Baker McKenzie Wong & Leow.

Healthcare
Singapore

# Clinical Trials for Medicinal Products

Clinical trials are regulated by the Health Products Regulations Group of the Health Sciences Authority of Singapore.

All clinical trials on medicinal products conducted in Singapore require:

- A Clinical Trial Certificate from the Health Products Regulation Group of the HSA; and
- Approval from the respective Institutional Review Board or Ethics Committee.

The Medical Clinical Research Committee provides advice on the licensing of clinical drug trials.

The legislation in Singapore governing the conduct of clinical trials in Singapore are:

i. The Medicines Act (Cap. 176); and

ii. The Medicines (Clinical Trials) Regulations.

In addition, the Regulations provide that every sponsor, principal investigator, or holder of a CTC shall comply with any guidelines or instructions. relating to the conduct of clinical trials. issued by

The GCP is a set of substantive guidelines, which are to be adhered to in maintaining an international ethical and scientific quality standard for the conduct of clinical trials.

## 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
Chambers Asia Pacific, Singapore 2010 - 2025

Tier 1 for Intellectual Property
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

## Clinical Trial Agreement (CTA)

As clinical trial agreements are private agreements between the parties and not subject to the HSA's review, there are 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.

It may be required to submit CTAs in connection with obtaining approval from the respective Institutional Review Board or Ethics Committee.

Apart from the CTA, it is necessary to obtain a CTC to conduct clinical trials in Singapore, for which an application has to be submitted to the HSA. A local representative acting in the capacity of a local sponsor is responsible for making the application for the CTC and procuring the approval from the appropriate Institutional Review Board or Ethics Committee before initiation of the clinical trial.

The HSA will issue the CTC to the clinical investigator, in the name of the principal investigator. The CTC is specific for each study protocol, and for each institution or site involved in the study. Each CTC is valid for a period of two years unless otherwise stated.

## The Sponsor

There are two possible meanings of "Sponsor " in the Singapore context:

i. The ultimate sponsor located overseas; or

ii. The local representative acting in the capacity of local sponsor for the purpose of submitting the CTC application, and therefore assuming the obligations of a sponsor as the term is referenced in the Regulations and the GCP.

In (i), the legal functions of a sponsor are contractually agreed between the parties, given that such a sponsor is not treated in the same manner in the Regulations and the GCP for setting out the obligations, responsibilities, and duties of a sponsor under the Regulations and the GCP.

In (ii), the legal function of a sponsor (which is a local representative acting in the capacity of local sponsor) is to ensure compliance with the Act, Regulations, GCP, and all other applicable laws, regulations, and guidelines in Singapore, with regard to conducting the clinical trial and allancillary matters. In this regard, the Regulations define a sponsor (as understood in ii) above) as an individual, company, institution, or organisation which takes responsibility for the initiation, management, or financing of a clinical trial.

A sponsor, which is a local representative acting in the capacity of local sponsor, is also responsible for submitting the CTC application form. The CTC application form contains a declaration which must be made by the local sponsor to the effect that it undertakes to abide by the Act, Regulations, GCP, and any other conditions imposed by the HSA in conducting the clinical trial. The local representative also undertakes not to initiate the clinical trial until approval is obtained from the responsible Institution Review Board or Ethics Committee reviewing the subject clinical trial.

If there is non-compliance with any guidelines or instructions in respect of sponsor obligations, duties and responsibilities under the Regulations and/or the GCP, a sponsor which is a local representative acting in the capacity of local sponsor may be exposed to criminal liability.

There is no requirement that the ultimate sponsor of a clinical trial must be located in Singapore and/or the region around Singapore. However, applications for a CTC are to be made by a local representative [in its capacity as a local sponsor], which must be a locally registered company. This local representative will assume the duties of a sponsor as defined in the Regulations and the GCP, in respect of the clinical trials conducted in Singapore pursuant to the CTC.

## The Investigator

The Regulations define a "principal investigator" as a doctor or dentist, as the case may be, specified in the CTC as the person responsible for conducting and supervising a clinical trial.

Pursuant to the Regulations, the principal investigator is responsible for (among others):

- Informing the HSA in the event of a change in principal investigator and providing the HSA with the particulars of the new investigator;
- Informing the HSA in the event of the discontinuance of the clinical trial, ensuring that the applicable requirements for the use of a subject in a clinical trial are satisfied (whether under normal circumstances or in emergency situations);
- Giving full explanation and information to subjects in clinical trials, ensuring that only a principal investigator or persons assisting him shall treat a subject or administer any test material on a subject; and
- Furnishing the HSA with such information as may be requested, ensuring that all test materials are properly labelled and stored, keeping adequate records of the clinical trial, and complying with all other relevant provisions as set out in the GCP.

In particular, a principal investigator is responsible for reporting to the HSA in writing, as soon as is practicable, any serious adverse event which is likely to affect the safety or well-being of the subject which has arisen during the clinical trial or which has come to his knowledge from reports of similar clinical trials conducted elsewhere.

## Study Drugs

There are no laws, regulations or guidance identifying the party responsible for financing the supply of study drugs, governing the provision of the study drugs for free, or requiring the sponsor to otherwise finance medical procedures provided for in the protocol. However, the GCP provides that the financial aspects of the clinical trial should be documented in an agreement between the sponsor and the investigator/institution.

Liability for the study is as set out in the Act, Regulations and GCP, and pursuant to general common law principles of liability. To the extent permitted by law, liability can also be agreed to and apportioned between parties via written contract.

## Intellectual Property and Data

Ownership of inventions and other IP rights is subject to the common law position governing the creation of intellectual property. The Act, the Regulations, and the GCP 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.

## Contact Us


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