A Quick Guide to Clinical Trials (Part 2: The Process)

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In Part 1 of this series, we discussed the different types of clinical trials and the phases of clinical trial studies. In this article, we look at the process of registering and conducting clinical trials as well as the ethical considerations.

Carrying out a clinical trial requires careful planning, diligent work, and the consideration of several legal and ethical aspects. During the process, valuable information is collected and analyzed to address specific research questions. The results of the study are then presented to different audiences in peer-reviewed journals or as clinical study reports.

Preparing a Clinical Trial

Each clinical trial starts with a clear idea that usually results from extensive laboratory studies. In such a trial, the most promising treatments from the lab are tested on a selected number of human subjects to confirm the safety, applicability, and effectiveness before being marketed and/or applied to the public.

At the beginning of the study, the researchers develop a study protocol, which is a plan in which all the questions and procedures are clearly defined. The study protocol must be designed very carefully in order to safeguard the participants' health and provide significant data for the study. It should clearly describe the reasons for conducting the

research and explain its relevance in the context of current knowledge. The *goals and objectives* of the study must also be defined, and this should be done as simply and specifically as possible.

The credibility and scientific value of a clinical study strongly depend on the *study design and methodology*, so detailed information on the expected duration of the trial; the type of measurements, tests, data analyses, and interventions that will be made; the procedures that will be used; and the characteristics of the participants (e.g. inclusion and/or exclusion criteria) should also be included in the protocol.

Informed Consent

To protect the interests of participants in a clinical trial, researchers must also provide them with enough information on the risks and potential benefits of the study so that they can decide whether they want to take part in the trial or not. Anyone planning to participate in the trial must then sign an informed consent document to declare that all the required information was provided and that he or she understands the implications. However, an informed consent document is not a contract and participants may withdraw from a study at any time, even after signing it.

Institutional Review Board

Most clinical trials in the United States are reviewed, approved, and monitored by an Institutional Review Board (IRB) to ensure that "the rights and welfare of human subjects are protected during their participation". An IRB is an independent committee that normally includes both individuals with scientific or medical expertise, who can review the procedures and scientific validity of the study design, as well as non-scientists, who may identify any risks related to social, legal, or cultural considerations. Read more about research ethics committees here.

Registering and Publishing a Clinical Trial

Registering a clinical trial when it begins and making all the information related to the study publicly available has many benefits. Registration is usually also mandatory for journal publication.

To register a clinical trial, researchers must:

- Determine who is responsible for registering the study and which Protocol Registration and Results System (PRS) account should be used.
- Understand the submission requirements.
- Login to the registration system and enter the required information.
- Preview, revise, and submit the record.

The results obtained in clinical trials are often published in peer-reviewed journals, and when doing so, it is important to maintain the statistical and reporting integrity of the published manuscripts (especially if they deal with research on human subjects). This can be achieved by checking the articles against common reporting guidelines, such as the Consolidated Standards of Reporting Trials (CONSORT) Statement, the Standards for the Reporting of Diagnostic Accuracy Studies (STARD), or the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Statement.

If the results of a clinical trial are particularly important, they may also be presented at meetings or featured in news media. Once a new approach has proven to be successful, it may become the standard of medical practice.

Cite this article

Enago Academy, A Quick Guide to Clinical Trials (Part 2: The Process). Enago Academy. 2017/03/22. https://www.enago.com/academy/a-quick-guide-to-clinical-trials-part-2-the-process/