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CLINICAL TRIALS HANDBOOK
Americas

PERU

Peru

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Introduction

In Peru, the National Institute of Health (*Instituto Nacional de Salud* or INS) is the national authority in charge of ensuring compliance with the provisions regulating the authorization, execution and surveillance of clinical trials.

The General Bureau of Medicines, Drugs and Supplies (*Dirección General de Medicamentos, Insumos y Drogas* or DIGEMID) — as the national authority regulating pharmaceutical products, medical devices and sanitary products — is in charge of issuing a binding technical opinion on the safety and quality of drugs under investigation that fall within its competence, as well as on the research protocol of bioequivalence studies. It is also in charge of authorizing, but only for research purposes, the import, manufacture and use of drugs under investigation.

Regulatory framework

The clinical trials on human beings are governed by the following laws:

- Act No. 26842 on General Health
- Supreme Decree No. 021-2017-SA - Regulations on Clinical Trials
- Resolution Nº 279-2017-J-OPE/INS, Manual for Clinical Trial Proceedings

Clinical trial agreements (CTAs)

As set forth by law, "clinical trial" is defined as an investigation conducted on human beings in order to identify or confirm the clinical, pharmacological and/or other pharmacodynamic effects, to detect adverse reactions, and to study the absorption, distribution, metabolism and elimination of one or more drugs under investigation, with the purpose of determining safety and/or efficacy.

In order to carry out a clinical trial, authorization from the General Office of Technological Transfer and Research (*Oficina General de Investigación y Transferencia Tecnológica* or OGITT) of the INS is required. To that effect, the sponsor or the contract research organization (CRO) must submit the following documents:

- Authorization form
- Copy of the registration in force of the research center authorized to carry out clinical trials
- Copy of the approval issued by the legal representative of the research institute(s) where the clinical trial will be carried out
- Copy of the approval of the research protocol and informed consent form issued by the Institutional Research Ethics Committee duly authorized by the INS
- Sworn statement of the sponsor by acknowledging compliance with the responsibilities as set forth by applicable law; if a foreigner, copy of the delegation of responsibilities to the legal representative

- Sworn statement of the principal investigator by acknowledging compliance with the obligations and requirements as set forth by applicable law
- Sworn statement of sponsor and principal investigator about the research center where the clinical trial will be carried out
- Copy of the insurance policy in force acquired by the sponsor
- Sworn statement of the sponsor stating that he or she has a fund that guarantees immediate medical assistance and treatment of the research subject in case of an adverse event resulting from the clinical trial
- Protocol of the investigation in Spanish and in the original language if different from Spanish
- Informed consent form
- Investigator's Manual in Spanish and in the original language if different from Spanish
- Sworn statement of the sponsor and principal investigator stating that there is no conflict of financial interest in carrying out the clinical trial
- Information related to the quality of the study drug
- Copy of the documents proving that all research team members underwent training on Good Clinical and Research Practices (said documents shall not be older than three years)
- Detailed budget of the clinical trial
- List of supplies needed for the development of the clinical trial
- Curriculum vitae of the research team of each research center
- Proof of payment of procedural law; for multicenter clinical trials, the right payment shall be made by each center.

At the request of the INS, DIGEMID shall issue a binding opinion on the safety and quality of the study drug, as part of the evaluation prior to authorizing the clinical trial.

Upon the applicant's compliance with all the requirements, the OGITT shall issue a decision authorizing the clinical trial within a time limit of 40 business days; for clinical trials involving biological products or controversial situations requiring the participation of technical commissions, 60 business days.

The clinical trial shall be authorized for such a total term as scheduled for carrying it out, which is stated in the authorization form.

For purposes of surveilling the clinical trials, the OGITT may carry out ordinary and extraordinary inspections, which shall be based on the Guidelines for Inspection approved by the INS. The inspections could take place at the beginning, during or at the end of the clinical trial at the research center, the manufacturing place of the study drug, and/or the facilities of the sponsor, the principal investigator, the CRO or the Institutional Research Ethics Committee.

Sponsor and contract research organizations

"Sponsor" is defined as a person or people, company, institution or organization (including educational), with legal representation in Peru, which undertakes the responsibility for the initiation, maintaining, conclusion and/or financing of a clinical trial. It must be duly registered in the Peruvian Register of Clinical Trials.

"Contract research organization" is defined as the public or private, national or foreign, organization, with legal representation in Peru, to which the sponsor transfers any or all of its duties and obligations regarding a clinical trial by means of a contract; however, the sponsor undertakes the final responsibility in the execution of the research protocol and the results of the clinical trial. It must also be duly registered in the Peruvian Register of Clinical Trials.

The sponsor is responsible, among others, for the following:

- To obtain the authorization for carrying out the clinical trial
- To assure the approval of the Institutional Research Ethics Committee of the research institute before carrying out the clinical trial
- To have legal representation in Peru for as long as the clinical trial is carried out
- To ensure that all the information about the study product and related documents are in compliance with the research protocol and the Good Clinical Practices
- To keep the principal investigator, the Institutional Research Ethics Committee and the OGITT informed about any new information on the study product
- To choose the investigator(s) for the clinical trial
- To submit preliminary and final reports to the OGITT
- To submit a copy of the publication of the authorized clinical trials to the OGITT
- To guarantee that the manufacturing of the study product is in compliance with the Good Manufacturing Practices, as well as with adequate packing and labeling requirements
- To keep samples of the study product and its control and manufacturing protocols
- To store all information for at least 10 years following conclusion of the clinical trial (By the second year, information can be stored in electronic devices, prior communication to the OGITT.)
- Upon conclusion of the clinical trial, to guarantee a research subject access to the study drug
- To have a fund that guarantees the immediate medical assistance and treatment of the research subject in case of an adverse event resulting from the clinical trial

Additionally, the sponsor is responsible for reporting all serious adverse events, serious adverse reactions, and suspicions of those.

The principal investigator

The principal investigator is the professional responsible for a research team that carries out a clinical trial in a research center. A research center is the functional unity of a health establishment authorized by the Ministry of Health, where the clinical trial is conducted and which fulfills the minimum requirements as required by law.

The principal investigator is responsible, among others, for the following:

- To be aware of all the available information of the study product and the content of clinical trial protocol

- To ensure that personnel and equipment are suitable and have enough time to assist patients, and to verify that the staff is well informed about the clinical trial and the proceedings that are to be followed in all situations
- To obtain the authorization from the research institute where the clinical trial will be carried out
- To have the clinical trial approved by the Institutional Research Ethics Committee of the national institute where the clinical trial will be carried out
- To adequately inform the patients in order to carry out the recruitment/enrollment according to research protocol
- To obtain the informed consent of the research subject
- To ensure that the research product is used, disposed and collected as indicated in the approved research protocol
- To facilitate inspection visits, which shall be conducted by officers appointed by the OGITT, at the beginning, during or at conclusion of the clinical trial
- To ensure the safety of research subjects enrolled and the soundness of the decisions that affect their treatment
- To guarantee that all persons involved in the execution of the clinical trial respect the confidentiality of research subjects and the information gained in its execution
- To submit preliminary and final reports to the Institutional Research Ethics Committee of the national institute where the clinical trial will be carried out.

The investigator is obliged to report all serious adverse events, serious adverse reactions, and suspicions of those, to the sponsor, or the CRO and the Institutional Research Ethics Committee, and provide all related information.

Study drugs

The study drugs for which the authorization for a clinical trial is requested must comply with the following conditions:

- Be authorized for research on human beings by the competent authority of a country of high sanitary surveillance
- Be manufactured in the country, has pre-clinical research, and adjusts to the research policies established by the Ministry of Health
- Be able to establish the therapeutic equivalence of pharmaceutical products or similarity of biological products
- Be considered a priority for public health or be within the research policies established by the Ministry of Health
- Those drugs that require a clinical trial — at the request of the Health Authority — in order to prove safety and efficacy for purposes of the sanitary registration

Informed consent

The clinical trials shall be conducted in conditions that: respect human dignity; protect the rights and welfare of research subjects; and safeguard physical and mental integrity, as well as data privacy.

In order to participate in a clinical trial, every research subject is required to give its informed consent. While it is the investigator who is in charge of obtaining the consent, the monitor is responsible for verifying that all patients have given their written informed consent before starting any proceeding regarding the clinical trial. For this, when elaborating about the informed consent, the investigator must use clear and simple language, preferably colloquial expressions commonly used in Peru, when referring to illnesses or special situations in order to clarify or make the understanding of the study easier.

Intellectual property and data

There are no provisions regarding inventions, so in the event that any person participating in the clinical trial develops a product or process within the study and/or by using the sponsor's confidential information, such product or process shall be the sponsor's property.

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