**STANDARD OPERATING PROCEDURE (SOP)**

**SOP Number: CP/R&D_008**

**SOP Title: Reconciliation of Investigational Medicinal Products**

| Role | Name | Signature | Date |
|---|---|---|---|
| **SOP Author** | Alex Weston – Principal Pharmacist R&D | | 02-Mar-2016 |
| **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 | 01-Dec-2012 | V.1- Initial Version | 14-Nov-2012 |
| 2 | August 2016 | V.2 – Reviewed to ensure content still current | |
| 3 | 1-June-2018 | Reviewed to ensure content still current | 05-Apr-2018 |

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## 1. PURPOSE AND CONTEXT

- Accurate records must be kept in order to provide a full audit trail of Investigational Medicinal Products (IMPs) and the compliance of patients participating in the clinical trial.

## 2. DEFINITIONS

- Compliance – a comparison of how much medication a patient in a clinical trial of an IMP has taken compared to the amount that should have been taken.

## 3. PROCEDURE and RESPONSIBILITIES

### 3.1. Accountability logs

3.1.1. Master drug and/or patient specific accountability logs are completed as part of the dispensing process when the patient is issued the IMP.

3.1.2. When IMP is returned the number of dose units returned should be counted and this information used to complete the master drug and/or patient specific accountability logs as required by the protocol.

### 3.2. Compliance

3.2.1. In order for a patient to continue in a clinical trial there must be evidence that they have taken at least the minimum number of doses and no more than the maximum number of doses allowed by the protocol.

3.2.2. Calculate the percentage compliance using the following calculation:

$$\frac{Number\ of\ doses\ taken}{Number\ of\ doses\ that\ should\ have\ been\ taken} \times 100 = \%\ doses\ taken$$

3.2.3. Check that the percentage is over the minimum and below the maximum allowed in the protocol

3.2.4. If the percentage is less than the minimum or more than the maximum follow the instructions in the protocol.

3.2.5. It may not be easy to assess compliance with some formulations of IMPs (e.g. using

pre-filled pens which are not graduated to allow individual dose compliance to be measured). In this case, seek sponsor advice on how compliance will be monitored.

### 3.3. Storage of returned drug

3.3.1. See CP/R&D_018

| | Responsibility | Undertaken by | Activity |
|---|---|---|---|
| 1 | Chief pharmacist | Clinical Trials Pharmacist | Checking that the level of compliance is checked, accountability logs are completed and returned IMP is stored correctly |
| 2 | Clinical Trials Pharmacist | Staff receiving returned IMP | Checking the level of compliance, completing accountability logs and storing IMP |
| 3 | | | |

## 4. SUPPORTING MATERIAL and ATTACHMENTS

- SH CP 1 Medicines Control, Administration and Prescribing Policy
- CP/R&D_018 Processing of returned clinical trial medication

## 5. TRAINING

- ICH-GCP training
- Protocol training to assess compliance in accordance with protocol requirements.

## 6. REFERENCES