Routemap

Ongoing Management & Monitoring

Recruitment Phase

Ongoing Management & Monitoring follows the Informed Consent station and precedes the GCP & Serious Breach Reporting station. This process occurs in parallel with Safety Reporting, Progress Reporting, and GCP & Serious Breach Reporting. It also has the potential to occur simultaneously with an MHRA Inspection, Audit, Substantial Amendments, Addition of New Sites & Investigators, Urgent Safety Measures, Temporary Halt, and Early Termination. Ongoing Management & Monitoring is a legal requirement which is relevant to all trials. This station is part of the 'recruitment phase' group of stations.

The expectation of the sponsor to develop appropriate trial management plans is outlined in the Trial Management & Monitoring station.

As the trial progresses, the sponsor must oversee its management and ensure that management strategies are adhered to. It is important, for example, to ensure that the monitoring performed for a particular trial, is in accordance with its monitoring plan. In addition, investigators must comply with the sponsor's instructions and study procedures.

The sponsor will re-appraise trial management strategies, clinical monitoring plans and quality assurance measures at necessary intervals and in response to events such a serious breach of GCP/protocol or a substantial amendment to the protocol. The sponsor will ensure that any changes are implemented in a timely fashion and where applicable, are communicated to all investigators.

Further reading & Workstream Documents:

- Trial Management & Monitoring station.
- The Summary of Trial Management Systems Workstream Document gives an overview of the activities associated with trial management as well as the oversight and documentation of those activities
- The Monitoring Procedures Workstream Document gives further information on the types of monitoring a sponsor may implement (for example on-site monitoring and central statistical monitoring).
- Further examples of risk adaptation are provided in the following workstream document;
    - Trial Scenarios in Monitoring illustrates the approach to monitoring applied to five very different trials.
- The MRC-NIHR TMRP host a series of webinars on trial conduct including, Monitoring trials efficiently: The role of central statistical monitoring.
- The Clinical Trials Transformation Initiative (CTTI) website provides useful information in their initiative on Trials Quality, and in particular, the application of Quality by Design (QbD) approach to clinical trials.
- Guidance for researchers and study coordinators on the General Data Protection Act can be found on the HRA website.