HEALTH SCIENCES AUTHORITY

REGULATORY GUIDANCE

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CLINICAL TRIALS GUIDANCE

ALTERNATIVE APPROACHES FOR INVESTIGATIONAL PRODUCT MANAGEMENT FOR CLINICAL TRIALS OF LOCALLY REGISTERED PRODUCTS

GN-IOCTB-08 Rev. No. 003

HSA Health Sciences Authority

PREFACE

This document is intended to provide general guidance. Although we have tried to ensure that the information contained here is accurate, we do not, however, warrant its accuracy or completeness. The Health Sciences Authority (HSA) accepts no liability for any errors or omissions in this document, or for any action / decision taken or not taken as a result of using this document. If you need specific legal or professional advice, you should consult your own legal or other relevant professional advisers.

In the event of any contradiction between the contents of this document and any written law, the latter should take precedence.

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REVISION HISTORY

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SUMMARY OF AMENDMENTS

- Updated the background (Section 1.2) to provide context by incorporating the key concept of proportionate and risk-based approaches to IP management for locally registered products in accordance with the ICH E6(R3) GCP Guideline.
- Included definition for registered product (Section 1.4).
- Included a new section (Section 2) on delegation, oversight, qualification and training in relation to IP management.
- Clarified risk proportionate approaches for IP storage (Section 4), preparation, dispensing and accountability (Section 5).

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1. INTRODUCTION

1.1. Purpose

The purpose of this guidance to provide alternative approaches for Investigational Product (IP) management for clinical trials of locally registered therapeutic products[1] or locally registered Class 2 cell, tissue or gene therapy products (CTGTPs)[1,2].

1.2. Background

In a clinical trial, locally registered products may be stored, prepared, dispensed, administered or destroyed in accordance with routine clinical practice, and may be managed using existing hospital/pharmacy systems and/or policies. As such in line with the ICH E6 (R3) Good Clinical Practice (GCP) guideline, a proportionate and risk-based approach is adopted to IP management for locally registered products without compromising the principles of GCP, and which avoids unnecessary burden on the investigator site team. Ultimately, IP management should be arranged and conducted in accordance with applicable regulatory requirements, and safeguards should be in place to ensure product integrity, product use in accordance with the trial protocol and participant safety.

[1] Therapeutic Product and CTGTP are defined in the First Schedule to the Health Products Act.

[2] Class 1 and Class 2 CTGTP are defined in the Health Products (Cell, Tissue and Gene Therapy Products) Regulations.

- Class 1 CTGTP means a CTGTP that —
  (a) is the result of only minimal manipulation of human cell or tissue;
  (b) is intended for homologous use;
  (c) is not combined or used with a therapeutic product or a medical device; and
  (d) is assigned by HSA as a Class 1 CTGTP due to a lower health risk to a user of the product.
- Class 2 CTGTP means a CTGTP other than a Class 1 CTGTP.

1.3. Scope

1.3.1. This guidance applies to clinical trials where:

(a) a Clinical Trial Certificate (CTC), Clinical Trial Authorisation (CTA) or Acceptance of Clinical Trial Notification (CTN) has been issued by HSA; and

(b) the Investigational Product is a locally registered therapeutic product or locally registered Class 2 CTGTP.

1.3.2. These alternative approaches will only be applicable to IP receipt, storage, dispensing, accountability, return and destruction.

1.3.3. These alternative approaches will not be applicable to the need to maintain written instructions for IP Management, IP Repackaging, and IP Labelling.

1.4. Definitions

1.4.1. Registered Product

A Registered Product refers to a product that is registered in Singapore (i.e., locally registered product), i.e., it has the same strength, composition, formulation, route of administration and is manufactured by the same manufacturer as the locally registered product.

2. DELEGATION, OVERSIGHT, QUALIFICATION AND TRAINING

The responsibility for IP management, including accountability, handling, dispensing, administration and return, rests with the investigator / institution.

2.1. Delegation

2.1.1. The investigator may delegate persons or parties involved in IP management. The investigator should ensure a record (e.g., delegation log) is maintained of the persons and parties to whom the investigator has delegated trial-related activities.

2.1.2. **Proportionate approach for documentation of delegation**

Documentation of delegation should be proportionate to the significance of the trial-related activities. In situations where the activities are performed as part of clinical practice, delegation documentation may not be required. For example, it may not be necessary to maintain a delegation log for the persons or parties involved in IP management if the IP is a registered product that is managed in accordance with routine clinical practice. However, it would be recommended to document their involvement in an alternative documentation (e.g., email to the relevant Head of Department or Note to File etc.), in order to provide clarity on their involvement.

2.2. Investigator Oversight

2.2.1. The investigator retains the ultimate responsibility and should maintain appropriate oversight of the persons or parties involved in IP management to ensure the rights, safety and well-being of the trial participants and the reliability of data.

2.2.2. **Proportionate approach for level of investigator oversight**

The level of investigator oversight of the delegated activities should depend on the nature of the delegated activities and be proportionate to the importance of the data being collected and the risks to trial participant safety and data reliability. In relation to IP management, the level of investigator oversight will depend on a number of factors, including the characteristics of the investigational product, route and complexity of administration, level of existing knowledge about the investigational product's safety and marketing status. For example, less intensive investigator oversight may be sufficient if the IP is a registered product managed in accordance with clinical practice.

2.3. **Qualification and Training**

2.3.1. The investigator should ensure that persons or parties to whom the investigator has delegated trial-related activities are appropriately qualified and are adequately informed about relevant aspects of the protocol, the investigational product(s) and their assigned trial activities (including activities conducted by staff provided by other parties in accordance with local regulatory requirements).

2.3.2. **Proportionate approach to training**

Trial-related training to persons assisting in the trial should correspond to what is necessary to enable them to fulfil their delegated trial activities that go beyond their usual training and experience. For example, it may not be necessary to train the persons or parties involved in IP management on the entire trial protocol if the IP is a registered product managed in accordance with routine clinical practice. However, it would be recommended to provide trial-related information about IP management (e.g., Pharmacy Manual, written instructions etc.) and relevant updates to them, and maintain relevant training documentation.

3. IP RECEIPT

3.1. The investigator should maintain records of IP receipt and inventory at the investigator (e.g., IP shipment receipts and inventory logs).

3.2. **Alternative approaches for IP Receipt**

3.2.1. **IP sourced from institution stock**

IP inventory Logs may not be required to be maintained if the IP is sourced from the pharmacy stock. If the pharmacy does not have a system of tracking the batch number and expiry date of the IP, this information should be tracked on the IP dispensing log or equivalent documentation.

4. IP STORAGE

4.1. The investigator should ensure that the IP is stored as specified by the sponsor and in accordance with applicable regulatory requirements.

4.1.1. Thus, the investigator should ensure that:

(i) Written instructions (e.g., Pharmacy Manual, Standard Operating Procedures (SOPs), Work Instructions etc.) are available and maintained for IP storage;

(ii) The IP is stored in an area where the access is secure and limited and within the recommended storage temperature range;

(iii) IP storage temperature records are maintained;

(iv) An alarm system is available to detect temperature excursions;

(v) In the event of a temperature excursion, the temperature excursion is reported to the sponsor, the affected batches of IP are quarantined, and a back-up plan is available; and

(vi) The equipment used for IP storage are calibrated and maintained, and calibration and maintenance reports maintained.

4.2. **Alternative Approaches for IP Storage**

4.2.1. Separate IP storage temperature records may not be required if the IP storage temperature is centrally monitored (e.g., by the pharmacy or facilities management etc.).

4.2.2. If the institution does not maintain temperature records for locally registered products stored at the pharmacy (e.g., ambient storage conditions) but has an alarm system in place to detect temperature excursions, the sponsor should request for a copy of the institution's temperature monitoring SOP. The sponsor should assess whether the arrangement adequately demonstrates that the storage conditions for the product would be adequately maintained within the required temperature range, despite the absence of temperature records.

5. IP PREPARATION, DISPENSING AND ACCOUNTABILITY

5.1. The investigator should maintain records of the use of the IP by each trial participant (including documenting that the participants were provided the doses specified by the protocol), and ensure that the IP is used only in accordance with the approved protocol.

5.1.1. Thus, the investigator should maintain IP preparation records, IP dispensing and accountability logs and IP administration records, where applicable.

5.2. **Alternative Measures for IP Preparation, Dispensing and Accountability and Administration**

5.2.1. IP dispensing and accountability logs may not be required if the protocol does not require the determination of IP compliance. However, it would be recommended to document the batch number and expiry date of the IP on the prescription or alternative document.

5.2.2. It may not be necessary to maintain separate IP preparation records if the IP is a registered product managed in accordance with routine clinical practice.

6. IP RETURN AND/OR DESTRUCTION

6.1. The investigator should maintain records of return and/or destruction of the IP.

6.2. **Alternative Measures for IP Destruction**

6.2.1. IP destruction records may not be required if the institution’s pharmacy system for destruction of pharmaceutical waste is utilised. It would be recommended to document and file the IP returns, and file a copy of the institution’s SOPs for destruction of pharmaceutical waste.

7. REFERENCES

(i) Health Products (Clinical Trials) Regulations

(ii) Medicines (Clinical Trials) Regulations

(iii) Health Products (Clinical Research Materials) Regulations

(iv) Medicines (Medicinal Products as Clinical Research Materials) Regulations

(v) ICH E6 (R3) Good Clinical Practice (GCP) Guideline

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