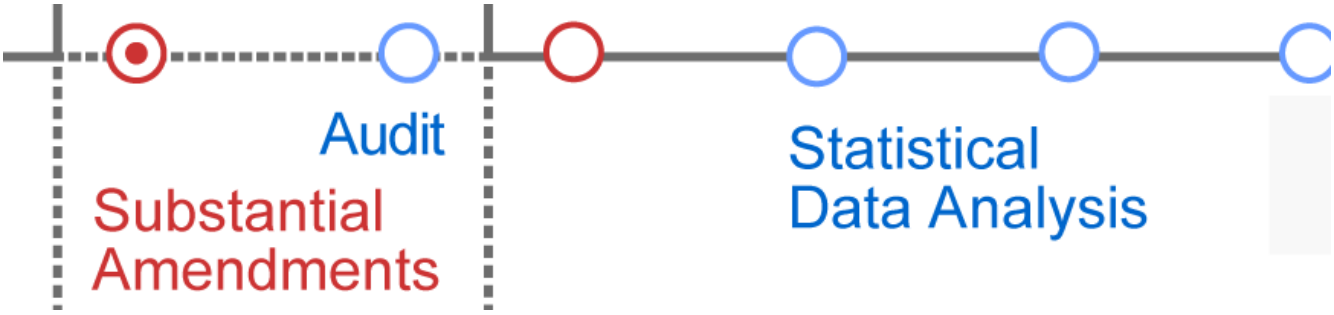
Routemap

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.

The sponsor of a clinical trial is responsible for implementing quality systems including the development of an audit plan for the trials they manage. Audit is designed to assess and assure the reliability and integrity of sponsor's trial systems against all relevant written standards.

Activities and system checks which may be undertaken during an audit include:

- Staff interview: To assess whether staff working on the trial are appropriately trained, are clear of their role and are working to all relevant standards, the protocol and standard operating procedures (SOPs)
- Facility Tour: To assess whether there are adequate resources and that any equipment is fit for its intended use
- Document Review: To assess whether data reported is verifiable from source data and that written records confirm that the trial was conducted appropriately.

Auditors should be independent of the trial team / process and should be appropriately trained for their role. Findings and observations from any audit conducted should be documented in a formal audit report. Any deficiencies identified during an audit should be followed up with appropriate corrective and preventative actions wherever possible.

Audits that are conducted by regulatory authorities (such as the MHRA) are termed inspections (see MHRA Inspection station for more detail).