FDA 101: Clinical Trials and Institutional Review Boards

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Clinical trials test potential treatments in human volunteers to see whether they should be approved for wider use in the general population. A treatment could be a drug, medical device, or biologic, such as a vaccine, blood product, or gene therapy.

Potential treatments are studied in laboratory animals first to determine potential toxicity before they can be tried in people. Treatments having acceptable safety profiles and showing the most promise may then be considered for use in clinical trials.

It is not known whether a potential new medical treatment offers benefit to patients until clinical research on that treatment is complete. Clinical trials are an integral part of new product discovery and development, and are generally required by the Food and Drug Administration (FDA) before a new product can be brought to the market.

How Are People Protected?

FDA has authority over clinical trials for drug, biologic, and medical device products regulated by the agency. This authority includes studies that are funded by the U.S. Department of Health and Human Services (with joint oversight by FDA and the Office for Human Research Protections), as well as studies that are solely funded by industry or by private parties.

Clinical trial procedures are reviewed by institutional review boards (IRBs). These boards are composed of at least five members that include scientists, doctors, and lay people. They review and approve clinical trials taking place within their jurisdiction before the trials can begin.

The purpose of an IRB review is to ensure that appropriate steps are taken to protect the rights and welfare of participants as subjects of research. If the risks to participants are found to be too great, the IRB will not approve the research, or it will specify changes that must be made before the research can be done.

As part of their review, IRBs consider participant inclusion and exclusion requirements to be sure that appropriate people have been identified as eligible for the trial. They often look at how and where recruitment for clinical trials will occur.

IRBs review the adequacy of the informed consent document to ensure that it includes all the elements required by law, and that it is at an appropriate reading level and understandable to study participants.

To help protect the rights and welfare of volunteers and verify the quality and integrity of data submitted for review, FDA performs inspections of clinical trial study sites and anyone involved in the research.

Many groups play important roles in looking out for the safety of research subjects. These groups include FDA, other government agencies, and institutional review boards. There is also monitoring of studies by industry or private sponsors, as well as oversight and reporting by investigators and their staff.

What Are the Risks?

Clinical trials should be carefully designed to answer certain research questions. A trial plan called a protocol maps out what study procedures will be done, by whom, and why. Products are often tested to see how they compare to standard treatments or to no treatment.

FDA often provides extensive technical input to researchers conducting clinical trials, which may help them design better trials that can characterize effects of a new product more efficiently, while reducing risks to those participating in the trials.

The clinical trial team includes doctors and nurses, as well as other health care professionals. This team checks the health of the potential participant at the beginning of the trial and assesses whether that person is eligible to participate. Those found to be eligible--and who agree to participate--are given specific instructions, and then monitored and carefully assessed during the trial.

Some treatments being studied can have unpleasant, or even serious, side effects. Often these are temporary and end when the treatment is stopped. Others, however, can be permanent. Some side effects appear during treatment, and others may not show up until after the study is over.

The risks may vary depending on the treatment being studied and the health of the people participating in the trial. All known risks must be fully explained by the researchers before the trial begins. If new risk information becomes available during the trial, participants must be informed.

FDA is committed to protecting the participants of clinical trials, as well as helping to ensure that reliable information is provided to those interested in participating. Although efforts are made to minimize risks to clinical trial participants, some risk may be unavoidable because of the uncertainty inherent in clinical research involving new medical products. It's important, therefore, that people make their decision to participate in a clinical trial only after they have a full understanding of the entire process and the risks that may be involved.

What Is Informed Consent?

FDA requires that potential participants be given appropriate information about the study to enable them to decide whether to enroll in the clinical trial. This process is known as "informed consent," and it must be in writing.

The informed consent process provides an opportunity for the researcher and patient to exchange information and ask questions. Patients invited to enter a trial are not obligated to join, but can consent to participate if they find the potential risks and benefits acceptable. A consent form must be signed by the participant prior to enrollment and before any study procedures can be performed.

Participants also have the right to leave a study at any time. At the same time, people need to know that circumstances may arise under which their participation may be terminated by the researcher, without their consent.

For example, sometimes it becomes evident early on that a trial is not working and researchers know they are not going to get enough meaningful information to make continuation worthwhile.