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CLINICAL TRIALS HANDBOOK
Asia Pacific

VIETNAM

Vietnam

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In Vietnam, the Administration of Science, Technology and Training (**ASTT**), which is under the Ministry of Health (**MOH**), manages clinical trials for drugs.

Regulatory framework

In general, clinical trials are governed by the Law on Pharmacy[1] Decree No. 54,[2] Circular No. 03[3] and Circular No. 08.[4],

Clinical trial agreements (CTAs)

CTAs that are entered into by a sponsor and an investigator must be based on the template provided by law. This template stipulates the content of contracts, timelines, expenditures, responsibilities and the rights of each party, as well as other general terms. In order to register a clinical trial, a CTA, inter alia, needs to be submitted to the ASTT.[5]

Clinical testing stages and procedures

There are four phases for clinical trials, as follows: registration for research on clinical trials for drugs; approval of the research on clinical trial for drugs; conducting clinical trial for drugs; and approval of the clinical trial's results.[6] The requirements for each phase may vary.

Sponsor and contract research organizations (CROs)

Sponsors may engage in service agreements with CROs in Vietnam, where the CRO will support the sponsor in conducting clinical trials.

Under Circular No. 08, organizations providing clinical research support activities in Vietnam (i.e., CROs) are required, among other things, to be a legal entity (which has juridical person status).

In order to provide clinical research support activities, CROs must be registered with the MOH.

Investigators

Circular No. 03 requires that principal investigators must be qualified and possess in-depth technical knowledge, be clinically experienced, be operationally competent to ensure compliance with the principles of good clinical practice,

[1] Law No. 105/2016/QH13 on Pharmacy, passed by the National Assembly on 6 April 2016 ("**Law on Pharmacy**").
[2] Circular No. 03/2012/TT-BYT guiding clinical drug trials, dated 2 February 2012, and issued by the MOH ("**Circular No. 03**").
[3] Decree No. 54/2017/ND-CP, dated 8 May 2017, of the government detailing certain provisions and the implementation of the Law on Pharmacy ("**Decree No. 54**").
[4] Circular No. 08/2014/TT-BYT providing activities supporting clinical trials research in Vietnam, issued by MOH ("**Circular No. 08**").
[5] Article 10 of Circular No. 03.
[6] Article 95.2, Law on Pharmacy.

be familiar with the requirements of clinical trials, be capable of implementing the trial as per the approved protocol in full and to schedule, and be GCP-certified by the MOH or by organizations accredited by the MOH.[7]

Investigators must have appropriate professional expertise, be trained in the necessary subject matter, have skills to conduct the trials, and be GCP-certified by the MOH or by organizations accredited by the MOH.[8]

Clinical trial drugs

Under the Law on Pharmacy, drugs for clinical trials must meet the following requirements:

- Have undergone pre-clinical studies
- Have a stable dosage form
- Meet quality standards as stated in the registration dossier for the clinical trials

The labels of clinical trial drugs must have the text "Thuốc dùng cho thử lâm sàng. Cấm dùng cho Mục đích khác" ("Drugs for clinical trial only. Using for other purposes is prohibited.").[9]

Sponsors are responsible for supplying the drugs for clinical trails and for providing the funding to carry out the clinical trials in accordance with the law.

Clinical trial data and findings may be published only after having been evaluated as being satisfactory by the MOH's Ethical Committee.[10]

Vietnamese law does not specify requirements relating to the provision of clinical trial drugs to clinical trial subjects after the clinical trial has been terminated.

Intellectual property (IP) and data

Sponsors of clinical trials have ownership rights over all research findings on the clinical trial drug.[11]

[7] Article 11.2, Circular No. 03.
[8] Article 11.3, Circular No. 03
[9] Article 88 of the Law on Pharmacy.
[10] Article 38.3 of Circular No. 03.
[11] Article 92 of the Law on Pharmacy.

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