

About Clinical Trials

What is a clinical trial and how does it work?

Clinical trials look at ways to treat diseases. The goal of a clinical trial is to learn whether an investigational medication or a medical device is safe and effective to use in a specific disease or condition.

Every trial is conducted according to a pre-approved protocol that helps to ensure the safety of participants and provides detailed information on:

- who can and cannot participate in the trial
- how long participants will be in the trial
- the investigational medications or medical device participants will take or use during the trial
- tests and assessments that participants must undergo
- potential risks and benefits for the participants

What is the role of the U.S. Food and Drug Administration (FDA) in planning, execution and approval of clinical trials?

To ensure safety and compliance, drug developers, or sponsors, must submit all trial protocols to the FDA before beginning clinical research. The FDA reviews the protocols to ensure they do not impose too much risk to the participants of the trial.

What are the phases of a clinical trial?

- **Phase I trials:** An experimental drug or treatment is studied in a small group of people to determine the best dose with the fewest side effects.
- **Phase II trials:** The experimental drug or treatment is given to a larger group of people to evaluate and determine its potential effectiveness and safety.
- **Phase III trials:** The experimental drug or treatment is administered to large groups of people to confirm its effectiveness and safety and then compare it with standard or equal treatments. The findings from these trials are traditionally used for submitting an application to a regulatory authority such as the FDA for potential drug approval.
- **Phase IV trials:** Once approved and available to participants, researchers track the drug's safety over time, and additional information on the drug's effectiveness.

What is the role of an Institutional Review Board (IRB)?

An Institutional Review Board (IRB) is an administrative group within an institution that reviews and monitors clinical research involving human subjects, with the goal of protecting subjects from physical and psychological harm. An IRB has the authority to approve, require modifications in or reject research protocols.

Why should I consider participating in a clinical trial?

Clinical trials can offer hope and help researchers identify new treatments. People participate in clinical trials for a variety of reasons, including the opportunity to help others, contribute to the advancement of science, the possibility of receiving the newest treatment(s) and additional care and attention from clinical trial staff.

There are usually no costs associated with participating in a clinical trial. The costs of the investigational medicine or medical device, trial visits and trial related tests and procedures are paid for by the clinical trial sponsor.

What can I expect if I participate in a clinical trial?

When considering participation in a clinical trial, participants should be aware of the risks involved. Participants should consider how a clinical trial could potentially pose harm, such as discomfort, medical complications and/or injury. These risks are described in detail in an informed consent document.

What is informed consent?

Informed consent is a process in which you are given detailed information about a clinical trial so that you can decide whether you want to participate. This information includes details about the trial's possible risks and benefits. After you review the information carefully, ask any questions you may have about the trial. If you agree to participate, you will need to sign the informed consent form to show that you understand the information shared.

Will my privacy be protected if I participate in a clinical trial?

Protecting the identity of participants in a clinical trial is very important. If you enroll in a clinical trial, your medical privacy will be protected. All information collected by the trial doctor during the trial will be labeled with a code, and only authorized persons (e.g., the trial doctor) will have access to the list of patients and matching codes.

What happens after a clinical trial is completed?

After a clinical trial is completed, researchers carefully examine information collected during the trial before making decisions about the meaning of the findings and about further testing. Results of the trial may be publicly shared at medical meetings and/or with a press release from the trial sponsor. The trial results are also sent to the FDA for review.

Speaking with your doctor

If you're considering participation in a clinical research trial, you should speak with your doctor first.

Here are some questions to keep in mind when speaking with your doctor:

1. What are the possible benefits and risks of participating in a clinical research trial?
2. Will I be guaranteed experimental treatment if I participate in a clinical trial?
3. If I join a clinical trial, will I need to see a new doctor?
4. Are there any additional options to receive treatment outside of a clinical trial?
5. Will I be able to try other treatments later after I participate in a clinical trial?
6. If I join a trial, will it affect my ongoing treatments, food habits and lifestyle?
7. What are the time and logistical commitments (travel, etc.) for participants in a clinical trial?
8. After the trial, can I remain on the investigational drug?

For more information about clinical trials, please visit this National Institutes of Health [resource](#). All listings for all clinical trials can be found at clinicaltrials.gov.

References

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