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CLINICAL TRIALS HANDBOOK
Asia Pacific

INDONESIA

Indonesia

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Introduction

Unlike in more developed countries, Indonesia does not have a very strong research community and is not often chosen as a country in which to conduct clinical research.

The Drug and Food Supervisory Board (*Badan Pengawas Obat dan Makanan* or BPOM) is the Indonesian regulatory agency responsible for the conduct and regulatory approval of clinical trials.

Regulatory framework

The principal legislation relevant to the conduct of clinical trials in Indonesia is BPOM Regulation No. 21 of 2015 on the Procedures for Clinical Trial Approval ("**BPOM Regulation 21**").

Below are the main features of the Indonesian clinical trial regime under BPOM Regulation 21:

- Not all clinical trials require approval from the BPOM (i.e., only pre-marketing clinical trials require prior approval from the BPOM). The approval will only be effective for a certain period. Upon the approval's expiry, parties must apply for an extension. Otherwise, they cannot continue conducting the trial.
- Generally, test products must be equipped with the preliminary safety data and quality requirements relevant to the clinical trial. Additionally, informed consent must first be obtained from the test subjects (i.e., individuals who participate in the clinical trial) involved.
- Clinical trials in Indonesia must be done in accordance with the Good Clinical Trial Practice (*Cara Uji Klinik yang Baik* or **CUKB**). The BPOM will inspect each clinic conducting clinical trial for CUKB compliance.
- BPOM Regulation 21 only regulates clinical trials on select types of products, namely, drugs, herbal medicine, health supplement, processed food and cosmetics.
- Any serious adverse reaction* and any serious adverse event** must be reported to the authority.

Notes:

**"Serious adverse reaction" means any adverse reaction triggered by a test product that causes death, life-threatening injury that requires care or intensive care from a hospital, disability or congenital defects.*

***"Serious adverse event" means any adverse medical event that occurs during a clinical trial that causes death, life-threatening injury that requires care or intensive care from a hospital, disability or congenital defects.*

Parties involved

There are three main clinical trial actors under BPOM Regulation 21:

(a) Sponsors

(b) Main researchers

(c) Contract research organizations (*Organisasi Riset Kontrak* or ORK)

Sponsors

"Sponsor" is a party (i.e., individual, company, institution or organization) who is responsible for initiating, managing and/or funding a clinical trial. A sponsor may cooperate with / appoint a main researcher who will conduct the clinical trial.

Though untested, there is no provision under BPOM Regulation 21 that prohibits a sponsor from also acting as the main researcher in a clinical trial. It is also unclear whether a party who performs a sponsor's roles as defined under BPOM Regulation 21 would be automatically considered as a sponsor. Arguably, if a sponsor borrows monies from another party, that other party would not be considered as a sponsor merely because it provides "funding" for the clinical trial.

Theoretically, a sponsor may therefore also act as the main researcher in a clinical trial. Conceptually, however, the two are distinct from each other. Simply put, a sponsor is the party who initiates, funds and manages the clinical trial. Similar with those in other countries, sponsors in Indonesia carry the medico-legal responsibility associated with the conduct of the trial. Clinical research organizations, as well as pharmaceutical companies, are common sponsors.

A foreign entity may become a sponsor. If a sponsor is a foreign entity, then it must delegate some or all of its duties to its representative or ORK that is located in Indonesia. There are no further provisions on the delegation requirements.

Based on BPOM Regulation 21, sponsors are responsible for carrying out the following tasks:

- Submit the application to obtain approval from the head of the BPOM for pre-marketing and post-marketing clinical trial
- Submit the request to the BPOM for extension on the pre-market clinical trial period
- In case the test product needs to be imported into Indonesian territory, obtain the approval from the head of the BPOM*
- Report to the head of the BPOM any serious adverse reaction
- Report any unexpected serious adverse drug reaction during a clinical trial in another country (which involves a clinical trial center in Indonesia) to the ethical commission and the head of the BPOM (report must be done in either Indonesian or the English language)
- Report on the progress of the clinical trial to the head of the BPOM: (i) once every six months; (ii) when the clinical trial ends; and/or (iii) if the clinical trial is stopped midway (with explanations provided)
- Submit any amended clinical trial document

***Note**: *The application for import mentioned above must be lodged together with the application to the head of the BPOM.*

Main researchers

"Main researcher" is an individual who has the capability to lead a research team in a research center, involving supporting researchers and other personnel, and is responsible for the overall clinical trial at the research center or

the location where the clinical trial is being conducted. We note that this role is similar to that of an "investigator" in Australia.

Basically, the main researcher is the person responsible for the conduct of the clinical trial at the trial site. Main researchers must hold a certificate of CUKB. The main researchers will often be employed by the institution that hosts the clinical trial.

Based on BPOM Regulation 21, sponsors are responsible for carrying out the following tasks:

- Observe CUKB
- Report to the sponsor and ethical commission any serious adverse event that occurs during a clinical trial in Indonesia*

Notes: **The report to the sponsor must be done immediately, or at the latest 24 hours after the main researcher becomes aware of the event; the report to the ethical commission must be done within three calendar days.*

ORKs

"ORK" is an individual or an organization (commercial or otherwise) contracted by the sponsor to carry out one or more of its tasks and functions in a clinical trial.

Given its role, the sponsor may delegate some or all of its duties mentioned in point C.1 above to the ORK.

The following requirements must be met by ORKs:

(a) Must be located in Indonesia

(b) Personnel must have good understanding of the CUKB

Procedures

Preparation

Dealing with Indonesian bureaucracy can be challenging if conducted without adequate preparation. To expedite the timeline of obtaining approvals from the relevant authorities, it is recommended that pre-submission preparations be made by the applicant. This consists of preparing and obtaining any information or documents that could be done before submission of the application.

If a sponsor wishes to cooperate with an ORK, then any actions needed to execute the agreement with the ORK should be completed at this stage.

Ethical commission approval

The first step in conducting a clinical trial is to obtain approval from the ethical commission (except for clinical trials that are done for education purposes). The ethical commission is an independent institution composed of medical/scientific professionals, as well as non-medical/non-scientific members, who are responsible for the protection, rights, safety and well-being of the test subjects. The applicant in this regard would be the sponsor or the researcher.

Obtaining supporting documents

In relation to the above, the applicant must also obtain the following items:

(a) Clinical trial documents (among others)

- Clinical trial protocol*
- Research brochure
- Informed consent from the test subjects**
- Application form

(b) Tested product documents (among others)

- Information on the tested product
- Certificate of Analysis (COA)
- Good Manufacturing Practice certificate (in relation to the product)
- Summary Batch Protocol (three consecutive batches) for biological product, including vaccine
- Special lot release for vaccine

(c) Other related documents (among others)

- Good Clinical Practice (GCP) certificate of the researcher
- Contract with the ORK (if relevant)
- Insurance (if any)
- Laboratory certificate
- Curriculum vitae of the main researcher

Notes: **Clinical trial protocol is a complete and detailed document that elaborates on (among others) the organization, background, purpose, design, methodology and statistic considerations of a clinical trial.*

***If the tested product contains certain materials that are sensitive to certain groups of people, this information must be included when obtaining the informed consent from the test subjects.*

All of the foregoing documents must be submitted to the BPOM for the next step, which is the submission for an approval or notification to the BPOM.

Pre- and post-marketing clinical trial approval/notification

Generally, clinical trials are divided into two types, each having its own formalities:

(a) Pre-marketing clinical trial

Pre-marketing clinical trial is basically a clinical trial that is done using unregistered products (or products that do not have product registration). Pre-marketing clinical trial can also be done using registered products

but only for the purpose of getting data on the safety and/or to test (or reaffirm) the efficacy or benefit of the approved products.

An approval from the head of the BPOM must be obtained before a pre-marketing clinical trial is done, except for processed food and cosmetic products (i.e., obtaining approval is optional for these types of products). Based on BPOM Regulation 21, the head of the BPOM will issue its approval at the latest 20 working days starting from the date after the required documents are received by the BPOM. However, in practice this timeline may be stretched, given that the government often begins counting down to the deadline only after the application is considered as "proper" (i.e., once they have no further comments on the application and there is no other issue with the application).

The approval will be effective for two years after its issuance.

(b) Post-marketing clinical trial

Post-marketing clinical trial is basically a clinical trial that is done using products that have already gone through a pre-marketing clinical trial and have been registered (have already obtained product registration), to obtain data on safety and/or to test (or reaffirm) the efficacy or benefit of the approved products.

Unlike a pre-marketing clinical trial, only a notification to the head of the BPOM needs to be filed as a prerequisite to conduct a post-marketing clinical trial. The head of the BPOM will issue its acknowledgement at the latest 20 working days after the required documents are received by the BPOM. The applicant may proceed with the clinical trial after the 20-working-day period has lapsed (even if the BPOM has not issued its acknowledgement). This requirement is also optional for processed food and cosmetic products.

Prior approval or submission of notification is not required if the clinical trial is done for the purpose of education, provided that only unregistered products are used for that purpose.

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