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EDITORIAL
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PHASE III CLINICAL TRIALS: NO ETHICS NO PARADIGM

ENSAYOS CLINICOS FASE III: SIN ÉTICA NO HAY PARADIGMA

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EDITORIAL

The phase III clinical trial is the paradigm of experimental health research and is the boundary between standard medicine and research medicine, so much so that two or more positive clinical trials support evidence-based medicine in routine clinical practice. The therapeutic, diagnostic and preventive advances of modern medicine rest to a large extent on the proper, ethical development and with the necessary scientific rigor established at the international and national levels.

In order for a new treatment to be available for daily use in patients, a model was proposed for more than four decades that consists of conducting sequential research studies, called clinical phases I, II, III and IV, which are initiated once the beneficial effects of the drug have been proven in cell and animal models (preclinical phase).

For the correct development of clinical trials it is necessary the responsible participation of the following characters: 1) The national regulatory body 2) The research center (site) and the Research Team 3) CRO and its monitors 4) Patients 5) Research Ethics Committee or IRB: Institutional Review Board 6) External Review Committee 7) Sponsor

All of them are responsible for solidarity and unavoidable and they work to assure society and the country the relevance of the clinical trial for the study population, the safety of the processes and the quality of the data, the integrity of the participants, the truthfulness and strict adherence to the study protocol and finally the scientific report and publication of the results, to only then be useful input for health decision-making.

In the United States, the regulatory body is the FDA: Food and Drug Administration. The other responsible regulatory bodies are COFEPRIS in Mexico, ALMAT in Argentina and in Peru, the INS (National Institute of Health) through the General Office of Research and Technology Transfer (OGITT) of the INS and the REPEC: Peruvian Registry of Clinical Trials. (https://web.ins.gob.pe/es/investigacion-en-salud/acerca-de-la-ogitt), offices that are in charge of the Peruvian Ministry of Health.

With regard to the research centers and the research team, it is clear that they must correspond to institutions with characteristics and competence in research, that the research team must, in addition to have the academic profile, possess the scientific and human aptitude, and the ethical quality to propose and develop it, the latter being the most important. In the world, clinical research ceased to be an exclusivity of large centers of high complexity, where patient selection biases, the availability of advanced technology and human resources does not translate into the actual practice of most health centers in the world, and even more so in our country. Therefore, research with pragmatic clinical trials, closer to the social, economic and political reality of the population, even in community trials, provide high quality evidence. From a public health perspective, working in primary health care and prevention protocols is a necessity and not just managing or prioritizing clinical trials of interest or funded by the pharmaceutical industry.

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The goal of a clinical trial is to test a hypothesis of an intervention to compare it with standard gold or the best available clinical support, which helps in the health and quality of life of people, and not only in economic developments of interest to a sector.

It is for the research institutions to submit and approve in their respective local research ethics committees the pertinence, suitability, balance of potential benefits and risks for the participants, and the conditions for the development of these protocols, because it is these committees that know the environment and the reality of the institutions. Centralizing and monopolizing with a single National Committee for Clinical Trials in a country of 33 million inhabitants does not seem logical, is not equitable and does not help to promote research. The regulatory body is responsible for promoting and validating institutional or local ethics and research committees, providing them with facilities and developing continuous training programs.

CROs: Contract Research Organizations are companies that provide support to pharmacists and are contracted by the sponsor to perform one or more of the sponsor's duties and functions related to the trial. They perform various functions before, during and at the end of the clinical trial and their monitoring role is highlighted with visits, records and reports of the normal or not development of the clinical trial.

The patients who participate in a clinical trial are the center and reason to be a phase III study. They deserve all the attention, their integrity must be safeguarded, their rights respected, they must be given all the information, and when invited to participate they must receive and sign an informed consent. Their participation should be voluntary, free, informed and they should know that you they leave the protocol at any time. They should also know that in a phase III clinical trial, there are generally two groups, the Intervention Group A, which will receive the active ingredient, and the Control Group B, which will not receive the product under investigation. This assignment of each patient should be done in a randomized way, which does not depend on the patient or the researcher, to avoid study bias.

The sponsor is directly responsible for the clinical trial. The responsibilities of the sponsor are multiple, some of them are: apply for approval by the local Ethics Committee, comply with national and international requirements, emphasize the benefits of local needs. It is essential that officials and public servants associated with the processes of submission and approval of clinical trials in our country can clearly differentiate commercial sponsors from academic sponsors. In Peru we should encourage more universities to participate as academic sponsors, with the aim of truly promoting research of interest to our country and not just approving "international canned projects" presented by transnational, that do not always respond to the priority needs of our country.

Clinical trials have multiple safety padlocks, one of them is to have "Good Clinical Practices" that every researcher and team member must know and put into practice, in order to avoid being a judge and party, they must have a "External Academic Review Committee" to the institution and the research team that carries out the clinical trial, with people who clearly do not present conflicts of interest.

A rigorous follow-up is necessary for a valid and quality research. Exclusions, withdrawals and losses generate biases and deviations from the protocol (alteration or modification to the previously approved protocol). A major deviation or violation of the protocol is considered to be one that impacts the subject's safety, or alters the risk/benefit balance, or compromises the integrity of the study data and/or affects the subject's willingness to participate in the study. Errors in relation to the criteria of inclusion and exclusion, error in the delivery or dosage of the drug is considered a flagrant violation of the protocol. The international scientific community looks with distrust at data from studies that do not strictly meet these criteria.

Clinical research is crucial for the advancement of medical knowledge and patient care. In particular, clinical trials are the cornerstone in the development of new treatments.

Ethics mark the course of research in health, without ethics there is no paradigm or research that benefits people and humanity. Anywhere in the world where ethics is taught, what happened in Peru during the pandemic and vaccines will be mentioned as an example of what should not be done in clinical research. It is one thing to know about ethics and the theory of clinical trials and quite another to put it into practice and comply with the principles that govern clinical trials and to transmit with the example what is presumed in the classrooms.

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