STANDARD OPERATING PROCEDURE (SOP)

SOP Number: CP/R&D_022

SOP Title: Set up of clinical trial pharmacy site file

Role	Name	Signature	Date
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Review History

Version	Effective Date	Review Undertaken/Significant Changes	Date Approved
1	27-May-2016	Initial Version	09-Feb-2016
2	1-June-2018	Reviewed to ensure content still current	05-Apr-2018

STANDARD OPERATING PROCEDURE (SOP)

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1. PURPOSE AND CONTEXT

1.1 To describe the procedures for setting up a clinical trial pharmacy site file (PSF) in order to ensure that the file contents permits accurate reconstruction of the clinical trial medications.

1.2 Covers the procedures to follow when setting up a clinical trial PSF, including information on the layout and contents of a paper based PSF. The procedure for maintaining PSF is covered in the procedure for internal audit and maintenance of clinical trial pharmacy site file

2. DEFINITIONS

PSF – Pharmacy site file

3. PROCEDURE and RESPONSIBILITIES

3.1 Supply of the pharmacy site file (PSF)

3.1.1 Assess the need to create a pharmacy site file (PSF) locally as part of the pharmacy feasibility assessment of a clinical trial. In general, PSF is supplied by the sponsor.

3.2 Indexing of pharmacy site file (PSF)

3.2.1 To ensure consistency of the PSF contents and to standardise local processes for clinical trial medication management, arrange a pharmacy-produced PSF in line with the *Pharmacy site file index* (Form 05).

3.2.2 For sponsor-supplied PSF, retain the original sponsor-supplied index in the PSF.

3.3 Creating a pharmacy site file (PSF)

3.3.1 Obtain a suitable file.

3.3.2 Index the spine of the PSF by adding the following information:

- Label the file as the "Pharmacy site file"
- EudraCT number
- Study short name
- Name of principal investigator

3.3.3 Create a PSF index using the Pharmacy site file index template (Form 05).

3.3.4 Add the PSF index to the front of the PSF.

3.3.5 Following the PSF index, add the relevant clinical trial documentation to each section.

3.3.6 Contact and request the sponsor to send any documentation that is required but missing. It is important to note that some documentation may not be needed in the pharmacy site file where risk adapted approach to trial management is being followed.

3.3.7 Where appropriate and relevant for the clinical trial concerned, create local documents such as clinical trial prescription, accountability logs, file notes etc (see section 3.4).

3.3.8 Add a file note to the relevant sections of the PSF in situations where documents are being stored centrally by pharmacy (e.g. temperature records) or are not required.

3.4 Creating clinical trial documents for local use

3.4.1 Locate document templates (electronically stored) and use them as templates to create trial specific documents for local use, including but not limited to:

- Trial specific pharmacy instructions
- Clinical trial prescription, where appropriate
- Accountability logs, where appropriate
- Clinical trial medication preparation worksheets, where appropriate
- File notes, where appropriate
- Pharmacy site initiation visit attendance log, where appropriate
- Pharmacy monitoring visit log, where appropriate

3.4.2 Ensure all locally created clinical trial documents are version controlled and where necessary approved by the sponsor prior to use.

3.4.3 Store master copy of these clinical trial documents in such a way that access is limited so to ensure its integrity.

3.4.4 Retain all superseded versions of locally created clinical trial documents in the pharmacy documents control folder (see SOP CP/R&D_026).

	Responsibility	Undertaken by	Activity
1	Chief pharmacist	Clinical trials pharmacist	The clinical trials pharmacist has overall responsibility for the set-up of the pharmacy site file but may delegate some tasks to other authorised members of the site team
2	Clinical trials pharmacist	Pharmacy and other authorised members of the site team	Setting up of the pharmacy site file
3			

4. SUPPORTING MATERIAL and ATTACHMENTS

- Pharmacy site file index template (Form 05)

5. TRAINING

- ICH-GCP training.
- An understanding of dispensing procedures.
- An understanding of the protocol procedures to write dispensing instructions which comply with protocol.
- An understanding of trial legal requirements needed before commencement of trial.

6. REFERENCES