

Chapter 8. Clinical Trials

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Because of research, today we have better and more effective prostate cancer drugs and therapies. As a result of these newer treatments, survival rates have increased, quality of life has improved, and treatment side effects are fewer for thousands of men with prostate cancer. Many of these drugs and therapies would not be available today if it were not for cancer research programs and cancer patients willing to participate in clinical trials. Some men feel that participating in a clinical trial gives them an opportunity to help other men with prostate cancer through the knowledge gained from the study.

What is a Clinical Trial?

A clinical trial is a research study designed to answer one or more questions about how a certain drug, treatment or medical device affects a disease such as prostate cancer. There are **potential benefits** to participating in a clinical trial, as well as **potential risks**. These benefits and risks are different for each clinical trial. You should discuss them with your own doctor, as well as with the clinical trial's research team.

Is Participating in a Clinical Trial Right for Me?

The treatment you receive during a clinical trial may help you. Clinical trial participants receive either the standard of care (what scientists and researchers consider the most effective known treatment available) or the new drug or treatment being considered. Newer therapies may lead to better results. On the other hand, they may not be any better, or even as good as, standard therapies already available. Participating in a clinical trial will require some extra time on your part. The research team will want to monitor you closely during the trial and collect follow-up information. This care is in addition to the care you will continue to receive from your oncologist and medical team.

Am I Eligible for a Clinical Trial?

Not everyone is eligible to participate in every clinical trial. Each clinical trial has criteria about who can participate, such as the stage of your cancer, previous treatment history and other medical conditions. These factors are not meant to reject men. They are used to ensure that researchers will be able to answer the questions they plan to study. Your doctor will determine if you are eligible for a clinical trial after a physical examination and a review of your health history and medical records.

Considering a Clinical Trial

If you are eligible for a clinical trial, members of your research team will meet with you to discuss a number of issues as part of the **informed consent process**. They will also provide you with a written document called an informed consent form. You will be given time to read this document and talk it over with your doctor, family or friends before deciding if you want to participate. The consent form will answer a number of questions, including:

- What is the purpose of the clinical trial?
- How long will the trial last?

- What is required of you to participate in this study?
- What treatments or drugs will you receive during the trial?
- What treatments, tests and/or procedures will be required during the study? How many and how often?
- Which treatments, tests, medications and/or procedures will be paid for?
- What are the risks and benefits of participating in this research study?
- What treatment would be recommended for you if you do not participate in the trial?

Voluntary Participation

Participation in clinical trials is always voluntary. You will not be enrolled in a clinical trial without your permission. You give permission to participate in a clinical trial by signing the informed consent form. You can change your mind about participating in the clinical trial at any time after signing the informed consent form. To stop your participation in a study, talk to your research team.

More Information on Clinical Trials

You can contact the National Cancer Institute (NCI) at 1-800-4-CANCER or www.clinicaltrials.gov for a comprehensive list of ongoing clinical trials. You can search for clinical trials available within the Sutter Health network in both the San Francisco Bay Area and the Sacramento area by visiting www.cancer.sutterhealth.org/research/index.html. You can also ask your doctor or health care team for specific information regarding clinical trials available in your area. The information in this section is not meant to replace the individual attention, advice, and treatment plan of your oncologist and medical team.