

The significance of clinical trials

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Abstract

Background: Clinical trials are essential for the development of new treatments. Whether a person should participate depends on their understanding of the risks and benefits for themselves and for society as a whole.

Discussion: There are rules in place to protect human research subjects and all studies involving humans are reviewed locally to ensure that subjects are treated safely, fairly, and confidentially. Nevertheless, each subject should consider for themselves whether participation is consistent with their values.

Conclusion: Clinical trials, when well-designed, can benefit the participants as well as the investigators, the sponsors, and the medical community.

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Every new medicine and treatment started with volunteers participating in clinical trials. We owe our current high standards of medical care to studies that have been conducted in the past under guidance of the US Food and Drug Administration (FDA). In addition to testing new drugs and devices, clinical trials provide a scientific basis for advising and treating patients. Even when researchers do not obtain the outcomes they predicted, trial results can help point scientists in the correct direction.

Physicians play a key role in referrals to clinical trials. Being well-prepared to answer the following common questions will help clinicians guide their patients and family members through the decision process.

Why participate in a clinical trial?

Well-designed and executed clinical trials provide an opportunity for participants to:

- Play an active role in their own health care
- Gain access to new research treatments before they are widely available
- Increase the options for treatment when standard therapy has failed
- Obtain expert medical care at leading health care facilities during the trial
- Help others by contributing to the advancement of medical knowledge

Are clinical trials safe?

The FDA works to protect participants in clinical trials and to ensure that people have reliable information as they decide whether to join a clinical trial. The FDA has regulations for

clinical research to protect participants from unreasonable risks. Although efforts are made to control the risks, some may be unavoidable because of the uncertainty inherent in medical research studies involving new treatments.

In addition to FDA oversight, every clinical trial in the US must be approved and monitored by an Institutional Review Board (IRB) to make sure the risks are as low as possible and are worth any potential benefits. An IRB is an independent committee of physicians, statisticians, community advocates, and others that ensures that a clinical trial is ethical and the rights of study participants are protected. All institutions that conduct or support biomedical research involving people must, by federal regulation, have an IRB that initially approves and periodically reviews the research.

Researchers are required to give prospective participants complete and accurate information about what will happen in the trial. Participants must sign an "informed consent" document indicating they understand that the trial is research, and that they can leave the clinical trial at any time. This informed consent is part of an ongoing process that ensures a prospective participant in a clinical trial understands what known risks might be associated with the study.

Some examples of possible risks in clinical trials include:

- unpleasant, serious, or even life-threatening side effects resulting from the treatment.
- treatment may not be effective for the participant.
- greater time and attention investment than standard treatment.

What else should be considered before participating?

People should know as much as possible about the trial and feel comfortable asking the members of the health care team about it. The following questions might be helpful for the participant to discuss with the trial team:

- What is the purpose of the study?
- What kinds of tests and treatments are involved?
- How do the possible risks, side effects, and benefits in the study compare with my current treatment?
- How might this trial affect my daily life?
- How long will the trial last?
- Who will pay for the experimental treatment?
- Will I be reimbursed for other expenses?
- Is long-term follow up care included in the study?
- How will I know the experimental treatment is working?
- Will results of the trials be provided to me?

Whether or not to participate in a clinical trial is a personal decision. Each patient and each clinical trial is different. When considering a clinical trial, a person should try to gather as much information as they can and then do what they feel is best in their own mind. Those who decide to volunteer may be contributing directly to our understanding of diseases and how to treat them.

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