
CLINICAL TRIALS
FOR MEN WITH ADVANCED PROSTATE CANCER.

FACTS YOU NEED TO KNOW

Thousands of men across the United States suffer from the difficult effects of prostate cancer and often undergo treatment that does not produce optimal results. If you have prostate cancer, you may feel that your treatment options are limited, or you may not know what to do from here.

Joining a clinical trial may be one of your options.

Hundreds of thousands of people have participated in clinical trials testing new interventional drugs that are now available.

A clinical trial is an investigation of an experimental drug to see if it is safe to use and effective in fighting a disease, such as prostate cancer.

CLINICAL TRIALS EVALUATE:

	INVESTIGATIONAL DRUGS & MEDICINES		*INVESTIGATIONAL COMBINATIONS OF TREATMENTS*
	INVESTIGATIONAL APPROACHES TO SURGERY OR RADIATION THERAPY		*INVESTIGATIONAL METHODS SUCH AS GENE THERAPY*

All clinical trials vary depending on the objective of the test.

MANY CLINICAL TRIALS CONSIST OF 2 GROUPS:

1. ***Participants who receive the experimental drug.***
2. ***Participants who are given either a drug for the disease or a placebo which has no direct therapeutic effect.***

Regardless of which group they are in, all participants receive the same study-related medical attention and care. In fact, all clinical trial participants receive at least the standard of care and often closer monitoring than usual practice.

Clinical trials are highly controlled and regulated. They are typically sponsored by pharmaceutical or biotech companies, the federal government, medical institutions, or private foundations.

1 IN 8 MEN GET PROSTATE CANCER DURING THEIR LIFE

UNITED STATES OF AMERICA

WHY ARE CLINICAL TRIALS IMPORTANT TO PATIENTS?

When standard medical treatments have failed, many patients want to explore new therapies that are being studied in clinical trials. Volunteers understand there are no guarantees for improved health yet know they are contributing to the development of potential new treatment options that may help other patients in the future.

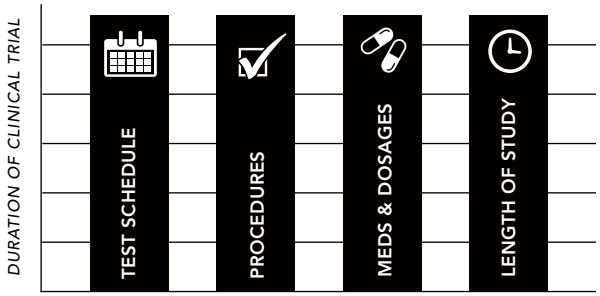
Participating in a clinical trial is a personal choice and depends on each man's unique set of circumstances. Many may benefit, while others may have adverse side effects such as nausea or loss of appetite.

VOLUNTEERS MAY HAVE POSITIVE RESPONSE TO TRIALS

VOLUNTEERS RECEIVE THE FOLLOWING:

HOW DOES A CLINICAL TRIAL WORK?

Clinical trials follow a carefully controlled "protocol," a plan that describes the schedule of tests, procedures, medications and dosages, and the length of the study.



CONTROLLED PROTOCOL

A research team of doctors, nurses and other health care professionals will track and evaluate your response to the experimental drug.

This teamwork helps ensure the best study-related care possible for clinical trial volunteers.

WHO MONITORS THE CLINICAL TRIAL?

Every clinical trial in the U.S. must be reviewed and monitored by an Institutional Review Board (IRB) to make sure the risks to the participants are as low as possible and are worth any potential benefits.

An IRB is an independent committee of physicians, statisticians, community advocates, and others who ensure the clinical trial is ethical and the rights of the participants will be protected.

HOW SAFE ARE CLINICAL TRIALS?

Clinical research is regulated by the federal government, with built-in safeguards to protect the volunteers in clinical trials.

The Food and Drug Administration *(FDA)* develops the policies and guidelines for all clinical research, regardless of the drug type, the kind of study being conducted, and who manufactures the study drug.

For the participants' protection, ethical and legal codes apply to clinical trials. **You also have the right to withdraw from the study at any time and it is your choice whether you share your reason for doing so.**

AM I ELIGIBLE TO JOIN?

Each clinical trial has its own guidelines on who can participate, and you will need to find out if you meet the eligibility requirements.

COMMON SELECTION CRITERIA:

- *TYPE & STAGE OF CANCER*
- *AGE RANGE*
- *GENDER*
- *FAMILY HISTORY*
- *TREATMENT HISTORY*
- *CURRENT SIDE EFFECTS*
- *OTHER HEALTH CONDITIONS*

Typically, volunteers are alike in many ways, with common factors such as the type and stage of cancer, age range, gender, family history, treatments already received and current side effects, if any, and other health conditions.

WHAT INFORMATION WILL I RECEIVE?

Study doctors and nurses will meet with you to explain the study in detail. You will have the opportunity to ask questions so you can learn as much as possible about the study, as well as its potential benefits and risks.

INFORMED CONSENT - A PATIENT'S BILL OF RIGHTS

If you are interested in participating, you'll be given an "Informed Consent" form that provides you with detailed facts about the clinical trial. The Informed Consent form is written in everyday, non-technical language, but if there is something you do not understand, you should ask a study doctor or nurse to explain it to you.

If you decide to participate in the study, you will sign the Informed Consent form to acknowledge that you understand and agree to all aspects of the study and the potential risks and benefits that are involved.

Throughout the clinical trial, you'll be informed of any new medical findings or other information relating to your participation.

WHAT ARE THE DIFFERENT PHASES OF A CLINICAL TRIAL?

Researchers extensively test investigational drugs in the laboratory and in animal studies, which can take many years. Those with the most promising results are then moved into clinical trials.

If the initial research is successful, the clinical trial sponsor may send the data to the Food and Drug Administration *(FDA)* for approval to begin research and testing with humans.

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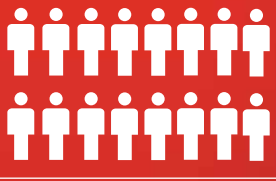
PHASE I TRIALS	**PHASE II TRIALS**	**PHASE III TRIALS**	**PHASE IV TRIALS**
			
20 - 80 VOLUNTEERS	**100 - 300 VOLUNTEERS**	**1,000 - 3,000 VOLUNTEERS**	**3,000 + VOLUNTEERS**
Researchers use a small group of volunteers *(20 - 80)* to evaluate the drug's safety and decide how it should be given *(ingestion or injection)*, to determine a safe dosage range, and to identify any side effects.	If the FDA agrees that the Phase I data show the drug is safe and that it may be beneficial to people, Phase II studies are conducted in a larger group of people *(100 - 300)* to test the drug's effectiveness and safety.	A larger group of volunteers *(1,000 - 3,000)* receives the drug to confirm its effectiveness. Researchers monitor for side effects, compare it to commonly used treatments, and collect more data on how it can be used safely.	At this phase, the drug or treatment has been granted FDA approval and is routinely taken by patients with the disease in an even larger group of people, with even more advanced rating scales and clinical measures. The goal is to evaluate how safe and effective the new drug or treatment is over time.

If you're interested in participating in a clinical trial, you should ask as many questions as you like in order to make an informed decision and be prepared for what's ahead.

Getting answers to your questions is the best way to ensure you're making a decision that is the right one for you.

FREQUENTLY ASKED QUESTIONS

	WHAT IS THE PURPOSE OF THIS STUDY? HOW LONG WILL IT LAST?
H	*WHAT KIND OF DRUGS WILL I RECEIVE? IS HOSPITALIZATION REQUIRED?*
	HOW WILL I KNOW IF THEEXPERIMENTAL DRUG IS WORKING? WHAT ARE THE POSSIBLE RISKS AND SIDE EFFECTS?
+	*IS MY PRIMARY HEALTH CARE PROVIDER STILL N CHARGE OF MY OVERALL HEALTH?*
$	*WILL I BE REIMBURSED FOR MY TRAVEL AND OTHER EXPENSES?*
	WHAT ARE MY OTHER TREATMENT CHOICES IF I DON'T WANT TO PARTICIPATE?
	IS THIS CENTER EXPERIENCED IN PERFORMING CLINICAL TRIALS

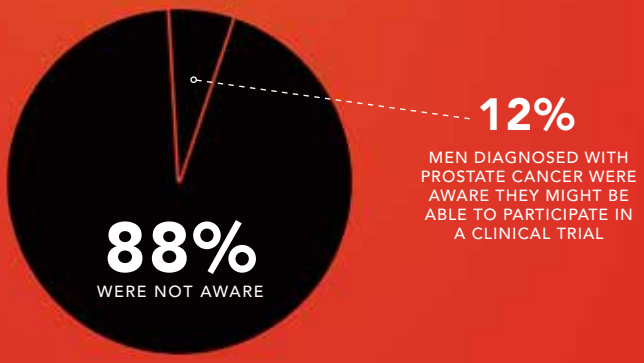
For answers please visit ZeroCancer.org

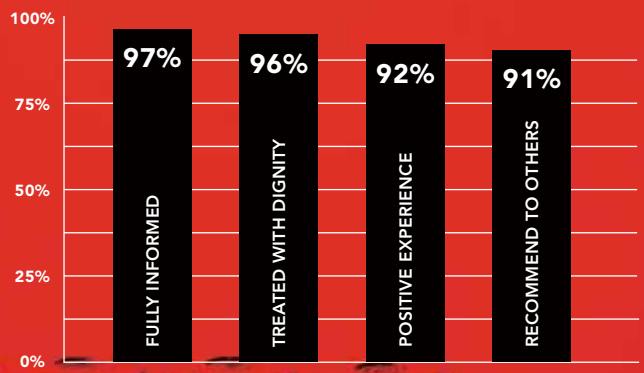
WHAT'S AVAILABLE?

CANCER SURVIVOR SURVEY

A survey of 2,000 cancer survivors conducted by the Coalition of Cancer Cooperative Groups and Northwestern University* found only 12 percent of men diagnosed with prostate cancer were aware they might be able to participate in a clinical trial.

**CancerTrialsHelp.org*





SURVEY OF CLINICAL TRIAL PARTICIPANTS

Of those who did participate in a clinical trial, the survey showed: 97 percent of participants said they were fully informed on the risks and benefits; 96 percent felt they were treated with dignity and respect; 92 percent had a positive experience; 91 percent would recommend a clinical trial to others.

Visit ZeroCancer.org for more informatin on availability for clinical trials.

ZERO
THE END OF PROSTATE CANCER

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