

**Baker
McKenzie.**

CLINICAL TRIALS HANDBOOK Asia Pacific



MALAYSIA

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Malaysia

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Introduction

Clinical trials are regulated in Malaysia by the National Pharmaceutical Regulatory Agency (NPRO), an agency under the Malaysian Ministry of Health (MOH). In addition to issuing licenses for clinical trials conducted in Malaysia, NPRO is also responsible for the registration of pharmaceutical products and cosmetics and the enforcement of drug quality control schemes.

The Research and Ethics Committees (IRB/IEC) of the respective institutions also assist in the regulation of clinical trials in Malaysia, as their approval is mandatory before a trial can commence.

Regulatory framework

The primary legislation governing the regulation of clinical trials in Malaysia is the Malaysian Sale of Drugs Act 1952 ("Act"). Section 26 of the Act empowers the Minister of Health to impose regulations with respect to drugs, including the regulation of clinical trials as provided for under the Control of Drugs and Cosmetics Regulations 1984 ("Regulations"). The Regulations apply to both molecule-based and biological-based study drugs.

Import license and exemption

With regard to clinical trials, the Regulations require a license or exemption as follows:

(a) Clinical Trial Import License ("Import License")

Regulation 12(1)(c): An application for the Import License is to be submitted where the drug will be imported into Malaysia for the purpose of clinical trials, even where the drug has not been registered with the NPRO.

(b) Clinical Trial Exemption ("Exemption")

Regulation 15(5): An application to request for the Exemption is required where the drug will be manufactured in Malaysia solely for the purpose of producing samples for clinical trials or for registration.

Legal definitions

A "drug" is defined under the Act as "any substance, product or article intended to be used or capable, or purported or claimed to be capable, of being used on humans or any animal, whether internally or externally, for a medicinal purpose." However, the Regulations exclude herbal remedies from such definition.

Further, the Regulations define "clinical trial" as "an investigation or series of investigations on persons conducted by or under the direction and supervision of persons with scientific training or experience for the purpose of finding out about, or determining, the safety, effectiveness and other effects of any products."

Guidelines and directives

Regulation 29(1)(l) of the Regulations empowers the Director of Pharmaceutical Services (who heads the Pharmaceutical Services Division of the MOH) to issue written directives or guidelines relating to clinical trials.

The applicable clinical trial guidelines in Malaysia are as follows:

- (a) Malaysian Guideline for Good Clinical Practice (**GCP**) Fourth Edition, which adopts the basic principles outlined by the International Committee on Harmonization of Good Clinical Practice but with appropriate modifications to suit local requirements ("**GCP Guideline**"), effective since January 2018
- (b) Malaysian Guideline for Application for Clinical Trial Import License and Clinical Trial Exemption in Malaysia, edition 6.4 ("**Application Guideline**"), effective since August 2017
- (c) Malaysian Guideline for Independent Ethics Committee Registration and Inspection, First Edition ("**Committee Guideline**"), effective since May 2016

The Director of Pharmaceutical Services (**DPS**) also issues written directives or circulars on the regulation of clinical trials from time to time, including the following:

- (a) The 2007 directive requiring all ethics committees that approve clinical trials in Malaysia to be registered with the Malaysian Drug Control Authority (**DCA**), a body established under the Regulations to regulate the quality, safety and efficacy of pharmaceutical products ("**2007 Directive**")
- (b) The 2009 directive requiring registration of all clinical trials that have applied for the Import License or Exemption to be registered with the National Medical Research Register ("**2009 Directive**"); in addition to the 2009 Directive, the DPS has also issued a directive on the need to register clinical trials involving medicines with the NMRR ("**2013 Directive**"), requiring all clinical trials to be registered with the NMRR.
- (c) Effective from 1 July 2016, all bioequivalence (**BE**) research made for the purpose of registering a product in Malaysia must be carried out in a BE research center that has been listed in the NPRA's Compliance Programme ("**2016 Directive**").

Penalty for noncompliance

The Regulations provide that any person who contravenes the Regulations or any condition of a license issued thereunder commits an offense.

In this regard, Section 12 of the Act provides that any person who commits an offense under the Act or the Regulations shall be liable on conviction to a maximum fine of MYR 25,000 (approximately USD 5,636) and/or a maximum term of three years' imprisonment for the first offense, and a maximum fine of MYR 50,000 (approximately USD 11,271) and/or a maximum term of five years' imprisonment for the second and subsequent offenses.

Specifically, a body corporate that commits an offense under the Act or Regulations is liable upon conviction to a maximum fine of MYR 50,000 (approximately USD 11,271) for the first offense, and a maximum fine of MYR 100,000 (approximately USD 22,543) for the second and subsequent offenses.

Clinical trial agreements (CTAs)

Approvals

Before commencing a clinical trial in Malaysia, two applications will need to be submitted for approval, namely:

- (a) Application to the relevant IRB/IEC
- (b) Application to the DCA, the executive body under the NPRA for the Import License or Exemption

IRB/IEC

The committees to whom the application should be submitted would depend on the clinical trial site:

- (i) Government health facilities under the MOH

The Malaysian National Institute of Health (NIH) issued the Guidelines for Conducting Research in MOH Institutions and Facilities ("**NIH Guidelines**") in October 2015. According to the NIH Guidelines, all clinical trials involving MOH facilities must register with the NMRR and obtain prior approval from the MOH, as follows:

- The government employee intending to act as investigator for the clinical trial must sign an investigator agreement and obtain approval from the head of his or her department and the organizational or institutional director of the relevant government department.
- Obtain permission to conduct research at the respective facilities/institutions.
- Where a private institution undertakes collaborative research with the MOH, a formal letter of agreement between the related MOH institution or division and the private institution is required.

The NMRR will review the documents submitted. If it is satisfied with the registration application, the NMRR will forward them to the Medical Research and Ethics Committee (MREC) for their review and approval.

- (ii) Universities or private institutions

Applications are to be submitted to the respective IRB/IEC of the university or institution, which will review and approve the trial proposal as per the functions of the MREC.

If the university or institution concerned does not have its own IRB/IEC, applications can be submitted to the MREC or such committees of other universities or private institutions.

Following the 2007 Directive, **all** ethics committees are now required to register with the DCA.

(A) Applicant

The application to the IRB/IEC is made by the investigator, that is, the person responsible for the conduct of the trial, or where conducted by a team, the person who is the leader of the team (principal investigator), subject to the particular policies of such IRB/IEC.

(B) Documentation

Section 3.1.2 of the GCP provides for the list of documentation to be submitted to the IRB/IEC for approval, which includes the following:

- i. Trial protocol

- ii. Written informed consent form
- iii. Consent form updates
- iv. Subject recruitment procedures and other written information to be provided to subjects
- v. Investigator's Brochure, which is a compilation of the clinical and non-clinical data on the trial drug relevant to its study in human subjects

Import License or Exemption

Prior to importing or manufacturing the trial drug in Malaysia, an application must first be submitted to the DCA for the Import License (where the trial drug is imported into Malaysia) or Exemption (where the trial drug is manufactured in Malaysia).

The Import License or Exemption is also required where the trial drug has already been registered with the DCA but is: (i) formulated or packaged in a way different from the registered form; (ii) used for an unregistered indication; or (iii) used to gain further information about a registered use.

The application for the Import License or Exemption can be applied for simultaneously with the application to the IRB/IEC. However, the DCA will not issue the Import License or Exemption without the IRB/IEC's approval.

(A) Applicant

An application for the Import License or Exemption can be made by either of the following:

- i. The principal investigator
- ii. The Sponsor, that is, the person or entity responsible for the initiation, management and/or financing of the trial; the sponsor must be a locally incorporated pharmaceutical company with a permanent address in Malaysia. Where the sponsor is not a local entity, it may assign its duties and functions to a Contract Research Organization (CRO) incorporated in Malaysia. The CRO may then apply on behalf of the sponsor, conditional upon submission of a letter of authorization from the sponsor.

(B) Documentation

Generally, the following documentation should be submitted together with, among others, the relevant application forms:

- i. The study protocol, which includes information such as the name and dosage form of the product, title and aim of the trial, description of the trial design and subjects, treatment profile, study parameters, operational aspects, adverse events and evaluation of results
- ii. Certificate of Good Manufacturing Practice for the study drug and comparator drug
- iii. Pharmaceutical data on the dosage form of the study drug, including information relating to the manufacture of the drug, quality control, stability, packaging and labeling
- iv. The Investigator's Brochure

The applicant would also need to submit the following documents:

- i. Table of contents to be included in each application dossier

- ii. Cover letter
- iii. Processing fee (for Import License)
- iv. Where the trial is not investigator-initiated, a copy of Company Registration Certificate
- v. A copy of the applicant's Poison Licence Type A for a pharmacist in the private sector or ARC for a public pharmacist, whichever is applicable
- vi. Letter of authorization, if applicable
- vii. A copy of the opinion(s) of the registered Ethics Committee
- viii. Declaration by the investigator
- ix. Label for all products that require Import License / Exemption
- x. Current copy of Certificate of GMP Compliance
- xi. Overall risk and benefit assessment
- xii. Any other trial-related documents that could be relevant for the review of the clinical trial application

(C) Conditions upon grant of Import License / Exemption

Upon the grant of the Import License or Exemption by the DCA, the Application Guidelines provide that the applicant must adhere to the following conditions:

- i. Collection of the Import License or Exemption within six months of issuance
- ii. Submission to the DCA of a Drug Accountability Report for Importation and evidence of delivery to the approved investigator or trial center on importation supply of each consignment of the study drug at the end of each study
- iii. The study drug shall only be supplied to the investigator at the approved trial sites for the purpose and use as stated in the Import License or Exemption. No change in investigator and trial center shall be made without the approval from the DCA.
- iv. The holder of the Import License or Exemption shall ensure that adequate precautions, such as storage in securely-locked cabinets with limited access to prevent theft or illegal distribution, are taken for all study drugs.
- v. The DPS may, at any time, revoke the Import License or Exemption and may amend the conditions to the Import License or Exemption.
- vi. The holder of the Import License or Exemption is responsible for the safekeeping of the Import License or Exemption. In case the Import License or Exemption is lost, the holder is required to file a police report immediately. The holder is required to inform the NPRA in writing about the loss of the Import License or Exemption, accompanied with a certified true copy of the police report. Should an Import License or Exemption be required for further importation or manufacturing, a certified true copy of the Import License or Exemption will be provided to the holder, upon request.
- vii. Where applicable, notification to the Centre for Investigational New Products (**CINP**) under the DCA of the decision to withdraw the Import License before the end of the validity of such license and the reasons for the decision, after which the Import License shall be invalidated and returned

- viii. Notification and reporting of local and foreign serious adverse events to the DCA, that is, any untoward medical occurrence that at any dose results in death, is life threatening, requires inpatient hospitalization or prolonged hospitalization, or results in persistent or significant disability/incapacity or a congenital anomaly / birth defect
- ix. Notification to the DCA of any change in information relating to the application
- x. Submission to the DCA of the End of Study Summary Report and Drug Accountability and Disposal Report within three months from the site closure and the Clinical Study Report within one year following completion of the whole trial

The DCA has the authority to inspect and audit the trial site to ensure accuracy of the information supplied in the application, and compliance with the Regulations, the GCP and the World Medical Association Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects ("**Helsinki Declaration**").

(D) Registration

In accordance with the 2009 Directive and with effect from 1 January 2010, all clinical trials that have applied for the Import License or Exemption must be registered with the National Medical Research Register. The purpose of the registration is to facilitate the monitoring of clinical trials in Malaysia by the MOH.

Insurance and indemnity

Section 5.8.1 of the GCP provides that the sponsor must provide insurance or indemnify the investigator against claims arising from the trial (except for claims arising from malpractice or negligence) where required by regulatory requirements.

At present, neither the Act nor the Regulations make it compulsory for the sponsor to take out insurance or provide an indemnity to the investigator. However, it is common for sponsors to include such provisions in a CTA, as the Ethics Committee would unlikely approve the trial if there are no such provisions in place.

Form of CTAs

Section 5.1.4 of the GCP provides that all agreements made by the sponsor with the investigator or any other party in connection with the trial should be in writing, as part of the study protocol or in a separate agreement.

In addition, Section 5.6.3 of the GCP lists the following terms and conditions that should be included in a CTA:

- i. Compliance with the approved study protocol, the GCP, and applicable regulatory requirements for the conduct of the trial
- ii. Compliance with procedures for data recording and reporting
- iii. Permission by the Investigator for the Sponsor to monitor and audit, and for the appropriate regulatory authorities to inspect the trial site and documents related to the conduct of the trial
- iv. Retention of trial-related essential documents (discussed below)

Review of CTAs

CTAs involving MOH facilities will require endorsement from Clinical Research Malaysia (**CRM**). CRM is authorized by the Malaysian government to represent the clinical research industry in Malaysia.

For CTAs involving negotiation with private hospitals and institutes of higher learning (e.g., university hospitals), the private institutes will usually have their local Clinical Research Centre (**CRC**) to manage, negotiate and finalize the contracting.

Please note that the necessity to include the CTA in the submission for approval may differ depending on the relevant ethics committee. For applications submitted to the MREC, submission of a CTA is optional. However, please note that the MREC reserves the right to ask for a CTA after the submission of documents. On the other hand, for applications submitted to the IRB/IEC of universities or private institutions, the requirement to submit the CTA for review and approval by the said committees is subject to the specific rules of the university or institution. In most cases, the CTA would be one of the documents required to be submitted for approval.

Sponsor and CROs

Sponsor

A sponsor is the person or entity responsible for the initiation, management and/or financing of the trial. Section 5 of the GCP provides for the functions and responsibilities of the sponsor in a clinical trial, including the following:

- i. Implementing and maintaining quality assurance and quality control systems with written standard operating procedures for compliance with the study protocol, the GCP, and regulatory requirements
- ii. Designating and utilizing qualified medical personnel to advise on trial-related medical questions or problems
- iii. Utilizing qualified individuals, as appropriate, throughout all stages of the trial process — from designing the protocol and CRFs and planning the analyses to analyzing and preparing interim and final clinical trial reports
- iv. Supervising the overall conduct and progress of the trial, possibly by an independent data-monitoring committee established by the sponsor
- v. Retaining sponsor-related essential documents with regard to the trial
- vi. Selecting the investigator who should be qualified by training (including approved GCP training) and experience and with adequate resources to properly conduct the trial
- vii. Allocating all trial-related duties and functions
- viii. Providing compensation to trial subjects and investigators where required by applicable regulatory requirements
- ix. Obtaining the relevant approvals, permits, and/or licenses from the regulatory authorities and confirmation from the investigator that the IRB/IEC has approved the trial
- x. Ensuring that sufficient safety and efficacy data are available to support human exposure
- xi. Ensuring the proper manufacture, packaging and labeling of the study drug, in accordance with the GCP and any other regulatory requirements

- xii. Supplying the investigators or institutions with the study drug
- xiii. Ensuring that it is specified in the protocol or other written agreement that the investigators or institutions provide direct access to source data or documents for trial-related monitoring, audits, IRB/IEC review, and regulatory inspection
- xiv. Verifying that each subject has consented in writing to have his or her medical records accessed directly for trial-related monitoring, audit and inspection
- xv. Ensuring the ongoing safety evaluation of the study drug
- xvi. Reporting all adverse drug reactions to the investigator and relevant authorities
- xvii. Ensuring that the trials are adequately monitored to verify that the rights and well-being of human subjects are protected; the reported trial data are accurate, complete and verifiable from source documents; and the conduct of the trial is in compliance with the currently approved protocol, the GCP and the applicable regulatory requirements
- xviii. Performing audits to evaluate trial conduct and compliance with the protocols SOPs, the GCP and the applicable regulatory requirements
- xix. Undertaking prompt action on noncompliance with the study protocol, standard operating procedures, the GCP, and regulatory requirements by the investigator and the sponsor's staff, including termination of the investigator's participation for serious or persistent noncompliance
- xx. Notification of termination or suspension of the trial to the investigator and relevant authorities
- xxi. Submission of clinical trial reports to the relevant authorities in accordance with the International Committee on Harmonization Guideline for Structure and Content of Clinical Study Reports

Retention of essential documents

The Application Guidelines require the sponsor and the investigator to archive all trial-related documents safely and to inform the DCA prior to destruction of any such documents.

In this regard, Section 5.5.6 of the GCP provides for the retention of essential documents, that is, those documents that individually and collectively permit evaluation of the conduct of a trial and the quality of the data produced. The minimum list of essential documents is provided for in the GCP at Section 8.

Subject to any longer period of retention agreed on between the investigator and the sponsor in the CTA, as required by any applicable regulatory requirement or if needed by the sponsor, Section 5.5.11 of the GCP states that essential documents should be retained by the sponsor for either of the following:

- i. At least two years after the last approval of a marketing application in an ICH region (member country of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use) and until there are no pending or intended marketing applications in an ICH -region
- ii. At least two years from the formal discontinuation of clinical development of the study drug

The sponsor should inform the investigator of the need for the retention of records and inform the investigator in writing when such records are no longer required.

Contract research organizations

There is no requirement for the sponsor to be located or based in Malaysia. However, as an application for the Import License or Exemption must be made by an entity that is registered with the Companies Commission of Malaysia, the sponsor may appoint a CRO incorporated in Malaysia to assume its duties and functions.

Section 5.2 of the GCP allows for a sponsor to transfer any or all of its trial-related duties and functions to a CRO, although the ultimate responsibility for the quality and integrity of the trial remains with the sponsor. The appointment of the CRO by the sponsor should be in writing and should specify all of the duties and functions transferred, including the implementation of quality assurance and control. Any duties or functions not specifically transferred are retained by the sponsor.

The specific requirements in relation to any of the sponsor's duties or functions as provided under the GCP shall equally apply to a CRO that has assumed such duties or functions.

Investigator

An investigator is the person responsible for the conduct of the clinical trial at the trial site. Where the trial is conducted by a team of individuals, the investigator is the responsible leader of the team and may be called the principal investigator. There may also be sub-investigators, that is, any member of the team designated and supervised by the principal investigator to perform critical trial-related procedures and/or to make important trial-related decisions.

The investigator should be qualified by education, approved training in GCP, and experience. Evidence of such qualifications may be requested by the sponsor, the IRB/IEC and/or the regulatory authorities prior to commencement of the trial.

Section 4 of the GCP lays out in detail the duties and functions of the investigator. The investigator's responsibilities are summarized as follows:

- i. Be thoroughly familiar with the appropriate use of the investigational product(s)
- ii. Maintain a list of appropriately qualified persons to whom the investigator has delegated significant trial-related duties
- iii. Be able to demonstrate (e.g., based on retrospective data) a potential for recruiting the required number of suitable subjects within the agreed recruitment period
- iv. Ensure that all assisting personnel are adequately informed about the protocol, the investigational product(s), and their respective trial-related duties and functions
- v. Ensure that adequate medical care is provided to a subject for any adverse events
- vi. Obtain the approval of the IRB/IEC before commencement of the trial and furnishing them with all required documentation during the trial
- vii. Conduct the trial in compliance with the approved study protocol without any deviation from, or changes to, the protocol without the agreement of the sponsor and approval of the IRB/IEC (except in the case of immediate hazards - Section 4.5.4)
- viii. Be accountable for the study drug at the trial site, including the delivery, storage, use and return of the study drug

- ix. Follow the trial's randomization procedures, if any, and ensure that the code is broken only in accordance with the protocol
- x. Obtain and document the subjects' informed consent in accordance with the GCP and the Helsinki Declaration
- xi. Ensure the accuracy, completeness, legibility and timeliness of all reports to the sponsor in the Case Report Forms (a printed, optical or electronic document designed to record all of the protocol-required information to be reported to the sponsor on each subject) and any other reports
- xii. Retain essential documents, as discussed under the responsibilities of the sponsor
- xiii. Submit written summaries on the status of the trial to the IRB/IEC on an annual basis or as and when requested by the said committees
- xiv. Submit reports to the sponsor and the IRB/IEC on any changes significantly affecting the trial and/or increasing the risk to subjects
- xv. Report immediately all serious adverse events other than those that the protocol or other document identifies as not requiring immediate reporting to the sponsor, followed promptly by detailed written reports on the same
- xvi. Upon termination or suspension of the trial, inform trial subjects of the same and ensure appropriate therapy and follow-up
- xvii. Where the trial is terminated or suspended by:
 - a. the investigator, the investigator should inform the sponsor and the IRB/IEC of the same and provide a detailed written explanation
 - b. the sponsor, the investigator should inform the IRB/IEC of the same and provide a detailed written explanation
 - c. the IRB/IEC, the investigator should inform the sponsor of the same and provide a detailed written explanation
- xviii. Provide the IRB/IEC with a summary of the outcome of the trial upon completion

Study drugs

Requirements for supply and administration

To administer the study drug, the investigator or sponsor first needs to obtain from the DCA the Import License or Exemption that would authorize the import or manufacture of the study drug in Malaysia. Once all licenses and approvals are obtained, the sponsor is responsible for supplying the investigator with the study drug and should ensure the availability of written procedures providing for the receipt, handling, storage, dispensing, and retrieval and return of unused study drugs from subjects. Section 5.14 of the GCP further provides for the following responsibilities of the sponsor in relation to the supply of the study drug:

- i. Timely delivery to the investigator
- ii. Maintaining records for the shipment, receipt, disposition, return and destruction of the study drugs

- iii. Maintaining a system for the retrieval of study drugs, such as deficient product recall, reclaiming after trial completion, expired product reclaim
- iv. Maintaining a system for the disposition of unused investigational products and for the documentation of this disposition
- v. Ensuring product stability over the period of use
- vi. Maintaining sufficient quantities to reconfirm specifications (if necessary) and records of batch sample analyses and characteristics

As mentioned above, the investigator is the party accountable for the study drug at the trial site. In this regard, Section 4.6 of the GCP provides that the investigator should maintain records that document the doses administered to subjects as specified by the study protocol. The investigator should also ensure that the study drugs are stored as specified by the sponsor and in accordance with applicable regulatory requirements. In addition, the investigator should ensure that the study drug is only used in accordance with the approved study protocol. The investigator should also explain the correct use of the study drug to each subject, and check at appropriate intervals during the trial that the subjects are following the instructions.

Administering the study drug after trial termination

There are no express regulatory provisions as to whether the study drug can be administered to trial subjects after the trial has been terminated. However, the Application Guidelines state that the Import License or Exemption should be returned to the DCA the soonest possible upon termination of the trial. Any unused study drugs must be either returned to the country of origin or original depot, or locally disposed of (and documented) by the authorized body or authority. Further, Regulation 7(1) of the Regulations prohibits any drug from being administered unless it is a registered product and the appropriate license has been issued. As such, if the investigator or sponsor wishes to continue administering the study drug after termination of the trial, a written request to extend the Import License or Exemption with justification may be submitted to the NPRA. There is currently no standard procedure for such request and the NPRA shall review each request on a case-by-case basis.

Financing

Sections 4.9.6 and 5.9 of the GCP provide that the financial aspects of the clinical trial should be documented in an agreement between the sponsor and the investigator. The GCP and other regulatory guidelines are otherwise silent on the financing of the study drug. However, it is usually the sponsor who will finance the trial and the supply of the study drugs.

Liability

As discussed above, the ultimate responsibility for the quality and integrity of the trial always resides with the sponsor. However, there is no requirement under the Act, the Regulations, or other regulatory guidelines for the sponsor to provide any indemnity in favor of the investigator or insurance for the trial. Nevertheless, such provisions are common in CTAs and it is advisable to include them for certainty as to the allocation of risk. It is particularly important for sponsors to include an indemnity by the investigator for any claims or losses arising out of the investigator's malpractice or negligence during the conduct of the trial.

Publication of trial results

There are no specific requirements in relation to the publication of the results of the trial, and thus the parties are free to provide for the same in the CTA.

It is common for the sponsor to require the investigator to provide, with at least 60 days' prior written notice, all manuscripts or materials for publication to give the sponsor the opportunity to review and comment on the same, and request for modifications.

Intellectual property (IP) and data

Ownership of IP rights

There are no express regulatory provisions as to the ownership of intellectual property rights arising out of the clinical trial ("Trial IPR"), and thus the parties are free to contract on the same. However, it is usually the sponsor who will retain full ownership of all Trial IPR.

In any case, as the sponsor has commissioned and financed the investigator/CRO to conduct the trial on its behalf, the Malaysian Copyright Act 1987 and the Malaysian Patents Act 1983 provide that all copyright and patent rights arising out of the trial are deemed to accrue to the sponsor who commissioned it in the absence of any contrary agreement between the parties. It should be noted, however, that where the invention acquires an economic value much greater than the parties could have foreseen at the time of contract, the investigator shall be entitled to equitable remuneration to be fixed by the courts in the absence of any agreement between the parties on the same.

The terms in the CTA with regard to Trial IPR should ideally provide for the following:

- i. The sponsor's sole and exclusive ownership of all right, title and interest in the Trial IPR
- ii. The investigator's undertaking to execute all documents and do all acts necessary to vest the Trial IPR in the sponsor, including assignments by the investigator's employees or subcontractors
- iii. The investigator's prompt disclosure of all inventions and Trial IPR arising out of the trial
- iv. The sponsor's responsibility for all costs incurred for the filing and maintenance of Trial IPR
- v. The investigator's undertaking not to do any act that would prejudice the Trial IPR
- vi. The investigator's duty to inform the sponsor of any actual, threatened or suspected infringement of the Trial IPR

Investigator-initiated trials

Investigator-initiated clinical trials are allowed in Malaysia, provided the necessary approvals from the IRB/IEC and the Import License or Exemption from the DCA have been obtained. Such trials are usually initiated by investigators based in government health facilities and rarely by investigators attached to private institutions. There are no express regulatory provisions prohibiting pharmaceutical companies from supporting investigator-initiated trials.



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