Clinical Trials & Research: What to Know Before You Go

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What are clinical trials and clinical research?
Clinical trials are one form of clinical research involving a researcher or researchers who directly observe a person or people, and/or collect data to answer a scientific or medical question about the safety or potential benefit of an intervention such as a medication, device, teaching concept, training method, or behavioral change. Clinical trials are used to determine whether new biomedical or behavioral interventions are safe, successful, and effective. Research with human subjects to develop or evaluate clinical laboratory tests (imaging or molecular diagnostic tests) might be considered as a clinical trial if the test will be used for medical decision making, or if the test itself imposes more than minimal risk for subjects.

Types of clinical trials
Clinical trials are designed to provide information about different types of outcomes. Some studies, particularly those involving pharmaceutical products, are designed to determine what the body does to the product. These are usually called pharmacokinetic (PK) studies. PK studies are usually the first phase of study and are performed to determine proper dosing. Dosing may be different for different populations based on age and genetics (which includes sex, race, and differences in metabolism).

Another type of outcome is to examine what the product does to the body. These studies are called pharmacodynamic (PD) studies. PD studies are used to examine the ability, safety, and clinical activity of a drug or device. Some studies combine a PK component and a PD component.

An additional category of clinical trials—called efficacy studies—establish the overall risks and benefits of any intervention. These studies must be of large enough size and must incorporate the proper design to allow the results to be analyzed and generalized, or applied to the general population.

Where to find opportunities
People usually become aware of the opportunity to participate in a clinical study through:

- Healthcare providers
- Public listings and registries of clinical trials (such as www.clinicaltrials.gov)
- Public notices in print or broadcast media
- Friends, family, or others who tell them about the clinical research
- Groups or organizations that conduct or sponsor clinical research

Getting involved in clinical research
People volunteer to enroll in clinical research. Volunteers will be notified of the potential risks, benefits, alternatives, and responsibilities before agreeing to participate. A clinical research volunteer may receive some form of compensation for time and expenses, but not all clinical research offers compensation.

Giving consent
When potential participants decide they are interested in taking part in a study, they begin discussions with various members of the scientific community who are also involved in the study. One of the primary safeguards for study participants is that they are informed about the potential risks, benefits, alternatives, and responsibilities of the clinical trial before they agree to participate. When a potential study participant understands the risks, alternatives, and responsibilities, he or she formalizes the decision to participate by communicating with the study investigator or representative and by documenting the agreement in writing. The interactive process of receiving information, asking questions, and indicating agreement is known as the consent process. For children or others who are not legally able to provide consent, a parent or legal guardian provides permission for the person to participate. Even though a person may not be legally able to provide consent, they are still informed about the clinical research to the degree that they are able to understand. They may also have the opportunity to provide their agreement to participate in an alternative way that includes the process of assent.

Protecting participants in clinical research

Federally funded clinical research has many safeguards in place to protect those who volunteer to take part. For study participants, especially those with complex illnesses, "protected" does not mean "risk-free"—all studies carry some risk.

Some of the protections for study participants include (but are not limited to):

- Knowing what will happen during a study—Study protocols. A study protocol is a document that describes in detail the plan for conducting a clinical study.
- Federal regulations define study protocol contents, particularly if the study involves investigational (not FDA approved) products.
- Clinical studies are designed to include a listing of the characteristics that allow a person to participate called the "eligibility criteria."
- Studies also schedule relevant procedures and evaluations for participants often enough so that potential risks can be detected and addressed in a timely manner.
- Study participants have specific contact information so they can get in touch with someone related to the study for any reason at any time.
- Knowing the possible risks and benefits of participating—Study participation consent process.
- Reviewing the study before it begins—Institutional Review Boards (IRB) are independent bodies authorized by federal regulations to evaluate a clinical research study to ensure ethics and safety. At the federal level, the Office for Human Research Protection regulates IRBs and ensures that they meet criteria for IRBs as described in federal regulations[1].
- If a study protocol uses a product regulated by the Food and Drug Administration (FDA), then the FDA may also review the protocol and has the option to request changes before the study can proceed.
- Monitoring the study while it is underway—Some studies rely on an additional independent committee to monitor the study results and its conduct while the trial is underway.
- Protecting privacy—In general, confidentiality of study participants is covered under the Health Insurance Portability and Accountability Act. In addition, if the release of study data could have negative consequences if linked to a certain participant, due to the nature of the disease or condition, the study can receive a Certificate of Confidentiality. A Certificate of Confidentiality is issued by the NIH, and is a legal document that protects investigators and institutions from being compelled to reveal information that would identify research participants.

Conclusion

Participants in clinical trials can play a more active role in their own healthcare, gain access to new research treatments before they are widely available, and help others by contributing to medical research. For more information on the benefits and risks of joining a clinical trial, visit www.clinicaltrials.gov.

[1] *The RLS Foundation only publishes clinical trials and/or research that has received IRB approval.*

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