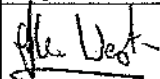

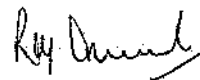


**STANDARD OPERATING PROCEDURE (SOP)**

SOP Number: CP/R&amp;D\_024

SOP Title: Set up of clinical trial pharmacy working documents file

Role	Name	Signature	Date
SOP Author	Alex Weston- Principal Pharmacist R&D		05-Mar-2018
SOP Reviewer	Victoria Croome- Clinical Trials Technician		08-Mar-2018
SOP Authoriser	Raj Parekh- Chief Pharmacist		05-APR-2018
SOP Review Date	June 2020	Effective date to 31/03/2020	

**Review History**

Version	Effective Date	Review Undertaken/Significant Changes	Date Approved
1	27-May-2016	Initial Version	9/2/16
2	1-June-2018	Reviewed to ensure content still current	05-Apr-2018

## STANDARD OPERATING PROCEDURE (SOP)

**SOP Number: R&D\_024**

**SOP Title: Set up of clinical trial pharmacy working documents file**

### 1. PURPOSE AND CONTEXT

- 1.1. To describe the procedures for setting up a clinical trial pharmacy working documents file 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 pharmacy working documents file, including information on the layout and contents of a paper based file.

### 2. DEFINITIONS

### 3. PROCEDURE and RESPONSIBILITIES

#### 3.1 Creating a pharmacy working documents file

- 3.1.1 Obtain a suitable file.
- 3.1.2 Index the spine of the file by adding the following information:
  - Label the file as the "Pharmacy working documents file"
  - EudraCT number
  - Study short name
  - Name of principal investigator
- 3.1.3 Create an index using the *Pharmacy working documents file index template (Form 08)*.
- 3.1.4 Add the index to the front of the file.
- 3.1.5 Following the pharmacy working documents file index, add the relevant clinical trial documentation to each section.
- 3.1.6 Documentation included but not limited to:
  - Trial specific pharmacy instructions ("How to" guides)
  - Delegation log
  - Signature log
  - Patient accountability log

- Drug accountability logs
- Receipt of drug logs
- Master log sheets
- Master label sheets
- Location reference of protocol

3.1.7 The pharmacy working documents file is for day-to-day use alongside the main pharmacy site file. When the trial is complete ensure all the documentation from the working file is put back into the main pharmacy site file.

	<b>Responsibility</b>	<b>Undertaken by</b>	<b>Activity</b>
1	Chief pharmacist	Clinical trials pharmacist	The clinical trials pharmacist has overall responsibility for the set-up of the pharmacy working documents 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 working documents file
3			

#### 4. SUPPORTING MATERIAL and ATTACHMENTS

- Pharmacy working documents file index (Form 08)

#### 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