Archiving

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Introduction

The documents which individually and collectively permit evaluation of the conduct of a clinical trial and the quality of the data produced are defined as essential documents according to ICH GCP E6 (pdf) (.PDF).

These documents service to demonstrate the compliance of the investigator, sponsor and monitor the standards of GCP and with applicable regulatory requirements. They should be filed in an organised way that will facilitate management of the clinical trial, audit and inspection (Trial Master File).

Essential documents must be retained (archived) for sufficient periods to allow for audit and inspection by regulatory authorities and should be readily available upon request.

The Trial Master File should be set up at the beginning of a trial and maintained throughout the trial. Archiving applies to both the investigator sites and the central trial coordinating office.

Storage

Essential records should be maintained in a legible condition. Prompt retrieval should be possible. Plans for archiving trial documents should be made in the design phase of a trial and costs of storage should be considered. Adequate and suitable space should be provided for the secure storage of all essential records upon trial completion. The facilities should be secure, with appropriate environmental controls and adequate protection from fire, flood and unauthorized

access. The storage of the sponsor's documentation may be transferred to a sub-contractor (e.g. a commercial archive) but the ultimate responsibility for the quality, integrity, confidentiality and retrievability of the documents resides with the sponsor (CPMP/ICH/135/95, 5.2.1). This means that the sponsor should audit the site and satisfy itself and document that the storage is appropriate.

Access to archives should be restricted to authorised personnel. Any change in the ownership and location of the documentation should be documented in order to allow tracking of the stored records.

An archive index/log should be maintained to record all essential documents that have been entered into the archive, and to track and retrieve documents on loan from the archive. The investigator should make the sponsor/trial organisers aware of the storage arrangements for the documents to be stored at investigator sites. If the investigator becomes unable to store their essential documents, the sponsor/trial organisers should be notified in writing so that alternative storage arrangements can be agreed. If the investigator is no longer able to maintain custody of their essential documents, the sponsor/trial organisers should be notified in writing and the investigator/institution see to it that appropriate arrangements can be made.

Storage of personal data is subject to applicable elements of EU Directive 95/46/EC and the Data Protection Act 1998.

Duration of archiving

The sponsor/someone on behalf of the sponsor should consider whether the results of a trial will or may be included in a marketing authorisation application and should take the necessary steps to ensure appropriate retention of the essential documents (see Trial Master File station).

Consideration of site specific archiving requirements, as detailed by each R&D Department, is essential as these may differ from those outlined below.

a. Trials which are not to be used in regulatory submissions

Essential documents of the sponsor/trial organisers and investigators, from trials that are not to be used in regulatory submissions, should be retained for at least five years after completion of the trial. These documents should be retained for a longer period if required by the applicable regulatory requirement(s), the sponsor

or the funder of the trial.

b. Trials to be included in regulatory submissions

i. Sponsor's responsibilities: The sponsor should retain all sponsor-specific essential documents in conformance with the applicable regulatory requirement(s) of the country / countries where the product is approved, and / or where the sponsor intends to apply for approval(s). The sponsor-specific essential documents should be retained until at least two years after the last approval of a marketing application in the EU. These documents should be retained for a longer period if required by the applicable regulatory requirement(s) or if needed by the sponsor. The requirements of Annex 1 to Directive 2001/83/EC (pdf) (.PDF) shall be complied with. In addition ICH GCP E6 (pdf) (.PDF) guidelines will apply.

ii. Investigator responsibilities: Essential documents should be retained until at least two years after the last approval of a marketing application in the EU. These documents should be retained for a longer period however if required by the applicable regulatory requirement(s) or by agreement with the sponsor. It is the responsibility of the sponsor/someone on behalf of the sponsor to inform the investigator/institution as to when these documents no longer need to be retained. In addition the requirements of Annex 1 to Directive 2001/83/EC (pdf) (.PDF) shall be complied with.

Destruction of essential documents

The reasons for destruction of essential documents should be documented and signed by a person with appropriate authority. This record should be retained for a further five years from the date that the essential documents were destroyed.

The sponsor/someone on behalf of the sponsor should notify investigators in writing when their trial records can be destroyed.