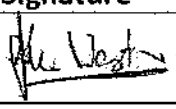
STANDARD OPERATING PROCEDURE (SOP)

SOP Number: CP/R&D_011

SOP Title: Archiving of pharmacy clinical trial documentation

Role	Name	Signature	Date
SOP Author	Alex Weston- Principal Pharmacist R&D		02-Mar-2018
SOP Reviewer	Victoria Croome- Clinical Trials Technician		06-Mar-2018
SOP Authoriser	Raj Parekh- Chief Pharmacist		05-APR-2018
SOP Review Date	**June 2018**		

Review History

Version	Effective Date	Review Undertaken/Significant Changes	Date Approved
1	01-Nov-2012	Initial Version	01-Nov-2012
2	27-May-2016	Template updated to include additional sections and further guidance in preparation of SOPs	
3	1-June-2018	Review to ensure that content is current	05-Apr-2018

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1. PURPOSE AND CONTEXT

1.1 To describe the procedures for archiving pharmacy clinical trials documentation following trial close-out.

1.2 Covers the procedures to follow at the conclusion of a trial, including:

- Preparation of the pharmacy site file for archiving
- Determining archiving arrangements

2. DEFINITIONS

3. PROCEDURE and RESPONSIBILITIES

3.1 Determining archiving arrangements

3.1.1 Refer to the clinical trial agreement/contract to confirm the agreed archived location and period for the clinical trial in question.

- The pharmacy site file should never be sent directly to the sponsor organisation unless it is a locally sponsored trial.
- The archiving period will be determined by a number of factors, taking into account the type of clinical trial and how the clinical trial data is intended to be used.

3.1.2 If in doubt, contact the named archivist or R&D department for information on archiving arrangements.

3.2 Preparation of pharmacy site file for archiving

3.2.1 Do not proceed with pharmacy site file archiving until all steps listed in the standard operating procedure for *Trial close-out SOP* (CP/R&D_017) have been completed.

3.2.2 Ensure all clinical trial medication has been disposed/destroyed locally or returned to the sponsor.

3.2.3 Check to ensure the following paper based records, as a minimum, are present in the pharmacy site file:

- Trial specific pharmacy instructions (all versions)
- Staff training records
- Completed prescriptions
- Clinical trial medication accountability records

- Clinical trial medication disposal/ destruction records
- Clinical trial medication preparation worksheets (if appropriate)
- Clinical trial medication order and receipt records
- All relevant correspondence
- Final close-out visit report
- Temperature records
- Calibration certificates of equipments

3.2.4 Where paper-based records listed in step 3.2.3 are archived separately (e.g. temperature data, staff training records), create a signed and dated file note detailing the archiving arrangement of these records and file in the pharmacy site file. Systems should be in place to ensure the retention schedule of these records meet the agreed archiving period for the trial.

3.2.5 Where records listed in step 3.2.3 are to be archived in an electronic format, create a signed and dated file note detailing the archiving arrangement of these records and file in the pharmacy site file. Systems should be in place to ensure the retention schedule of these records meet the agreed archiving period for the trial.

[Note: Electronic records should be archived in such a way as to ensure their reliability, authenticity, integrity and usability at all times. The requirements for electronic archiving should have been considered as a key aspect at the point of the procurement or development any computerised system that creates, captures and manages electronic records. Technical and functional requirement specifications for such computer systems should include requirements for long-term storage, preservation, management, retrieval of their electronic records and security.]

3.2.6 Remove all contents of the pharmacy site file from its folder/lever arch file, ensuring any plastic wallets are also removed. Secure the documents using treasury tags to ensure the previous file order is maintained.

3.2.7 If appropriate, bundle all documents together in a paper file wallet.

3.3 Archiving of paper-based records (via third parties e.g. R&D department)

3.3.1 Liaise with the principal investigator or named archivist or R&D department to arrange a date for collection of the pharmacy site file.

3.3.2 Create an inventory/record including information on:

- Trial reference
- Archived reference (if appropriate)
- Basic list of contents of the pharmacy site file
- Name of the person collecting the pharmacy site file
- Job title, telephone number (and email address if appropriate) of the person collecting the pharmacy site file
- The date and time the file was collected
- Where the pharmacy site file will be taken in the first instance
- The intended archiving location/ organisation

3.3.3 Hand over the pharmacy site file.
3.3.4 Obtain a signature from the person collecting the pharmacy site file.
3.3.5 Retain the inventory/record in pharmacy for reference.

3.4 Archiving of paper-based records (in pharmacy)

3.4.1 Create a signed and dated file note detailing the archiving arrangement of the pharmacy site file.
3.4.2 Provide the principal investigator with the signed and dated file note; the file note is to be filed in the main investigator site file.
The length of time of archive must be agreed with the Sponsor
3.4.3 For trials not being used in Regulatory Submissions this should be **at least five years** after the completion of the trial
3.4.4 For trials to be included in Regulatory Submissions this should be **at least two years after the last approval of a marketing application in the EU** or 15 years (whichever is longer).

	Responsibility	Undertaken by	Activity
1	Chief Pharmacist	Clinical Trials Pharmacist	Ensure processes are in place for the archiving of documents
2			
3			

4. SUPPORTING MATERIAL and ATTACHMENTS

- CP/R&D_017 – Trial close-out SOP

5. TRAINING

- Knowledge of the Trial protocol
- Knowledge of the Sponsors arrangements for archiving
- Knowledge of the Medicines for Human Use (Clinical Trial) Regulations and ICH-GCP

6. REFERENCES