

Standard Operating Procedure

Archiving	
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SHIELD Study – Archiving procedure

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1. Introduction

Appropriate documents must be in place to archive relevant study documents and data at the end of the SHIELD study, in accordance with regulatory requirements^{1,2}. As SHIELD is a clinical trial of investigational medicinal products (ctIMP), the Medicines for Human Use (Clinical Trials) Amendment Regulations 2006 (Statutory Instrument 2006, No 1928) apply and confirm legal obligations for archiving essential documentation².

This procedure documents the responsibilities and procedures for archiving documents at the end of the SHIELD study, according to sponsor requirements. This procedure applies to all personnel who have responsibility for archiving documents for the SHIELD study on behalf of the sponsor.

2. Definitions

Essential Documentation – Documents which individually and collectively permit evaluation of the conduct of the SHIELD study and the quality of the data produced. Essential documents show whether the trial has been conducted in accordance with applicable regulatory requirements.²

Site closure – The process of ensuring that all study-related activities at participating sites are reconciled and/or complete.

Study closure – The process of ensuring that all study-related activities are reconciled and/or complete.

3. Procedure for archiving documents

3.1 Responsibility for archiving

The sponsor is responsible for ensuring that arrangements are in place to archive essential documentation in accordance with regulatory requirements, although for the SHIELD study this task is delegated to the Chief Investigator and study team.

As SHIELD is a multi-centre study, responsibility for archiving essential documentation at an individual site is delegated to the Principal Investigator under guidance of the Sponsor and Chief Investigator. Arrangements are agreed with the Sponsor and Chief Investigator, and documented during site set-up and in the Clinical Trial Agreement.

Any subsequent transfer of ownership and responsibility for data retention and archiving must be agreed and documented, including where a Chief/Principal Investigator leaves an institution during the period of archive².

3.2 Archiving essential documents

3.2.1 When to archive

Essential documents should be archived as soon as is practical after site/study closure. Ensure that documentation is kept for a minimum of 15 years following the end of the study, unless local arrangements require a longer period.

3.2.2 What to archive

All essential documentation must be archived, according to applicable regulatory requirements. This may include:

Trial Master Files

Investigator site files

Source documents (including medical records where relevant)

At the end of the study, each site will receive a CD from the Study Centre with their individual patient data, obtained from the SHIELD Study data collection website (www.shieldstudy.co.uk). This disc should be archived with all other study material.

3.2.3 How to archive

The nature, location and duration of archiving will be as defined by the study sponsor or delegate and/or study documentation^{1,2}. Essential documents must be archived in a way that ensures that documents remain complete and legible and are readily available on request if needed for subsequent audit or inspection.

Archiving facilities must be secure, environmentally controlled, with access restricted to named individuals who are responsible for the archives². Data must also be stored in a way to ensure that the confidentiality of participants remains protected¹.

Following the required archive period, the sponsor or delegate must inform the investigator(s)/institution(s) in writing that archival records are no longer needed³. Disposal must be performed in a manner that maintains confidentiality and in accordance with sponsor or delegate requirements.

4. References

1. "Department of Health Research Governance Framework for Health and Social Care"
(http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4108962)
2. The Medicines for Human Use (Clinical Trials) Amendment Regulations 2006 (Statutory Instrument 2006, No 1928) <http://www.legislation.hmsso.gov.uk/si/si2006/20061928.htm>)
3. International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use. ICH Harmonised Tripartite Guideline. Guideline for Good Clinical Practice E6(R1), Current Step 4 version (dated 10 June 1996) (<http://www.ich.org/LOB/media/MEDIA482.pdf>)