

## Understanding Clinical Trials: Exploring another option in your prostate cancer journey



A prostate cancer diagnosis is the beginning of a journey, whether you are the one diagnosed or a loved one along for the ride. Choosing a treatment route, if any, can be confusing and overwhelming. That's why we designed this fact sheet. It is a guide to learning more about clinical trials as a possible route in your journey. More information can be found on our website at: [www.womenagainstoprostatecancer.org](http://www.womenagainstoprostatecancer.org)

### What Are Clinical Trials?

Clinical trials are research studies that help doctors find new safe and effective medicines, therapies, and devices to prevent, diagnose, and treat diseases. They also help determine whether the treatment's risks are worth the benefits. In the field of prostate cancer there are hundreds of trials currently recruiting patients. It is worth exploring whether there is one that's right for you or your loved one.

### Different Types of Clinical Trials

There are 4 different kinds of clinical trials:

- **Treatment trials** test new drugs, surgeries, therapies or a combination of these.
- **Prevention trials** test new medicines, vitamins, or changes in lifestyle to find the best ways to prevent disease.
- **Screening trials** find the best way to identify diseases, especially in their early stages.
- **Quality of Life trials** try to explore ways to improve comfort and quality of life for patients. In prostate cancer this may include ways to reduce pain associated with bone metastases or improve side effects like incontinence or erectile dysfunction.

### Phases of Clinical Trials

Most clinical trials will pass through several phases to examine the safety and effectiveness of a drug:

- **Phase I** trials test a new drug or treatment in people for the first time to evaluate safety, dosage amounts, and side effects.
- **Phase II** trials continue safety testing and begin evaluation of how well the drug or treatment works in a larger group of people.
- **Phase III** trials compare a new drug, treatment, or surgical procedure to the current standard treatment. These studies typically enroll large numbers of people at multiple locations across the country. These trials confirm effectiveness, monitor side effects, and accumulate data that allows the drug to be used safely.
- **Phase IV** trials take place after a treatment has been approved by the Food and Drug Administration (FDA) and marketed to consumers. These studies continue to gather information on the treatment's side effects, benefits and risks to ensure that it is safe and effective.

### How Many People Participate in Clinical Trials?

According to the National Cancer Institute, less than 5% of cancer patients participate in clinical trials. It is estimated that if just 10% participated, most studies would take only one year to complete compared to the current three to five years, helping innovative treatments reach patients quicker.

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### What are the benefits?

There are a number of possible benefits to participating in a clinical trial:

- Participants may get new treatments before they are widely available.
- The costs directly related to the clinical trial, including treatments, tests and doctor visits are provided at no cost to the patient. This provision was included in the Patient Protection and Affordable Care Act of 2010.
- If a patient has unsuccessfully tried other available treatment options, a clinical trial may provide patients and families a renewed hope for successful treatment.
- Participants will receive care from some of the leading physicians and health care facilities in the country.
- Clinical trials give doctors and researchers information to develop new treatment options and possibly save lives. Many of today's most effective treatments have been made available thanks to previous clinical trial results. With a disease like prostate cancer that kills over 32,000 men every year these new options are desperately needed.

### What are the risks?

When a new treatment is being studied doctors and researchers don't know all of the risks and side effects that may be involved. Below are a few possible risks that should be considered:

- The new treatment may not work as well as the standard treatment or it may not work at all.
- The new treatment may have unpleasant side effects.
- You may have to make more trips to the doctor and undergo more testing compared to the standard treatment.

### How do I know if a clinical trial is safe?

If you or a loved one are considering participating in a clinical trial you may have some concerns about whether they are safe and how they are monitored. However, the Federal Government has put in place several strict guidelines and measures to ensure that patient safety is put first.

First, clinical trials must follow a protocol, or plan for the study, created by the lead doctor or researcher for the trial. The protocol thoroughly explains what the trial will do, how the study will be conducted, and the importance of each part of the study. It makes certain that patients are treated exactly the same no matter where they are receiving treatment and that every doctor conducts the trial properly.

Additionally, each center that offers a clinical trial is monitored by an Institutional Review Board (IRB). An IRB must approve a clinical trial before it can begin, and members carefully watch the progress of the research throughout the study.

In some trials, often larger, multi-site trials, a Data Safety Monitoring Board (DSMB) may be used. The DSMB tracks data to ensure patient safety and make sure that results are being reported completely. If they find that a treatment is harmful to patients or if one treatment is significantly better than another they may stop a study altogether or switch patients to the more effective treatment.

Remember, every participant in a trial is carefully observed by doctors to determine how the treatment is working and to track any side effects.

### How do I participate in a clinical trial?

Keep in mind that clinical trials may not be right for everyone. If you or a loved one are considering participating in a clinical trial it is important to educate yourself as much as possible about the potential benefits, risks, and outcomes of the trial. To learn more about participating, please visit our website: [womenagainstprostatecancer.org/clinicaltrials](http://womenagainstprostatecancer.org/clinicaltrials) for more information and links to other helpful sites.

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