Swansea University
Prifysgol Abertawe

Swansea Trials Unit
Uned Dreialon Abertawe

Guidance - Types of monitoring/oversight

There are a number of different types of monitoring. A combination of one or more methods may be adopted, depending on the risks associated with a particular study. In general, there is a need for on-site monitoring before, during and after the study. However, in some circumstances, the sponsor may determine that central monitoring in conjunction with procedures such as investigator training, investigator meetings and extensive written guidance can assure appropriate conduct of the study in accordance with GCP.

1. Trial oversight committees

Oversight is strongly recommended for all studies and this may be performed by a TMG, Trial Steering Committee, Data Monitoring Committee, or combined Trial Oversight Committee (see STU-CT061 Research Project Operational Committees).

2. Central monitoring

Central monitoring procedures should be employed where possible. These may include:

- remote review of study data for omissions
- statistical to identify outliers and data patterns/trends
- inconsistencies or invalid information
- range and calendar checks
- central review of consent forms
- delegation logs and eligibility checklists
- remote site training through webinars or teleconferences
- verification of participant existence
- review of recruitment rates
- rates of reporting
- withdrawals and losses
- rates of adverse events

3. Site monitoring

A degree of on-site monitoring may be required, whereby the monitor will visit participating sites to review study conduct, adherence to the protocol and GCP, participant eligibility and data collection. The role of the monitor is considerably greater than undertaking SDV and checking the site file. These activities may not necessarily reveal issues at site therefore it is important that the monitor communicates effectively with the site personnel, including the PI. Discussing the study with personnel may reveal variances that would otherwise not be identified through other methods.

At each site visit, the monitor should continually review the acceptability of site personnel, facilities and study progress. Concerns regarding study conduct or potentially serious breaches or fraudulent activity must be raised with the sponsor.

4. Site self-monitoring

This may be utilised alongside central monitoring, where deemed appropriate,

following completion of the study risk assessment. Sites complete a self-monitoring form which covers areas such as recruitment status, study participant documentation, status of approvals, content of the ISF and review of SAE forms. This may done as a standalone exercise or with support from the Trial Manager e.g. through a teleconference. The completed form is then returned to the Trial Manager for review and further action if required e.g. site monitoring visit or issuing of training.

5. Source data verification

Monitoring should ensure that reported study data is complete, accurate and verifiable from source documents. This does not imply that every item of data recorded must be supported by a source document or checked, but where there are original documents, the study data should be in agreement with the information they contain. Checking original documentation also confirms the identity and existence of study participants.

Site or even central monitoring may involve SDV on a minimum percentage of study data, or directed to more critical data for a particular study, such as consent, eligibility or endpoint data and/or SAEs. The monitoring plan should document what source documentation will be available for a particular study and the requirements for SDV. The decision on which items of source are verified lies with the Chief Investigator (CI) and Trial Oversight Committee(s) and should be reviewed during the course of the study.

6. Triggered Monitoring

Risk-based monitoring using triggering techniques can be adopted that enables resources to be focused on high-priority sites without compromising safety or quality of research.

Risk-based monitoring is a program of risk assessment for clinical conduct and data collection that applies available monitoring resources according to the identified risks—and reassesses those risks on a regular basis throughout the study. Under risk-based monitoring using triggering techniques, the premise is that monitoring sites where there's little or nothing to monitor is not useful.

Risk-based monitoring promotes the use of data to initiate a site visit only when justified by on-site workload or other quality triggers. The method involves the identification of risks and then links each risk with appropriate triggers that will initiate source data verification. Study risks may include past site performance; the number of subjects and rate of site recruitment; staff feedback on protocol compliance, site contact, and record keeping; information received from data management, such as missing case report forms (CRFs), query rates, and CRF completion delays; inaccurate or repetitive data; and safety issues. It's important to emphasise that risk-based clinical monitoring using triggering techniques doesn't compromise quality, but rather improves it.