

FAQs

What is a clinical trial?

- Research studies that evaluate the safety and effectiveness of new medications in humans.
- Before human testing, these potential treatments undergo rigorous lab animal testing to verify safety.
- They are closely regulated by the US Food and Drug Administration (FDA). FDA approval is required for new treatments, ensuring they meet stringent quality and safety standards before public availability.

Why should I join a clinical trial?

- **In-depth Healthcare Attention:** Benefit from closer health monitoring and personalized care from healthcare professionals throughout the trial.
- **Access to New Treatments:** Gain early access to innovative treatments and contribute to the development of new medical therapies.
- **Complimentary Health Assessments:** Receive free health screenings, lab tests, imaging, and exams, providing valuable insights into your health.
- **Contribute to Medical Advancements:** Play a crucial role in advancing medical knowledge and treatments, helping to improve public health.
- **Safety and Volunteer Well-being:** Enjoy the assurance of a safety-focused environment, with the option to withdraw at any time for your comfort.

Can anyone participate in a clinical trial?

No, specific requirements and eligibility criteria exist for participating in clinical trials. Here are some key things to keep in mind about who can participate:

- **Age** - There are often age minimums and maximums, depending on the study.
- **Health status:** To be eligible for the treatment, participants must have the medical condition that the treatment intends to alleviate. There are usually criteria around the type and severity of symptoms. Certain other health conditions may also exclude someone from participating if it could impact results.
- **Gender:** Some trials are limited to a single gender, especially early-stage trials testing drugs that interact differently with men vs. women.
- **Prior treatments/therapies:** Another criterion often considered is Whether someone has undergone previous treatments related to the condition.

Ultimately, clinical trials set rigorous guidelines on age, health, gender and more. The specifics are narrowed down based on what they want to test and study for any potential new treatment. Getting enrolled can be selective.

What are clinical trial benefits and risks?

Benefits include:

- Active participation in health care.
- Access to scarce and often costly treatments.
- Free testing (i.e. imaging, bloodwork, exams).
- Assisting others by participating in trials for potential approval and public availability.

Participating in a clinical trial may carry risks your doctor will disclose. Possible risks of experimental treatment include:

- Side effects, both known and unknown.
- Study procedures.
- Treatment ineffectiveness.
- Treatment is not practical for all patients.

Some clinical trials give patients a placebo instead of experimental treatment. Along with the risks above, the trial may need time and attention from participants, including trips to the research location, more treatments, hospital stays, or complex dosage requirements.

Is there any cost to me or my insurance company to participate?

Participating in a legitimate clinical trial is free. Key clinical trial expense points to consider:

- In a typical clinical trial, the sponsor is responsible for covering the cost of study drugs, procedures, testing, and research appointments.
- Health insurance companies do not pay for medical costs associated with clinical trials. Some exceptions apply to problems or routine care outside the trial.
- Depending on the trial, participants may be eligible for travel reimbursement, with most reimbursement maximums set in advance. Participation in legitimate clinical studies is free. Sponsors pay the trial protocol's medical costs to get data.

Do I get paid if I participate in a clinical trial?

Individuals who participate in numerous clinical studies receive compensation for their involvement. Some important things to know about paying:

- Payment is for the time and effort outlined and specified in the study protocol. Payment amounts vary based on study length, required processes, and participant needs. The sponsor sets the amounts for these payments.
- Studies also offer free medical checks, lab tests, and medicines.

The current payment system does not incentivize taking personal risks. Such pressure is against ethical standards.

Before enrolling in a trial, the research site will disclose payments for time and travel.

Payment should never be the main reason for participation; the primary goal should be advancing medical study.

What should I consider before enrolling in a research trial?

All potential volunteers must learn as much as possible about their disease and the clinical study they are pursuing. Participants should ask members of the study team questions about the trial, the care they can expect while participating, and the potential risks.

Participants are encouraged to ask the trial's study team the following questions:

- What is the purpose of the trial?
- Why do the researchers feel the experimental treatment will be effective?
- Has it been tested previously?
- What types of tests and experimental therapies are used?
- How do the research's potential risks, side effects, and benefits compare to my present treatment?
- How will my illness and the effectiveness of the treatment be tracked?
- How will this trial affect my daily life?
- How long will the trial be?
- Who will pay for the experimental treatment?
- Will I get compensated for additional expenses?
- Will I receive the trial results? When?
- Who will be in control of my healthcare?