Archiving

Trial Close-Out Phase

Archiving is the final station on the routemap and follows the Dissemination of Results station. Archiving is a legal requirement which is relevant to all trials. This station is part of the 'trial close-out phase' group of stations.

Archiving

The amended Clinical Trials Regulations define the archiving requirements for Clinical Trials of Investigational Medicinal Products (CTIMPs). All essential records must be archived, including those held by investigators, sponsors and others involved in the conduct of the trial, for example, service providers.

Consideration should be given to the archiving of both paper and electronic records (such as databases and electronic trial systems). The Medicines and Healthcare product Regulatory Agency (MHRA) provides further guidance on archiving on its website, including the requirements for a named individual responsible for archiving and a retention period of at least 25 years, beginning the day after the conclusion of the trial, which is the date specified in the protocol.

Archiving at the Trial Location

In multi-site trials, trial records held by the Principal Investigator may be archived by the host organisation. Responsibilities for archiving should be clearly defined

in trial agreements, and researchers should ensure they understand the specific arrangements in place for their study.

Where sites intend to replace paper medical records with scanned copies, processes must be in place to ensure that authentic and complete copies are created before any destruction of original records. The Medicines and Healthcare product Regulatory Agency (MHRA) Position Statement and Guidance on Electronic Health Records (.PDF) (.PDF) provides further detail on acceptable approaches.

Non-CTIMPs

For non-CTIMP research, archive retention periods are usually defined by the sponsor and/or local SOPs and policies.

Further Reading

- EMA: (.PDF) Reflection paper on expectations for electronic source data and data transcribed to electronic data collection tools in clinical trials (PDF, 127 KB).
- Arkivum: MHRA Inspection Findings - Key Issues in Clinical Trial Data & Archiving Compliance.
- Trial Documentation station.
- Trial Master File station.