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CLINICAL TRIALS HANDBOOK Asia Pacific



TAIWAN

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Taiwan

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Introduction

In Taiwan, studies involving human subjects are supervised by the Ministry of Health and Welfare (**MOHW**) and the Taiwan Food and Drug Administration (**TFDA**), in accordance with the Human Subjects Research Act, the Medical Care Act, the Regulations on the Human Trials, the Human Biobank Management Act, the Pharmaceutical Affairs Act (**PAA**), and the Guidelines for Good Clinical Practice on Drugs (**GCP**).

Among the studies involving human subjects, clinical trials on investigational drugs conducted for application of marketing approval and post-marketing studies on approved drugs are primarily regulated by the PAA and the GCP. The competent authority is the TFDA.

Regulatory framework

The GCP's general principles are substantially the same as the International Conference on Harmonization Guidelines for Good Clinical Practice, including: (1) the principles of conducting a clinical trial; (2) protection of trial subjects; (3) establishment and operation of the Ethics Committee/Institutional Review Board (**IRB**); (4) duties of the investigator, institution and sponsor; and (5) the application for approval of clinical trials, review of clinical trial applications, and the implementation and termination of clinical trials.

Molecule-based Investigative Medical Products (**IMPs**) or study drugs and biologically based IMPs are subject to the same legislation, that is, the GCP. Clinical trials on medical devices conducted for marketing approval applications, on the other hand, are subject to the Guidelines for Good Clinical Practice on Medical Device ("**GCP on Medical Device**"), whose content is substantially the same as the GCP.

Clinical trial agreements (CTAs)

To conduct Phase I, II, III and IV clinical trials, a prior approval from relevant IRB is required. A prior approval from the TFDA is also required for Phase I, II and III clinical trials. Depending on the risk caused to the subjects, the TFDA's approval may be required for Phase IV study.

In practice, the application for the TFDA approval is usually made by the sponsor or contract research organization (**CRO**). The application for the IRB approval is normally prepared by the sponsor or CRO and filed in the name of the investigator.

Insurance is required for a clinical trial. In accordance with practice and the GCP, the sponsor must purchase liability insurance so as to indemnify the investigator/institution against claims arising from the trial.

Clinical trial agreements are not subject to regulatory or the IRB's review or approval.

Sponsor and CROs

The sponsor is usually the initiator and administrator of a clinical trial. In general, its duties include: (1) designing the clinical trial; (2) obtaining approval from or preparing and sending a notification to the TFDA or the IRB; (3) appointing an investigator; (4) providing study drugs; (5) monitoring and controlling the quality of the trials; (6) reporting to the

regulator any information in relation to the safety of the investigational drugs; (7) analyzing trial data and filing clinical trial reports with the regulator; and (8) procuring liability insurance to cover the risks of the clinical trials.

For clinical trials initiated by an offshore sponsor, there must be a local sponsor who will be responsible for applying for regulatory approval from the TFDA. The local sponsor can be the offshore sponsor's affiliate or a CRO in Taiwan. Nonetheless, the offshore sponsor is not prohibited from entering into contracts directly with the investigators and institutions in Taiwan to conduct clinical trials.

In any of the aforementioned cases, the local sponsor, rather than the offshore sponsor, will be considered by the TFDA as the sponsor of the clinical trial to be conducted in Taiwan. Accordingly, the local sponsor bears all regulatory obligations imposed by Taiwan law on the sponsor of the clinical trial. The local sponsor and the offshore sponsor may separately enter into an agreement to allocate the obligations and liabilities of the clinical trial.

A sponsor may transfer any or all of the sponsor's trial-related duties and functions to a CRO. However, under the GCP, the ultimate responsibility for the quality and integrity of the trial data always rests with the sponsor. Taiwan does not have special requirements for the choice of CRO. According to the GCP, a CRO may be an individual or an organization, although the former is unlikely in practice. In addition, the sponsor must appoint the CRO in writing.

Investigator

In Taiwan, the investigator must be a physician specializing in an area related to the study drug. The investigator's main duties include: (1) conducting the clinical trial; and (2) reporting any adverse events to the sponsor, the IRB or the regulator.

Study drugs

After the volunteers/patients agree to participate in a clinical trial by giving their written informed consent, the investigator may administer the study drug. Usually, the study drugs used in Phases I, II and III are provided by the sponsor for free, and thus the volunteers/patients need not pay for the study drugs. The cost of such study drugs cannot be reimbursed either by the governments or the institution. Study drugs used in Phase IV may be reimbursed by the National Health Insurance in Taiwan or provided by the sponsor for free. In either case, the volunteers/patients are not required to pay for the study drugs.

The main rules regarding the liability for a clinical trial are set forth under the Civil Code, Consumer Protection Act, Medical Care Act and the GCP. In accordance with the GCP, the sponsor is liable for the personal injuries of a volunteer/patient arising from the trial, unless such injuries are caused by medical malpractice of the investigator or institution. In the latter case, the investigator or institution should be responsible for the personal injuries of the volunteer/patient.

It is advisable to include a liability or indemnification clause in the clinical trial agreement so as to: (1) define to what extent the investigator or institution should be liable for the volunteer's/patient's injury, as well as confirm the scope of the sponsor's liabilities so that the sponsor may procure the sufficient insurance coverage in advance; and (2) require the investigator and institution to notify the sponsor of the volunteer's/patient's claim for personal injuries, and to allow the sponsor to control the proceedings and defend the claim.

Taiwan does not have special requirements for the publication of study results. The publication of study results is subject to the agreement between the sponsor and the investigator or institution. In practice, when negotiating a clinical trial agreement, the investigators or institutions might request to publish the study results they produce and determine the ranking of authors and content of the publication at their own discretion, while the sponsor will ask to review the draft before the draft is submitted for publication, primarily for the protection of confidential information.

The trial subject can be provided with the study drug after termination of the clinical trial, as long as such provision has been approved by the authority.

Intellectual property (IP) and data

Under the Taiwan Patent Act, where a fund provider engages another party to conduct research and development, patent ownership should be subject to the agreement between both parties. If there is no agreement, patent ownership will belong to the inventor or creator. In the latter case, the fund provider is entitled to put such invention into practice.

Accordingly, because the patent ownerships over the study results will belong to the institution or investigator if there is no agreement between the sponsor and the institution or investigator, it is advisable for the sponsor to specify in the clinical trial agreement that any inventions and other IP rights arising from the trial must be the immediate and exclusive property of the sponsor.

Aside from the pharmaceutical or medical device company, the investigator may initiate trials on his or her own, which the pharmaceutical or medical device company may support.



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