardise the monitoring of clinical drug trials managed by NorCRIN
- Maintain a high level of expertise on GCP, national and international laws and regulations for drug trials
- Strengthen the NorCRIN monitoring network

This SOP ensures compliance with ICH Guideline for Good Clinical Practice (ICH GCP) and national and international laws and regulations, specified in [Legislation and Guidelines](#).

## 2 SCOPE

This SOP is valid for all clinical drug trials sponsored by hospitals that have implemented the NorCRIN SOPs and for trials for which this SOP has been accepted by sponsor.

## 3 RESPONSIBILITY

The monitor's line manager is responsible for the monitors that perform co-monitoring of clinical drug trials and ensuring compliance with this SOP.

## 4 PROCEDURES

### 4.1 General requirements for co-monitoring

Co-monitoring is part of a monitor's continuing profession development. Co-monitoring provides opportunities for sharing experience, clarification of procedures and monitoring practice and assessing additional need for training.

Each monitor should ideally participate in a co-monitoring visit every other year.

A co-monitoring visit should be done as part of an ordinary scheduled monitoring visit and not cause extra work for the investigator / trial personnel.

Co-monitoring should be carried out by a person with extensive experience in monitoring who preferably belongs to a different institution than the site where the co-monitoring visit is done. It is recommended that the co-monitor already is familiar with the study and is monitoring own sites in the same study, and may well be the lead monitor of the trial.

### 4.2 Preparation

The monitor shall notify the principal investigator / trial personnel about co-monitoring visit, in advance.

The co-monitor will prepare for the visit by familiarising themselves with the:

- Status of the trial
- Protocol
- Procedures for the trial
- Monitoring plan

### 4.3 Conduct of the visit

The co-monitor will verify that the monitoring plan for the trial is followed, and observe how the different monitoring tasks are done.

The monitor and co-monitor should discuss their common understanding of protocol, study procedures and monitoring plan.

The co-monitor and the monitor should prepare a [Co-monitoring visit report](#) together with lessons for both parties.

Unresolved / significant issues, or issues that can be of value to discuss in the monitoring group, will be escalated to the head of the monitoring group. The co-monitoring report will be signed and dated by both parties and sent to the head of the monitoring group within 14 calendar days after the co-monitoring visit. . The issues raised in the report will be discussed in the monitoring group at the bi-annually meetings.

All monitors should plan for at least one co-monitoring visit across the region per year and inform the head of the monitoring group about the plan. The head of the monitoring group has the responsibility to update the co-monitoring log.

### 4.4 Review of co-monitoring

The monitoring group will review the “topics of interest to the monitoring group” identified on co-monitoring visit reports on an annual basis, and take action as required to ensure compliance with ICH GCP monitoring requirements and NorCRIN SOPs.

## 5 DOCUMENTATION

Reports will be filed by the head of the monitoring group, and should not be filed in the TMF. It is recommended that the monitor and co-monitor file a copy of the report in their training file, and forward the report to own line management as agreed locally.

## 6 NON-COMPLIANCE MANAGEMENT

All non-compliance should be handled according to the procedures for handling non-compliance of the individual health trust / institution and to SOP [Protocol Deviation Handling](#).

## 7 REFERENCES

### 7.1 EXTERNAL REFERENCES

- [ICH Guideline for Good Clinical Practice E6 \(R2\)](#) section 5.18

## 7.2 INTERNAL REFERENCES

SOP [Monitoring](#)

## 8 ATTACHMENTS

[Co-monitoring report](#)

## 9 DEFINITIONS

[Definitions.](#)

## 10 CHANGES SINCE LAST VERSION

CT SOP version no 1.0

Minor changes from LM SOP No.1.07 version No.3.0