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Healthcare
Singapore

Clinical Trials for Therapeutic Products

Clinical trials of therapeutic products and Class 2 cell, tissue, and gene therapy products (CTGTP) are regulated by the Health Products Regulation Group of the Health Sciences Authority of Singapore (HSA).

Regulation Of Clinical Trials

The key legislation in Singapore governing the conduct of clinical trials of therapeutic products and Class 2 CTGTPs in Singapore are:

i. The Health Products Act
ii. The Health Products (Clinical Trials) Regulations (CT Regulations); and.
iii. The Health Products (Clinical Research Materials) Regulations (CRM Regulations)

A clinical trial is a research study of a health product to investigate the following in humans:

- Discover or verify its clinical, pharmacological or pharmacodynamics effects
- Identify any adverse effect that may arise from its use
- Study its absorption, distribution, metabolism and excretion
- Ascertain its safety or efficacy

All clinical trials on therapeutic products and Class 2 CTGTPs conducted in Singapore are required to be submitted through either of the following submission routes:

- A Clinical Trial Authorisation (CT Authorisation); or
- A Clinical Trial Notification (CT Notification).

A CT Authorisation is required for a higher risk clinical trial of a locally unregistered therapeutic product or Class 2 CTGTP, or involving an unapproved use of a locally registered therapeutic product or Class 2

Awards & Accolades

Band 1 for Life Sciences
Chambers Asia Pacific, Asia Pacific Region 2014 - 2025

Medical and Healthcare Law Firm of the Year
Asian Legal Business Southeast Asia Law Awards 2020 and 2021

Band 1 for Intellectual Property
Chambers Global, Asia Pacific Region 2009 - 2025

Band 1 for Intellectual Property, Singapore
Chambers Asia Pacific, Singapore 2010 - 2025

Tier 1 for Intellectual Property, Singapore
Legal 500 Asia Pacific, Singapore 2010 - 2025

Tier 1 for Patents and Copyrights/Trademarks in Singapore
ALB Asia IP Rankings 2018 - 2025

Asia Pacific Patents Firm of the Year
Asia IP Law 2023

Asia Pacific Trademark Firm of the Year
Asia IP Law 2024

Tier 1 for Trademark Contentious and Trademark Prosecution in Singapore
Asia IP Law 2025

Singapore: Copyright & Design;
Trade Mark Prosecution Firm of the Year
Asia Pacific: IP Law Firm of the Year (Foreign Firms)
Managing IP Asia Pacific Awards 2024

IP Transactions & Advisory Firm of the Year
Managing IP Asia Pacific Awards 2021 and 2023

Copyright & Design Firm of the Year
Managing IP Asia Pacific Awards 2019 – 2023

Global IP Firm of the Year
Managing IP Asia Pacific Awards 2017, 2018 and 2022

CTGTP. In contrast, a CT Notification is required for a lower risk clinical trial of a local registered therapeutic product or Class 2 CTGTP.

In addition, clinical trials regulated by the HSA must comply with the HSA's guidance the ICH E6 (R2) Good Clinical Practice Guidelines.

Clinical Research Materials (CRM)

The manufacture, import and supply of CRM in Singapore must comply with certain regulatory controls and obligations under the CRM Regulations. While the duties of a local manufacturer, importer and supplier may vary slightly, common obligations shared across all three groups include, but are not restricted to:

- Maintaining records of receipt and supply;
- Ensuring compliance with labelling requirements;
- Reporting CRM defects; and
- Notifying the HSA before the recall of any CRM

In addition, importers, manufacturers and wholesaler's generally must not import, manufacture or supply health products (e.g., therapeutic products and Class 2 CTGTP) without a valid importer's licence or importer notification, manufacturer's licence or manufacturer notification, or wholesaler's licence or wholesaler notification, respectively.

There may also be additional licenses and requirements to be met if the CRM contains specific materials (i.e., controlled drugs, psychotropic substances, poisons, or radiopharmaceuticals).

For HSA-regulated clinical trials, the CRM notification is made by the sponsor on behalf of the importer or the local manufacturer. This provides assurance that the importer or local manufacturer is authorised by the sponsor to import or manufacture the CRM.

There are also certain situations where a CRM notification is not required (e.g., locally registered CRM obtained from local commercial sources; unregistered therapeutic product CRM is obtained from stock already available at the hospital pharmacy, or imported via an exemption drug route on a named-patient basis or as buffer stock).

Clinical Trial Agreement (CTA)

As clinical trial agreements are private agreements between the parties and not subject to the HSA's review, there are generally no requirements that the parties must fulfill before entering into the CTA for clinical trials to be conducted in Singapore.

However, it is prudent to ensure that the CTA is reviewed for compliance with all applicable laws, regulations, and guidance in Singapore, so that the parties' respective rights and obligations do not fall foul of these.

The Sponsor

A sponsor, in relation to a clinical trial, means a person who takes responsibility for the initiation, management or financing of a clinical trial.

Every clinical trial may generally only have one sponsor. However, the HSA may allow in its discretion more than one sponsor for a clinical trial where all sponsors of the trial appoint a lead sponsor from amongst themselves.

The sponsor should be a locally registered business entity registered with the Accounting Corporate Regulatory Authority (ACRA) in Singapore, and has to comply with regulatory obligations including the following:

- Obtain the CT Authorisation or acceptance of CT Notification;
- Obtain approval for, or acceptance of notification of, substantial amendments to the clinical trial;
- Ensure that the clinical trial is conducted at location(s) specified in the clinical trial application;
- Carry out functions of the sponsor in accordance with the principles of good clinical practice;
- Put and keep in place arrangements to ensure compliance with the principles of good clinical practice;
- Notify the HSA of serious breaches within stipulated timelines;
- Notify the HSA of urgent safety measures taken to protect trial participants against immediate hazard within stipulated timelines; and
- Report unexpected serious adverse drug reactions within stipulated timelines.

If there is non-compliance with any guidelines or instructions in respect of sponsor obligations, duties and responsibilities under the relevant regulations, the sponsor may be exposed to criminal liability.

The Principal Investigator

The sponsor must ensure that the clinical trial is conducted by or under the supervision of a principal investigator. The CT Regulations require a principal investigator to be either:

- A qualified practitioner (i.e., a locally registered medical practitioner under the Medical Registration Act or a registered dentist under the Dental Registration Act);
- A qualified pharmacist (i.e., a locally registered pharmacist under the Pharmacists Registration Act who
  holds a valid practicing certificate and is in active practice as defined in the Pharmacists Registration (Practicing Certificates) Regulations); or

- A person qualified by education, training and experience who has adequate resources to properly conduct the trial.

For clinical trials assessing investigational products in specialised therapeutic areas (i.e., those which require complex diagnostic evaluation of the disease condition or involve study procedures requiring specialised skills), the principal investigator should at least be an Associate Consultant in the specialised therapeutic area.

The principal investigator has to comply with regulatory obligations including the following:

- Conduct clinical trials in compliance with the protocol, applicable regulations, the principles of good clinical practice, and any relevant standard operating procedures during said conduct;
- Conduct the clinical trials in the location(s) specified in the clinical trial application;
- Ensure that there is a system of traceability established and maintained at the trial site if the trial involves a class 2 ctgtp;
- Ensure that any individual to whom a task is delegated is qualified by education, training and experience to perform the delegated task;
- Maintain a list of appropriate qualified persons to whom significant trial-related duties have been delegated;
- Ensure that informed consent requirements are complied with;
- Declare every financial interest, including that of any person assisting the principal investigator, to the relevant institutional review board (irb); and
- Report serious adverse events within stipulated timelines to the sponsor, and the IRB if required.

If there is non-compliance with any guidelines or instructions in respect of principal investigator obligations, duties and responsibilities under the relevant regulations, the principal investigator may be exposed to criminal liability.

Intellectual Property and Data

Ownership of inventions and other IP rights are subject to the common law position governing the creation of intellectual property. The applicable regulations do not prescribe any specific rules in this regard.

Generally, issues related to intellectual property should be addressed by the parties at the outset via suitable contractual clauses in the CTA and ancillary agreements.

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