

Clinical Trials Fact Sheet

Urology Care
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*The Official Foundation of the
American Urological Association*



Patients with a urologic condition may wish to participate in a clinical trial. Clinical trials offer hope in that they are research studies that explore whether a new treatments are effective.

Clinical trials aim to find better ways to prevent, screen, diagnose or treat a disease or condition. They may offer a new choice for patients who have not had success with other treatments. They teach doctors and patients about the benefits and drawbacks of a new approach to care.

The Food and Drug Administration (FDA) requires that 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. People who take part in a clinical trial are helping to advance science and knowledge. Participants can make a big change in their lives and the lives of future patients.

What are clinical trials?

Clinical trials allow doctors to test advances in medicine that may be better than current approaches to care.

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. Clinical trials study:

- Prevention: how to reduce the risk of disease
- Screening: how to find disease early
- Diagnostics: how to test for disease
- Treatment: how to give care or fight/cure the disease
- Quality-of-life: how to offer comfort for people with long-term issues

There are many experts involved in developing new treatments. These researchers are often from cancer centers,

universities, town clinics, pharmaceutical labs or hospitals.

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

- **Phase I:** First, the drug is tested in small numbers. 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:** Next, researchers study safety and the best way to give the care in a small number of patients. These are where side effects are found.
- **NOTE:** If a new drug or treatment does not show that it helps to reduce disease or if it causes troubling side effects, the research is stopped or changed (and side effects are treated!).

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- **Phase III:** Only the most hopeful treatments (those that may help patients and are safe) are moved to the final phases. About 1/3 of all drugs tested move to Phase III. Here, hundreds to many thousands of patients may participate. In Phase III trials, patients are often randomly chosen 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

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no treatment at all. Often the study is “blinded” where 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 (2-5 years later)

- **Phase IV:** 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 that new medicines, tests or techniques can be offered to patients safely. Each medicine that is commonly offered today was once tested in a clinical trial. For more information about the phases of Clinical Trials, learn from groups like Clinical Trials Transformational Initiative (www.ctti-clinicaltrials.org) or the Bladder Cancer Advocacy Network (www.bean.org/clinical-trials).

Could clinical trials offer better care than standard treatment?

Patients who enter a clinical trial are the first to try a new treatment or technique. Doctors perform clinical trials because they would like to test the idea that the therapies they are studying could be better or safer than current ones.

Because a clinical trial must follow a strict plan (“protocol”), it’s a proven way to get high quality care. Patients in clinical trials are very closely watched. This is how researchers can be sure the information they collect is accurate and complete. Many patients value this extra care, but it can feel like a burden as well. Clinical trials can become time consuming with repeat lab and imaging tests.

As with all medical treatments, there may be risks. These risks include side effects and the chance that the new treatment may not work as well as hoped. In some cases, the treatment may cause new, unexpected problems. Before you agree to enter a study, your healthcare provider will fully explain all the risks and answer your questions. Researchers want patients and loved ones to be well informed. It’s your choice whether or not to be in a clinical trial. It’s also important to know that once you agree to be a participant in a clinical trial, you may stop participating at any time.

Should I take part in a clinical trial?

- Your healthcare provider(s) can help you learn if you are

eligible for a clinical trial. People of all ages can volunteer and have the chance to benefit from these research studies. A clinical trial may be a good choice for you if past treatments haven’t helped.

- Doctors want to make sure that a drug or treatment works in all types of people, to include the young, old, men, women, Black, Asian, Hispanic and so on. At this time, more than 83% of clinical trial participants are White, and mostly men. Researchers wish to involve a wide variety of clinical trial participants to make sure that their findings help all people.

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- Taking part in a clinical trial is a useful way to be involved in the frontline of research. You can offer important feedback. Participants play a worthy role in making care better for themselves and for future patients. For example, since cancer can be a genetic disease, your help may even bring benefits to care for your own children or grandchildren.
- People who take part in clinical trials have rights and protections. Most clinical trials need you to sign an “informed consent” form before you start. This form states that you and your loved ones fully understand the study, and its risks and benefits. You may drop out at any time. If you or your loved ones have any concerns, talk to someone on the clinical trial staff. Your privacy is well-guarded. Clinical trial participants are not “guinea pigs”. They are treated with care, honesty and have full control over their rights.
- Before you sign the clinical trial’s informed consent form, review exactly what is being offered and how it’s different from other treatments. Ask how much time this

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will take and learn about the process and possible side effects (see sample Questions to Ask in this fact sheet). This information will help you make a good decision. The clinical trial nurse is often a great resource for information. He or she can serve as your counselor and advocate.

Are there fees with clinical trials?

Before you start, learn what your insurance does and does not cover. Many insurance groups don't cover extra costs from a clinical trial. However, the treatment provider, clinic or company involved in the study may cover added costs. Ask if added research tests, lab tests and doctor visits that go beyond standard treatment, will be covered and how. You can ask to get financial coverage before you agree to take part in the trial.

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

Questions to Ask Your Provider about Clinical Trials

There are many questions you can ask your healthcare provider before you start a trial, such as:

- How can this new treatment or technique help me?
- Am I a good candidate?
- How do the risks, side effects and benefits in the study compare with my current treatment?
- What is involved? What will I need to do/take and for how long?
- How many visits per week or month are expected?
- What type of lab and/or imaging tests will I have to take and how often?
- Is a hospital stay needed?
- Who will be in charge of my care?
- If I have questions along the way, to whom do I ask?
- How much will this cost? Will the trial, or my insurance, cover all or part of it?
- Will I be paid back for any costs such as transportation or lodging?

- What type of long-term, follow-up care is part of this study?
- How will I know that the treatment is working? Will the results of the trial be given to me?
- Are there other experts or trial participants I can talk to about this study?
- If I want to drop out for any reason, what do I need to do?
- If the treatment studied in my clinical trial works, but I was randomized to get a different type of care, will I be able to get the active agent after the study is completed?
- When or how will I learn the results of the trial?
- If I've participated in a clinical trial in the past, can I take part in another one?

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

First, ask your urologist or oncologist if you qualify for a nearby clinical trial.

You can also find listings of local trials through these resources:

- Urology Care Foundation's Clinical Trials Resource center
- Studies at the National Institutes of Health: Search for government-funded clinical studies carried out by the National Institutes of Health.
- National Cancer Institute (NCI) Clinical Trials: Search for government-funded clinical studies by the National Cancer Institute.
- ClinicalTrials.gov: Search for federally and privately supported clinical research trials carried out in the United States and around the world. This page gives information about a trial's purpose, who may take part in the trial, locations and contact phone numbers.
- CenterWatch.com Clinical Trials Listing: Search for private clinical trials (i.e pharmaceutical group). Patients may search by medical condition, medical area (such as urology) or place. CenterWatch also offers an alert email when a clinical trial in your interest area is available.

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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 or go to UrologyHealth.org/FindAUrologist to find a doctor near you.

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 urologists or health care provider about your health concerns. Always consult a health care provider before you start or stop any treatments, including medications.

For copies of printed materials about Bladder Cancer and other urologic conditions, visit UrologyHealth.org/Order or call 800-828-7866.

For more information, contact:

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