

Clinical Trials

What You Should Know



What are clinical trials?

Clinical trials are research studies that explore whether new treatments are effective and allow doctors to test advances in medicine that may offer more choices to current approaches to care. The Food and Drug Administration (FDA) requires all new treatments go through clinical trials before they are approved to use on the general public. They serve a vital role in medical research and treatment guidelines.

Clinical trials study:

- **Prevention** to reduce the risk of disease
- **Screening** to find disease early
- **Diagnostics** to test for disease
- **Treatment** to give care or treat the disease
- **Quality-of-life** to offer comfort for people with long-term issues

What are the phases of clinical trials?

Clinical trials are done in phases. Each phase has a purpose and helps researchers answer questions.

- **Phase I:** The drug is tested in small numbers. One of the main goals is to test if the drug is safe and what dose may be best. It must show promise in the lab. The clinical trial is taken to the next level if the new approach is found to be better in some way than standard care.
- **Phase II:** Researchers study safety and the best way to give the care in a small number of patients. These are where side effects are found. If a new drug or treatment does not show it helps to reduce disease or if it causes troubling side effects, the research is stopped or changed (and side effects are treated).
- **Phase III:** Only treatments found to safely help patients are moved to the final phases. About one third of all

drugs tested move to Phase III. Here, hundreds to many thousands of patients may participate. In Phase III trials, patients are often chosen at random for one of many treatment choices. A patient may be assigned to get the new drug or treatment, a combination of treatments, the standard treatment or no treatment at all. Often the study is “blinded” so no one involved knows who gets what (computer assignments). This phase involves testing for safety, use and dose. All groups are compared at the end of the study.

- **Phase IV:** This phase is when the new drug has been approved by the FDA and is safe, but further studies are performed in order for researchers to learn more about long-term use.

This process is the only way new drugs, tests or techniques can be offered to patients safely. Each drug offered today was once tested in a clinical trial.

Could clinical trials offer better care than standard treatment?

Clinical trials may offer new choices for patients who have not had success with other treatments. Clinical trials are available for many different diseases and for patients at varying disease stages. Often, a new treatment or technique is compared to standard care. If the standard care is no treatment, then a placebo (fake pill) may be used. The results teach doctors and patients about the benefits and drawbacks of a new approach to care.

Clinical trials must follow a strict plan (“protocol”), and patients in clinical trials are very closely watched. This is how researchers ensure the data they collect is accurate and that patients are receiving good care.



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As with all medical treatments, there may be risks. These risks include side effects and the chance the new treatment may not work as well as hoped. Researchers want patients and caregivers to be well informed, so they will fully explain all risks and answer questions. It's a person's choice whether or not to be in a clinical trial, and people may drop out at any time.

Who should take part in a clinical trial?

- **You** may learn if you are eligible for a clinical trial from your health care team. A clinical trial may be a good choice for you if past treatments haven't helped.
- **Diverse people** are needed to help ensure a drug or treatment can help all types of people with a variety of lived experiences and living conditions, as well as characteristics like race and ethnicity, age and gender, so that all may benefit from scientific advances.
- **Those who share feedback** as part of clinical trials help the frontline of research which may help themselves, future patients and family. For example, since cancer can be a genetic disease, clinical trials may bring benefits for your own children or grandchildren.

How are people protected when in a clinical trial?

People who take part in clinical trials have rights and protections. All clinical trials must be approved by an Institutional Review Board (IRB) to ensure the protection of the patient is at the forefront of the trial. Most clinical trials have an informed consent form to ensure the study's risks and benefits are clear. Privacy is well-guarded and those in the study have full control over their rights and may drop out at any time.

Are there fees with clinical trials?

It is of great value to learn what your insurance does and does not cover before starting a clinical trial. Many insurance groups don't cover extra costs from a clinical trial, but in most cases the treatment provider, clinic or company involved in the study cover added costs. You can ask to get financial help before you agree to take part in the trial.

For more information about financial support, learn from groups like the Patient Advocate Foundation (patientadvocate.org) or CancerCare (cancercare.org).

Questions to ask your doctor about clinical trials:

- How many patients should take part in this clinical trial?
- How long has this clinical trial been open?
- What is the early data on safety and treatment results for this clinical trial?
- What is your experience with this clinical trial?

How can I find a clinical trial for my urologic condition or disease?

You may ask your health care provider or oncologist if you qualify for a nearby clinical trial. You may also find more information at ClinicalTrials.gov.

About the Urology Care Foundation

The Urology Care Foundation is the world's leading urologic foundation – and the official foundation of the American Urological Association. We provide information for those actively managing their urologic health and those ready to make health changes. Our information is based on the American Urological Association resources and is reviewed by medical experts.

To learn more, visit the Urology Care Foundation's website, UrologyHealth.org/UrologicConditions.

Disclaimer

This information is not a tool for self-diagnosis or a substitute for professional medical advice. It is not to be used or relied on for that purpose. Please talk to your urologist or health care provider about your health concerns. Always consult a health care provider before you start or stop any treatments, including medications.

For more information, visit UrologyHealth.org/Download or call 800-828-7866.

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