Routemap

MHRA Inspection

Recruitment Phase

The MHRA Inspection station follows the Progress Reporting station and precedes the Audit 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 Audit, Substantial Amendments, Addition of New Sites & Investigators, Urgent Safety Measures, Temporary Halt, and Early Termination. An MHRA Inspection is a legal requirement for trials within the Clinical Trial Regulations scope. This station is part of the 'recruitment phase' group of stations.

The Medicines and Healthcare Products Regulatory Agency (MHRA) inspect Clinical Trials of Investigational Medicinal Products (CTIMPs) conducted by both commercial and non-commercial organisations. GCP Inspectors assess whether organisation sponsoring and/or conducting CTIMPs have systems in place to meet the requirements of the Clinical Trials Regulations (now amended by The Medicines for Human Use (Clinical Trials) (Amendment) (EU Exit) Regulations 2019).

Details of the types of inspections undertaken and the activities performed during an inspection can be found on the MHRA webpages. Similar information for inspections relating to the manufacture of Investigational Medicinal Products can be found on the MHRA webpages: Good Manufacturing Practice: The Inspection Process.

The MHRA has introduced a risk based approach to inspection which now takes into account the number of Type A trials sponsored by an organisation. The risk ratings for organisations with a high proportion of Type A trials may be reduced. (See MHRA page on Risk Based Inspections).

The NHS R&D Forum has produced guidance: How to prepare for an inspection for Good Clinical Practice by the MHRA (PDF, 1.1 MB) (.PDF) to help non-commercial sponsors and investigators prepare.

A number of EC Guidance Documents have also been published which serve to illustrate what would be evaluated during an inspection of a clinical trial. See Chapter IV- Inspections: Annex I-V.

Once an inspection has been completed, a formal report outlining the findings will be sent to the inspected organisation. A response to this report (describing any corrective and preventative actions) must be produced. The MHRA have published guidance (PDF) (.PDF)on how to prepare a response to the inspection report.

Further reading:

- Audit station.