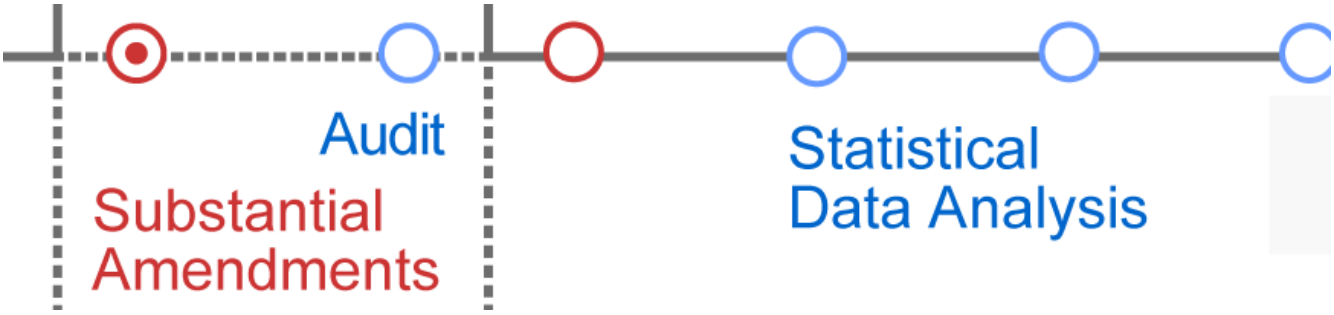
Clinical Trials Toolkit Routemap

Audit



Recruitment Phase

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

Audit

The sponsor of a clinical trial is responsible for establishing and maintaining robust quality systems, including designing and implementing a formal audit plan. Audits are performed to verify trials, trial processes, site systems, data, and operations against all relevant written standards (e.g., Good Clinical Practice, the protocol, standard operating procedures and regulatory requirements).

Activity during an audit may include:

- Staff interviews to confirm that personnel are appropriately trained, understand their roles, and are operating in compliance with SOPs, the study protocol, and relevant regulations.

- Facility tours to inspect infrastructure, assess resource adequacy, and verify that key equipment is validated and fit for its intended use.
- Document review, including source data verification and/or source data review.
- System audits, which look at the performance of specific functions, such as the systems and processes used for data management.

Auditors must remain independent from the trial team and the activities they audit and be properly qualified for their roles. All findings and observations from audits must be recorded in a formal report. Any deficiencies found should be addressed through appropriate corrective and preventative actions (CAPA). The CAPA process needs to be formalised, with responsibilities clearly assigned, deadlines established, and completion verified.

Further Reading

- MHRA Inspection station.
- UK CRF Network (.PDF): Guidelines for developing a Quality Manual, including conducting internal audits.