Trial Records (formerly Trial Documentation)

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Trial Planning Phase

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

Trial Records

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

Essential records allow the reconstruction of the trial's conduct and the quality of the data generated, demonstrating that the trial adhered to all applicable regulatory requirements. They are stored in a Trial Master File (TMF) by the sponsor or delegate, or an Investigator File (ISF) at each trial location. Some may be source records from routine medical care, archived in medical records and service files.

The European Medicines Agency (EMA) has published a Guideline on the content, management and archiving of the clinical trial master file (paper and/or electronic) (.PDF). It supports GCP compliance for the TMF and provides advice for both sponsors and investigators on its content, management, archiving, audit and inspection.

When electronic TMFs are used, they must be validated to ensure functionality, including reliable document capture, retrieval, storage, and security over the lifetime of the trial and its archiving period, which under the amended Clinical Trials Regulations is at least 25 years. The EMA Guideline (.PDF) provides information on the additional controls and requirements.

Electronic Source Records

Source records may be maintained in either paper or electronic form. To support compliance with the Clinical Trial Regulations, the Medicines and Healthcare product Regulatory Agency (MHRA) has issued a Position Statement (.PDF) (.PDF) on the implementation of Electronic Health Record (EHR) systems. Similarly, EMA Guideline on computerised systems and electronic data in clinical trials (.PDF) (.PDF) outlines requirements for computerised systems and electronic data to help ensure these systems are fit for purpose. The Food and Drug Administration (FDA) also provides guidance.

Non-CTIMPs

For non-CTIMP, it is good practice to retain any records that support the full reconstruction of study conduct. GCP guidelines provide a framework. The sponsors and host organisations may provide further guidance on TMF/ISF content through their policies and procedures.

Further Reading

- National Institute for Health and Care Research: Suggested Investigator File contents.
- MHRA Blog: Inspecting Clinical Trials - The Trial Master File
- World Health Organisation (WHO): Guidance on best practice for clinical trials.

Note: The NIHR Clinical Trials Toolkit has been updated to reflect the amended Clinical Trials Regulations, which took effect in the UK on 28 April 2026. Content and terminology has been updated across the CT Toolkit site, however the interactive routemap is still in the process of being updated accordingly.