STANDARD OPERATING PROCEDURE (SOP)

SOP Number: CP/R&D_003

SOP Title: Maintaining a pharmacy site file

Role	Name	Signature	Date
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SOP Reviewer	Victoria Croome – Clinical Trials Technician		06-MAR-2018
SOP Authoriser	Raj Parekh - Chief Pharmacist		05-APR-2018
SOP Review Date	**June 2020**		

Review History

Version	Effective Date	Review Undertaken/Significant Changes	Date Approved
1	November 2012	V.1- Initial Version	14-Nov-2012
2	August 2016	V.2 – checked to ensure SOP is still current and make reference to other applicable SOPs	
3	1-June-2018	Reviewed to ensure content is still current	05-Apr-2018

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1. PURPOSE AND CONTEXT

1.1. This standard operating procedure (SOP) describes how a pharmacy site file must be maintained, to ensure that there is a complete record of medicines management of the Investigational Medicinal Product (IMP)

2. DEFINITIONS

- Medicines Management- this term covers all activities relating to IMPs.

3. PROCEDURE and RESPONSIBILITIES

3.1 Procedure

3.1.1 The main pharmacy site file may contain the following documents:

- Protocol and any amendments
- Regulatory and ethics approvals
- Latest version of the investigator's brochure
- Copy of patient information leaflet
- Drug accountability logs
- Prescription forms
- Receipt and return of study medication forms
- Signature log
- Correspondence
- Temperature logs
- Clinical Trials Pharmacist Curriculum Vitae
- Financial and confidentiality documents
- Code break procedure information

3.1.2 Whilst the trial is active some of the documents listed above may be put into the pharmacy working documents file. See SOP CP/R&D_024 for reference.

3.1.3 If a document is filed somewhere other than in the pharmacy site file then a file note should be used to indicate where the document can be found.

3.1.4 Pharmacy staff and site staff involved with medicines management should ensure that the pharmacy site file contains the correct versions of documents and that the trial paperwork is fully completed whenever any activities are undertaken.

3.1.5 Any errors must not be obliterated. They should be crossed through with a single line and signed and dated.

	Responsibility	Undertaken by	Activity
1	Chief pharmacist	Clinical trials pharmacist / Clinical trials technician/Site staff	The clinical trials pharmacist has overall responsibility for maintaining the pharmacy site file, but on a day-to-day basis the responsibility for keeping the file up to date may be delegated to other staff.
2			
3			

4. SUPPORTING MATERIAL and ATTACHMENTS

- SH CP 01 Medicines Control, Administration and Prescribing Policy
- CP/R&D_022 Set up of clinical trial pharmacy site file
- CP/R&D_024 Set up of clinical trial working documents file

5. TRAINING

- ICH-GCP training
- An understanding of protocol requirements

6. REFERENCES