





## Investigational Product Management 301-02

### 1. Purpose

The purpose of this operating procedure is to define the procedure for management of the investigational product inventory.

### 2. Responsibilities

**Qualified Investigator (QI):** Is responsible for following the protocol and associated procedures concerning the management of Investigational Product.

**CERU:** CERU, under the guidance of the Sponsor, is responsible for ensuring government legislation and ICH Guidelines regarding the handling, storage and supply of the investigational product are followed.

### 3. Procedures

#### Investigational Product Management

- 3.1 CERU, under the direction of the Sponsor, is responsible for supplying the research sites with the investigational product (IP).
- 3.2 CERU may delegate the IP inventory management to an external party (e.g. manufacturer of the product).
- 3.3 CERU should not supply a research site with IP until all site activation requirements have been met (refer to SOP 214: Research Site Activation).
- 3.4 CERU should ensure that the research site is provided with written procedures concerning:
  - 3.4.1 IP storage conditions
  - 3.4.2 IP shipping and handling instructions
  - 3.4.3 IP dispensing
  - 3.4.4 IP destruction or return
- 3.5 CERU should ensure that the research site maintains, and when requested, provides written documentation concerning:
  - 3.5.1 Handling and receipt of IP.
  - 3.5.2 IP storage conditions, including temperature logs.
  - 3.5.3 IP delivery, inventory and return.
  - 3.5.4 IP use records, including accountability and inventory logs, training of staff involved with these processes (e.g. site Pharmacy staff).
  - 3.5.5 IP destruction or return.
- 3.6 CERU, or delegate, should ensure timely delivery and adequate IP supplies at the research sites.
- 3.7 CERU, or delegate, should maintain documentation concerning investigational product shipment, receipt, disposition, return and destruction.



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3.8 CERU, or delegate, should maintain a tracking system for the investigational product to ensure easy retrieval of recalled product (e.g. defect recall, trial completion, expired product) and unused product.

3.9 CERU should maintain documentation concerning investigational product stability, specification conformance and batch sample analysis.

### Investigational Product Labeling

3.10 The manufacturing, labeling, packaging and shipping of IPs (including placebo, if applicable) is the responsibility of the product manufacturer, unless these tasks have been delegated to another party.

3.11 The labels applied to the IP must not be hidden or covered, withdrawn or modified without authorization from CERU.

3.12 An additional patient specific study label should be applied to IP once it has been assigned to a particular randomized patient. The patient specific product label should contain at a minimum:

3.12.1 A statement indicating that the IP is an investigational drug to be used only by a qualified investigator.

3.12.2 The name, number of identifying mark of the IP.

3.12.3 The expiration date of the IP.

3.12.4 The recommended storage conditions for the IP.

3.12.5 The lot number of the IP.

3.12.6 The name and address of the Sponsor.

3.12.7 The protocol code or identification number.

### Investigational Product Storage

3.13 IP should be stored in a secure location with controlled access.

3.14 The secure location should have controlled temperature and humidity.

3.15 The storage conditions of the IP should be recorded regularly, either automatically or manually.

3.16 A disaster plan should be in place to relocate the IP if the necessary storage requires are unable to be met in the regular storage environment.

3.17 Storage records should be within easy access of the IP.

3.18 All documentation related to storage should be maintained in the study files.

### Return/Destruction of Investigational Product

3.19 At the end of the study, unused IP should be returned or disposed of as per the study specific procedures.

3.20 File IP return/destruction records with the study files.



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#### **4. References**

- 4.1 ICH GCP Section 5.13: Manufacturing, Packaging, Labeling, and Coding of Investigational Products
- 4.2 ICH GCP Section 5.14: Supplying and Handling Investigational Products
- 4.3 Food and Drug Regulations, Division 5: Drugs for Clinical Trials Involving Human Subjects section C.05.012, 3(e).
- 4.4 Network of Networks Standard Operating Procedures for Clinical Research (N<sub>2</sub> organization).