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# CLINICAL TRIALS HANDBOOK
## Americas


CHILE

# Chile

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## Introduction

The Ministry of Health and the Public Health Institute (ISP) are the main regulators of clinical trials in Chile.

## Regulatory framework

The regulatory framework governing clinical trials consists of the following:

a) Law 20.120 titled "About Scientific Investigation in the Human Being, his Genome, and Prohibition of Human Cloning" and its Regulations

b) Technical Norm 57 ("TN57"), "Regulation for the Execution of Clinical Trials that Utilize Pharmaceutical Products in Human Beings"

c) Law 19.628 titled "About Protection of Private Life"

d) Law 20.850, which creates a "Financial Protection System for High Cost Diagnoses and Treatments"

## Clinical trial agreements (CTAs)

In Chilean jurisdiction, a clinical trial project is filed by the principal investigator with the Ethical-Scientific Evaluation Committee (EC). To be initiated, a project requires a written and dated authorization granted by the EC. The import and use authorization of the product is granted by resolution of the ISP. The lead investigator must also obtain the authorization of the director of the clinical facility.

In terms of notification, the main or lead investigator must periodically inform the EC about the evolution of the trial and provide a copy of the final report. The lead investigator must also notify the ISP's National Centre of Investigation of Medicaments and Pharmaceutical Vigilance, the sponsor and the EC of any adverse event. In case the event comes to the knowledge of the sponsor first, even if it took place abroad, the sponsor must communicate it to the lead investigator, the EC, the authorities and the Ministry of Health.

The sponsor must grant insurance (or other sufficient guarantee) to cover medical attention and indemnification for adverse effects derived directly from the use of the drug or the procedures directly related to the execution of the clinical protocol.

The general requirements of the Phase I clinical trial are the following: informed consent (following the model form of Addendum 1 of TN57); the investigator's compromise to adhere to the ethical guidelines (set out in Addendum 1 of TN57); sufficient insurance or guarantee; information on potential benefits to voluntary participants; protocol, which includes basic criteria to define "healthy individual," or in exceptional cases, expressly mentions a "situation of compassionate use"; detailed investigation protocol; a previous toxicity study in animals; Investigational Drug Brochure; information on the number of patients; a facility that complies with basic infrastructure and adequate personnel requirements; and the corresponding report issued by the EC, approving the trial after evaluating the previous antecedents. Some specific requirements exist in connection with different phases of the trial. For example, Phases III and IV, if pertinent, contemplate the result of prior phase studies, and Phases III and IV require a report of cumulative adverse effects.

## Sponsor and contract research organizations (CROs)

The requirements that the sponsor of the clinical trial must comply with are the following:

- Proposing a clinical trial that complies with the principles established in TN57 (Respect, Search of Good, and Justice)
- Identifying and proposing a lead investigator who fulfills the requirements established in TN57
- Ensuring that the facilities comply with the requirements established in TN57
- Providing the lead investigator with all the chemical, pharmaceutical, toxicological, and pharmacological information that guarantees product security, as well as all the information necessary for the adequate conduct of the trial (said information will be filed with the pertinent EC)
- Informing the lead investigator of all significant adverse effects related with the drug under study (whether the incidents occurred in Chile or abroad, or whether they happened prior to or during the clinical study) so as to ensure immediate communication thereof to the committees, institutional authorities and the Health Ministry
- Granting insurance (or other sufficient guarantee) that covers medical attention regarding any adverse effects derived directly from the use of the drug or the procedures directly related to the execution of the clinical protocol
- Ensuring the correct execution of the study by constant evaluation and submission of periodic reports to the corresponding authorities
- Paying the fee for the evaluation of the protocol as fixed by the authority

There is no legally set requirement for the sponsor to be located in Chile. In order to act in Chile, pertinent legalized powers of attorney must be granted to a representative with legal capacity to enter into juridical acts and to act in representation of the sponsor. The authority will analyze the technical and financial capacity of the appointed person, and more precisely of the appointed company, to operate all aspects related to the protection of the participating patients.

There are no provisions in internal laws and regulations governing CROs specifically; however, they do operate in Chile and their acts are recognized by the authority, even when acting on behalf of a sponsor. Nonetheless, it is worth pointing out that the sponsor maintains ultimate legal responsibility for the trial.

In principle, pursuant to the regulations, CTAs do not have to be submitted to the authority; nonetheless, pursuant to TN57, Annex 5, A) 2., 2.3, the EC may inquire on the existence of an agreement between the sponsor and the site/institution executing the trial.

## Investigator

The legal functions and responsibilities of the investigator are quite numerous. We have grouped them between those regarding compliance of the protocol; those in its relation to the EC; those related to the investigation itself; those regarding the product subject to investigation; those related to reporting of adverse effects; and those regarding participating patients.

Responsibilities in protocol compliance: The lead investigator must: (i) not modify the protocol without approval from the EC, unless the patient is in danger; (ii) initiate the trial only when written authorization with a specific date has

been granted by the committee, and the import and use authorization of the product is granted by resolution of the National Health Institute; and (iii) inform the sponsor if the committee withdraws its authorization for the trial.

Responsibilities regarding the Ethical-Scientific Evaluation Committee: The investigator must: (i) periodically inform the committee about the progress of the trial; and (ii) send the committee a copy of the final report on the study.

Responsibilities regarding the product undergoing the investigation: The investigator must: (i) protect its integrity and conservation; and (ii) explain to every patient the correct use of the product, and verify during the trial compliance with his or her indications.

Responsibilities regarding the notification of adverse events: The investigator must, as mentioned, inform the National Centre of Investigation of Medicaments and Pharmaceutical Vigilance of the ISP, the sponsor and the EC of any adverse events. (The Committee will inform the Health Ministry of adverse events related to the trial within a term of 15 days.)

Responsibilities towards patients participating in the trial: The investigator must: (i) comply with TN57 with regard to the informed consent; and (ii) inform patients once the trial has ended, or in the case of any potential suspension of the trial, ensure that the patients receive adequate treatment, if needed.

## Study drugs

Once the trial has been approved by the EC, and the import and use authorization of the drug to be employed in the trial has been granted by ISP, the study drug can be administered pursuant to trial requirements as set out in the protocol. Regardless of the silence of the regulations in this regard, in our experience, everything that has to do with the supply and finance of study drugs and of medical procedures provided for in the protocol is the responsibility of the sponsor and/or its delegate/CRO.

Please note that the main rule regarding liability for the study refers to the final obligation of the sponsor to provide insurance and guarantee in the terms expressed above.

Nonetheless, the lead investigator and participant-investigators may be held liable for their potential malpractice. (Of course, the allegedly aggrieved party will ascribe responsibility to all who may potentially indemnify said party). Clauses disclaiming responsibility for medical negligence are not enforceable against patients. We recommend adding a clause referring to liability and/or indemnification in the CTA, particularly outlining the obligation of the lead investigator and participant-investigators, and site to maintain their separate insurances to cover the scope of their operations.

There are no particularities regarding publications. Please note that informed consent must contemplate a declaration by the study subject in the sense that he or she acknowledges that the results of the study may be published, but that his or her identity and clinical data will remain confidential, unless required to be revealed by law.

## Intellectual property (IP) and data

We recommend introducing in the CTA Intellectual Property clauses to expressly protect inventions and other intellectual property rights to benefit the sponsor. Pursuant to Law 19.039, such intellectual property clauses are perfectly allowable and would safeguard the interests the sponsor may have over the resulting industrial property.

Law 20.120, Article 8 states that:

"*Knowledge of the human genome is common patrimony of the humanity. Consequently, no one may claim nor constitute property over it neither over part of it. The knowledge of a gene structure and of the total or partial sequences of DNA is not subject to patent.*

*The biotechnological proceedings deriving from the knowledge of the human genome as well as the products obtained directly from them, for diagnosis or therapy, are patentable according to general rules.*"

Accordingly, results related to the said subject matter will be considered as non-eligible, pursuant to the aforementioned law.

With regard to data exclusivity, Articles 89 et seq of Law 19.039 establish a five-year term protection for non-disclosed information related to the safety and efficacy of pharmaceutical products using a new chemical entity and which had not been previously approved by the corresponding sanitary authorities.

## Continuation of treatment

In accordance with Article 17 of Law 20.850, patients subject to clinical trials shall have the right, from the holder of the special authorization for provisional use for research purposes or from the owner of the sanitary registration, where appropriate, to the free continuity of the treatments received according to the study protocol, even when the latter has finalized and while its therapeutic utility subsists.

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