

Study Monitoring Overview and Role of the Study Monitor

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Definition

- The act of overseeing the progress of a clinical study, and of ensuring that it is conducted, recorded, and reported in accordance with the protocol, SOPs, GCP and applicable regulatory requirement(s).

Monitoring

ICH E6 5.18.1

The purpose of monitoring is to ensure that:

- The rights and well-being of subjects are being protected
- The data are accurate, complete and verifiable
- The trial is being conducted in compliance with the protocol, SOPs, GCP, regulatory requirements

Monitoring

ICH E6 5.18.2 and 5.18.3

Sponsor is responsible:

- Ensuring that trials are adequately monitored
- Selecting monitors that are adequately trained
- Determining the extent and nature of monitoring

Site Visit Activities: What happens?

- Confirm adequate staff qualifications and resources
- Verify investigational products
- Verify informed consent obtained
- Confirm performance of study functions

Site Visit Activities: What happens?

- Verify participant eligibility
- Confirm accuracy and completeness of source documentation and CRFs
- Verify all investigator-required reporting
- Determine timely reporting of adverse events
- Ensure maintenance of essential documents

Monitoring Reports

Monitoring reports:

- Must be submitted by the monitor to the sponsor after each monitoring visit
- Summarize what the monitor reviewed during visit
- Includes summary of findings and actions recommended or taken to ensure compliance

Monitoring, Auditing & Inspecting

- **Monitoring**
 - Sponsor initiated, continuous, part of the research team.
- **Auditing**
 - A systematic and independent examination of study-related activities.
 - Initiated by Sponsor or Regulatory authorities
- **Inspecting**
 - The act by a regulatory authority(ies) of conducting an official review of all elements deemed by the authority(ies) to be related to the clinical study
 - These may be located at the site of the study, at the sponsor's and/or contract research organisation's (CRO's) facilities, or at other establishments deemed appropriate by the regulatory authority(ies).

EMBLEM SCHEDULED VISITS

- Pre-Study visits
- Initiation visit
- Monitoring visits
- Close Out visit
- Outputs of Monitoring visits
 - 1) Report to the sponsor
 - 2) Follow up action points
 - * Basis for future monitoring

Monitors Expectations

- Openness and truthfulness
- Access to Consents
- Access to all source documents(hard copy and electronic)
- Presence of key line staff for query response
- Old identified queries resolves by the next visits

Lessons from EMBLEM Study

- Inability to appreciate that the monitor plays a supportive role and not a police officer
- Failure to openly discuss issues at debriefing
- Defensiveness to the monitor's report
- Failure to carry out follow up activities
- Lack of continuous communication with monitors
- Lack of right cadres at the sites