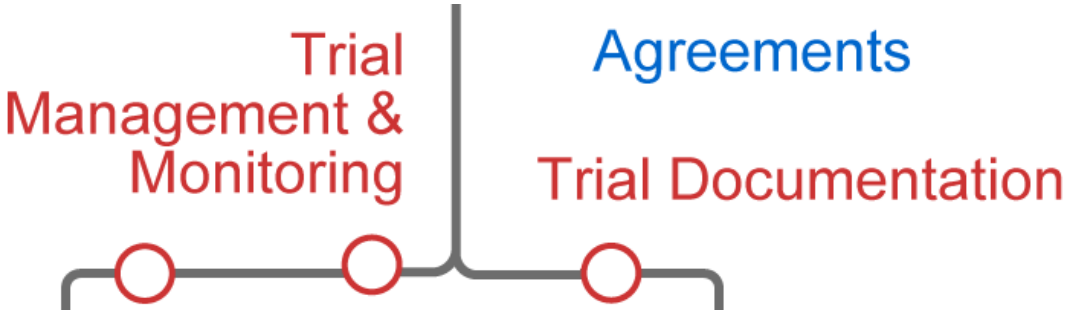
Routemap

Trial Documentation



Trial Planning Phase

The Trial Documentation station follows the Trial Management & Monitoring station and precedes the Trial Supplies station. Trial Documentation is a legal requirement which is relevant to all trials. This station is part of the 'trial planning phase' group of stations.

Good Clinical Practice (GCP) requires that all clinical trial information shall be recorded, handled and stored in such a way that it can be accurately reported, interpreted and verified.

Essential documents are:

"*...those which enable both the conduct of the clinical trial and the quality of the data produced to be evaluated; and show whether the trial is, or has been, conducted in accordance with the applicable regulatory requirements*"

Many essential documents are filed in a Trial Master File / Investigator Site File. Some, essential documents may also be source documents, which are often generated as part of the subject's medical care and therefore documented and archived in medical records and other service departments.

The EMA has published Guideline on GCP compliance in relation to trial master file (paper and/or electronic) for content, management, archiving, audit and inspection of clinical trials (2017) (.PDF) which assists sponsors and investigators to comply with the Clinical Trials Regulations.

Electronic Source Data

Source data and other essential documents may be kept in either paper or electronic format. The EMA published a document in 2010: Reflection paper on expectations for electronic source data and data transcribed to electronic data collection tools in clinical trials (PDF, 127 KB). (.PDF)

For sites considering a move from paper medical records to electronic health records (eHR), the MHRA have produced a position statement (.PDF) on the implementation of eHR systems to ensure compliance with the Medicines for Human Use (Clinical Trials) Regulations 2004 (as amended). The position statement details common problems found with eHR systems during GCP inspection and provides a comprehensive list of factors to consider when trial sites are establishing an eHR system.

Further reading:

- Trial Master File station
- Archiving station.