Routemap

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.

The Clinical Trials Regulations and specifically, Regulation 31A of the Medicines for Human Use (Clinical Trials) Amendment Regulations 2006, define the archiving requirements for Clinical Trials of Investigational Medicinal Products (CTIMPs). All essential documents should be archived and this includes essential documents held by investigators, sponsors and others involved in the conduct of a clinical trial (including services departments such as pharmacy, laboratories and radiology).

The Joint Project Notes on Archiving give further information on the storage and destruction of essential documents and the duration/timelines appropriate for archiving.

Funders, journals, sponsors and host organisations will also have local policies/procedures covering archive requirements, which must also be followed.

Consideration should be given for the archive of both paper and electronic data (such as databases). EMA Guideline on the content, management and archiving of the clinical trial master file (paper and/or electronic)' (.PDF) (December 2018) should be considered when developing systems for archive. This document includes guidance relating to the media used for storage of documents (including

requirements when original records are transferred to electronic media for the purpose of archive).

Scanning & destruction of original Patient Medical Records

Archive requirements also apply to source documents kept at trial sites. When the site wishes to replace paper medical records with scanned copies, there must be a process to ensure authentic copies are produced prior to any destruction of original source documents. The MHRA Position Statement and Guidance: Electronic Health Records (.PDF) provides further guidance.

The Clinical Trials Regulations require the sponsor to appoint '**named individuals**' for archiving to ensure all requirements are met and systems are in place to track and retrieve archived documents. Named individuals should ensure that archive facilities are secure with appropriate environmental control and adequate protection from physical damage.

In multi-site trials, it is common practice for trial documents held by the Principal Investigator to be archived by their host organisation and responsibilities should be defined in any relevant agreements. Researchers should be aware of the specific arrangements for their trials.

For non-CTIMP research, the archive time period is usually stipulated by the sponsor and/or local SOPs/policies.

Further reading & Workstream Documents:

- Trial Documentation station.
- Trial Master File station.
- EMA Reflection paper on expectations for electronic source data and data transcribed to electronic data collection tools in clinical trials (PDF, 127 KB (.PDF)).
- MRC Ethics Series: Good research practice: Principles and guidelines.