



PROSTATE CANCER CLINICAL TRIAL CORNERSTONE DIRECTORY



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WHAT ARE THE GOALS OF PROSTATE CANCER CLINICAL TRIALS?

- Create truly curative therapies
- Develop therapies that can work when others have failed
- Decrease the side effects of treatment and improve quality of life

TIPS FOR LEARNING ABOUT & FINDING CLINICAL TRIALS

- Know your prostate cancer stage and subtype type and obtain a copy of your pathology report.
- Learn about eligibility criteria such as age and physical fitness.
- See if there are financial resources that can help assist with travel and other costs.
- Ask what the risks are to participating.

QUESTIONS TO ASK YOUR PROSPECTIVE CLINICAL TRIAL MEDICAL TEAM

- What kinds of tests, medicines, surgery, or devices are involved in the trial? Are any procedures painful?
- What are the possible risks or side effects of taking part in the study?
- What are the potential benefits of participating in this study? How would this be more beneficial than my current treatment option or the typical standard of care?
- How will this trial affect my daily life? Will I have to be in the hospital for a long period of time?
- Will I have to travel for this trial? Where and how often? Are telehealth visits an option?
- How long will the trial last?
- What will happen after the trial?

Cost-specific questions

- Who will pay for the tests and treatments I receive?
- Are there additional costs if I enroll in the trial?
- Does my insurance cover any of these trials?
- Will I be reimbursed by the trial sponsors for other expenses (for example, travel and childcare)?

WHAT TYPE OF TREATMENTS ARE USED IN A CLINICAL TRIAL?

Several types of treatments under study (or already approved) for people with localized prostate, advanced prostate cancer, and hormone-resistant prostate cancer include combinations of:

Localized Prostate Cancer

Hormone Therapy: The male hormones of testosterone and dihydrotestosterone are needed for prostate cancer cells to grow.

Hormone therapy, also known as androgen deprivation therapy (ADT), decreases the amount of testosterone produced by the testicles so that cancer cell growth slows down.

WHAT TYPE OF TREATMENTS ARE USED IN A CLINICAL TRIAL? (CONT.)

Bilateral orchiectomy: A surgery that removes both testicles to carry out androgen deprivation.

Luteinizing Hormone Releasing Hormone (LHRH) Agonists and Antagonists

- Leuprolide acetate (Eligard or Lupron)
- Leuprolide acetate implant (Viadur)
- Histrelin implant (Vantas)
- Goserelin acetate (Zoladex)
- Triptorelin (Trelstar)

High-Intensity Focused Ultrasound (HIFU): This ultrasound procedure is a minimally invasive treatment that uses high frequency ultrasound waves to create extremely high temperatures to destroy targeted cancer cells.

The procedure targets the prostate, usually treating the entire gland.

WHAT TYPE OF TREATMENTS ARE USED IN A CLINICAL TRIAL?

Cryotherapy: This treatment, though it has not been studied as much as surgery and radiation, utilizes extremely cold temperatures to kill prostate cancer cells.

Brachytherapy: This procedure involves the placement of radioactive wires or radioactive seeds to deliver radiation to cancer cells to cause prevention of cancer cell division and cancer cell death.

External Beam Radiation: This treatment utilizes machines to place high-energy rays to prevent cancer cell division and to cause cancer cell death. The machines use various high-energy sources that may include alpha, beta, neutron and proton particles; and x-ray and gamma waves. The technology methods include external beam radiation therapy (EBRT), proton beam therapy (PBT), CyberKnife robotic system, 3-dimensional conformal radiation therapy (3DCRT), intensity-modulated radiation therapy (IMRT), and Calypso tracking system.

WHAT TYPE OF TREATMENTS ARE USED IN A CLINICAL TRIAL?

Radical Prostatectomy: This surgery removes the entire prostate in addition to both seminal vesicles and a portion of both vas deferens.

This treatment can cure the cancer providing no cells have spread outside the prostate gland.

Surgeons can often perform a nerve-sparing radical prostatectomy, which can preserve quality of life in the patient's sex life.

The success rate depends on several factors including patient health, patient age, and expertise of the surgeon.

Radical prostatectomy types include robot-assisted laparoscopic radical prostatectomy (RALP), laparoscopic radical prostatectomy (LRP), radical perineal prostatectomy (RPP), and radical retropubic prostatectomy (RRP).

WHAT TYPE OF TREATMENTS ARE USED IN A CLINICAL TRIAL?

Autologous Cellular Immunotherapy: This treatment utilizes the body's own immune system to fight cancer cells.

The currently approved therapy for prostate cancer is sipuleucel-T (Provenge).

Active Surveillance: This monitoring method involves the routine use of prostate specific antigen (PSA) tests, digital rectal exams, and MRIs to closely monitor prostate cancer.

Watchful Waiting: This monitoring method is the least invasive and involves the use of PSA monitoring and periodic digital rectal exams.

WHAT TYPE OF TREATMENTS ARE USED IN A CLINICAL TRIAL?

Advanced Prostate Cancer

Autologous Cellular Immunotherapy: This treatment utilizes the body's own immune system to attack cancer cells. The currently approved therapy for prostate cancer is sipuleucel-T (Provenge).

Antiandrogen Therapy Drugs: This class of drugs includes ones that block male hormone action, including testosterone and androgens from the adrenal glands or produced by prostate cancer cells.

- Bicalutamide (Casodex)
- Flutamide (Eulexin)
- Nilutamide (Nilandron)
- Enzalutamide (Xtandi)
- Abiraterone acetate) in combination with prednisone (Zytiga)
- Apalutamide (Erleada)
- Darolutamide (Nubeqa)

WHAT TYPE OF TREATMENTS ARE USED IN A CLINICAL TRIAL?

Advanced Prostate Cancer

Estrogen Therapy Drugs: Administering estrogen hormones decreases production of testosterone and has some direct impacts on limiting growth of androgen-independent and androgen-dependent prostate cancer cells.

- **Diethylstilbestrol (DES)**
- **Estradiol (Estraderm)**
- **Stilbestrol diphosphate (Stilphosterol)**

WHAT TYPE OF TREATMENTS ARE USED IN A CLINICAL TRIAL?

Other Drugs

Chemotherapy: Chemotherapies are systemic drug treatments used to stop cancer cells from dividing and growing. Chemotherapy is often linked with unpleasant side effects since it targets all rapidly growing cells, as well as cancer cells.

Systemic Radiation Therapy: This type of radiation therapy involves intravenous injection of radiation to attack cancer cells that have spread to the bones. Radium-223 (Xofigo) is the one treatment that has shown significant success in this group.

5-alpha Reductase (5-AR) Inhibitors: This treatment blocks testosterone conversion to DHT, which stimulates prostate cancer growth at a higher level than testosterone. Some 5-AR inhibitors that may be used in clinical trials are:

- Finasteride) (Proscar, Propecia)
- Dutasteride (Avodart)

WHAT TYPE OF TREATMENTS ARE USED IN A CLINICAL TRIAL?

Other Drugs

P450 Enzyme Inhibitors: This treatment inhibits the synthesis of several hormones, including testosterone, that stimulate prostate cancer cell growth.

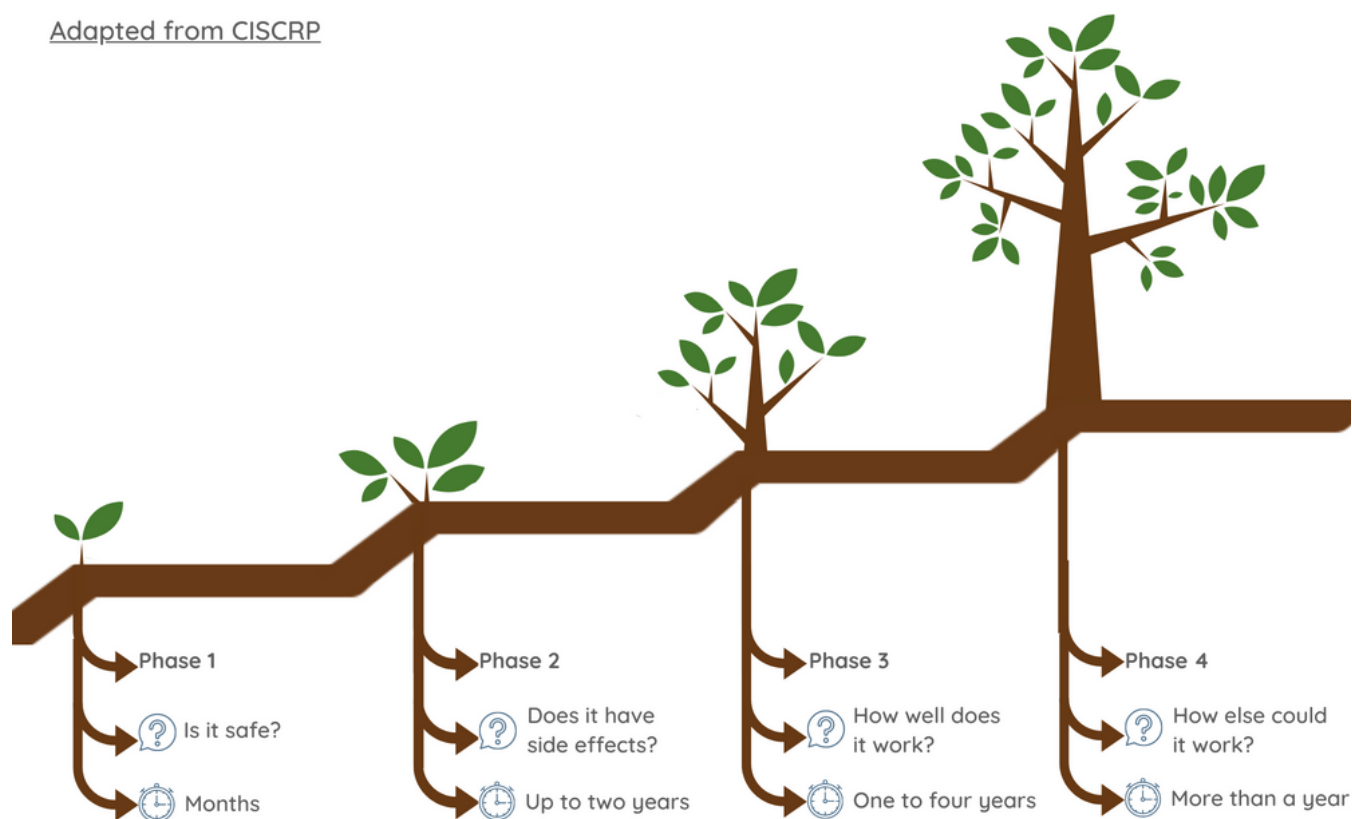
Ketoconazole used in combination with hydrocortisone (Nizoral) may be used in clinical trials to disrupt cancer cell growth.

Hormone-Resistant Prostate Cancer: This prostate cancer type involves prostate cancer that no longer responds to hormone therapy, also known as hormone refractory prostate cancer (HRPC), castrate-resistant prostate cancer (CRPC) or androgen-independent prostate cancer. Treatment or clinical trials may involve the use of:

- Abiraterone Acetate (Zytiga)
- Enzalutamide (Xtandi)

CLINICAL TRIALS & PHASES

Adapted from CISC RP



Planting the seed - In Phase I trials, researchers test a new drug or treatment in a small group of people (20-80) for the first time to evaluate its safety, determine a safe dosage range, and identify side effects.



Laying down roots - In Phase II trials, the study drug or treatment is given to a larger group of people (100-300) to see if it is effective and to further evaluate its safety.



Preparing for harvest - In Phase III trials, the study drug or treatment is given to large groups of people (1,000-3,000) to confirm its effectiveness, monitor side effects, compare it to commonly used treatments, & collect information that will allow the drug or treatment to be used safely.



Expanding the yield - In Phase IV trials, studies look at real-world experience over a long time and provide additional information on the drug's risks, benefits, and optimal use.

ADVANCED PROSTATE CANCER: DAVID'S CLINICAL TRIAL PROFILE



"You need that support of your family and friends. It's very important for them to be there with you."

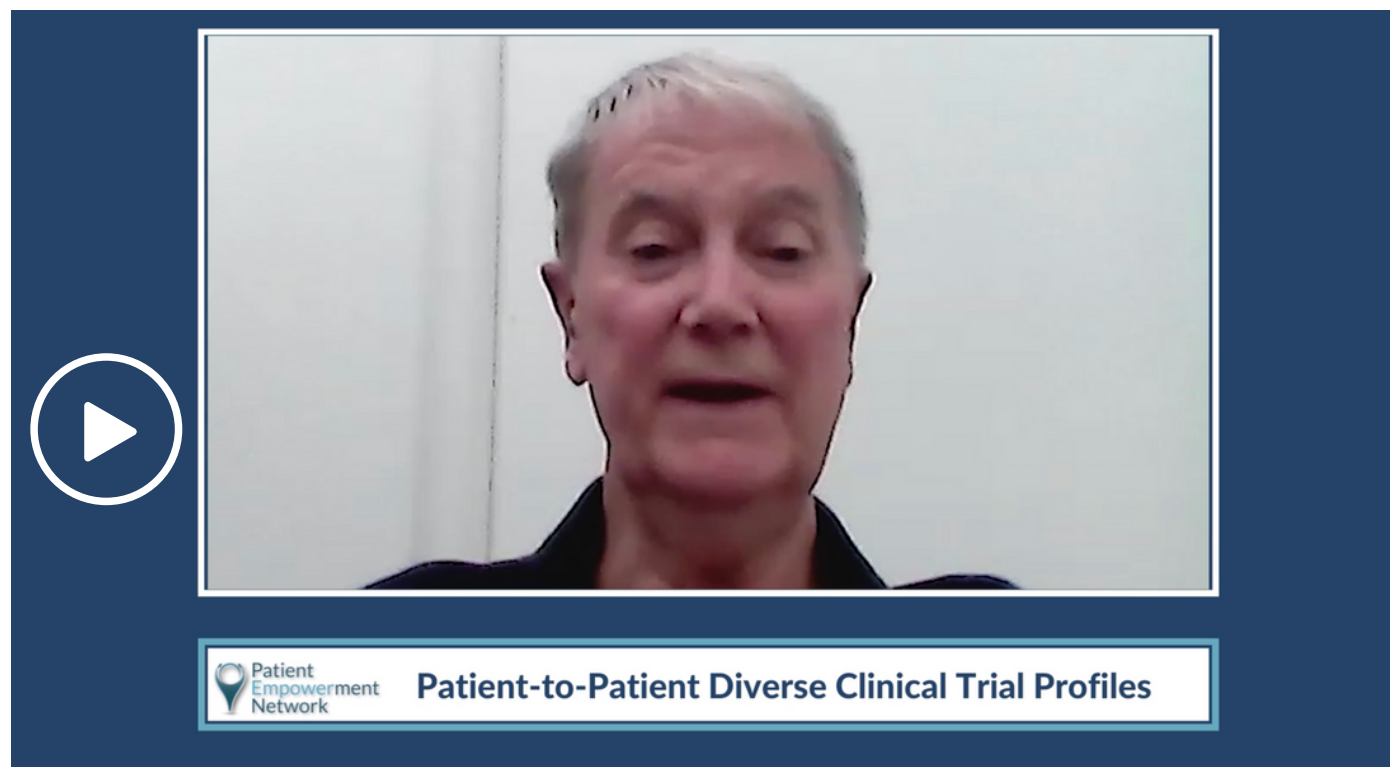


Patient-to-Patient Diverse Clinical Trial Profiles

Prostate cancer patient David received a diagnosis at stage IV during a routine PSA check.

Watch as he shares his prostate cancer journey, his experience with clinical trials and treatments, and his advice to other patients about lessons learned about prostate cancer side effects and the impacts of clinical trials.

ADVANCED PROSTATE CANCER: GARY'S CLINICAL TRIAL PROFILE



Advanced prostate cancer patient Gary was an athlete in the first Oncology Olympic Games in Rome.

Watch as Gary shares his prostate cancer journey, benefits and knowledge he's gained from clinical trials, and his advice to others considering participating in a clinical trial.

ADVANCED PROSTATE CANCER: WILLIE'S CLINICAL TRIAL PROFILE



"A clinical trial to me is the work of getting you with your prostate taken care of. I experienced a lot of goodness after I realized what this was really about."



Patient-to-Patient Diverse Clinical Trial Profiles

Prostate cancer patient Willie was diagnosed in 2021 at the age of 65.

Watch as he shares his prostate cancer story from diagnosis to how he's doing today, his experience with a patient navigator and a clinical trial, and his advice to both Black men and to all others with prostate cancer.

HOW CAN I GET THE BEST PROSTATE CANCER CARE NO MATTER WHERE I LIVE?



How can prostate cancer patients and providers help ensure quality care?

Host Dr. Nicole Rochester asks Dr. Petros Grivas to share insights about available patient resources and ways that providers can help extend improved prostate cancer diagnostics and treatments to patients for better care.

HOW CAN PROSTATE CANCER PATIENTS AND PROVIDERS HELP ENSURE QUALITY CARE?



You are watching a Patient Empowerment Network program

How can prostate cancer patients and providers help ensure quality care?

Host Dr. Nicole Rochester asks Dr. Petros Grivas to share insights about available patient resources and ways that providers can help extend improved prostate cancer diagnostics and treatments to patients for improved care.

WHY PROSTATE CANCER PATIENTS SHOULD CONSIDER PARTICIPATING IN A CLINICAL TRIAL



Dr. Sumit Subudhi explains why prostate cancer patients should consider participating in clinical trials, the role they play in treatment options for prostate cancer and resources available to find trials. Dr. Sumit Subudhi is a Medical Oncologist at The University of Texas MD Anderson Cancer Center.

WHY YOU SHOULD CONSIDER A PROSTATE CANCER CLINICAL TRIAL



Dr. Alicia Morgans, a hematology and oncology specialist, explains the importance of prostate cancer patients of different geographic locations participating in clinical trials and the role trials plays in clinical care.

Dr. Alicia Morgans is an Assistant Professor of Medicine at the Robert H. Lurie Comprehensive Cancer Center of Northwestern University.

CLINICAL TRIAL RESOURCES

[Clinicaltrials.gov](https://clinicaltrials.gov)

Provides information on publicly and privately supported clinical studies on a wide range of diseases and conditions. The website is maintained by the National Library of Medicine at the National Institutes of Health.



Each clinical trial record presents summary information about a study protocol and includes the following:

- Disease or condition
- Intervention (for example, the medical product, behavior, or procedure being studied)
- Title, description, and design of the study
- Requirements for participation (eligibility criteria)
- Locations where the study is being conducted
- Contact information for the study locations

CLINICAL TRIAL RESOURCES (CONT.)



Clinical Trial Finders

UsTOO Prostate Cancer Clinical Trial Finder

Contact Us: (877) 769-4830; Website

CenterWatch

Offers online tools to:

- Search clinical trials
- Receive email notifications about specific clinical trials
- Review results from completed clinical trials
- Search drug information
- Learn about the informed consent process
- Read an overview of the clinical trials process
- Find disease-specific health associations and other educational resources
- Review definitions of commonly-used clinical research terms

NIH National Cancer Institute

Contact: Call 1-800-422-6237, live chat through [LiveHelp](#) or email NClinfo@nih.gov

Search portal to find National Cancer Institute (NCI)-supported clinical trials. Search by cancer type or keyword, your age (to determine which trials you could be eligible for) or U.S. ZIP code



Contact: 1-800-887-0639; email info@clinicalconnection.com

Founded by a team of medical researchers whose goal has been to efficiently connect patients with clinical trial opportunities that are relevant and timely. Options to create a free member account to be notified when clinical trials that match your health interests become available in your area.

Search for trials (both in U.S. and internally) by ZIP code, keyword, or distance (select distance ranges starting from within 5 miles up to over 250 miles)

CISCRP

(Center for Information and Study on Clinical Research Participation)

Contact: 877-MED-HERO (633-4376) or info@ciscrp.org.

Provides education and information about clinical trials. Search Clinical Trials is a free service designed to help people find clinical trials that are relevant to their needs.

CISCRP staff will work with you to understand your options and will help you find local clinical trials in your community, or as far as you would be comfortable traveling.

**Antidote**

1-888-509-1308 (US) or +44 808-196-0665 (UK)

Email: hello@antidote.me

Search for clinical trials by condition, city or ZIP code, age, and gender. Receive list of clinical trials that could be a match for you by answering series of questions. Watch educational webinars and patient stories.

FINANCIAL ASSISTANCE

Cancer Lifeline

Contact Us: (206) 832-1282 |

financialassistance@cancerlifeline.org

The fund provides financial assistance to low-income patients actively being treated for cancer or within 3 months of active treatment.

For more information, visit:

<https://cancerlifeline.org/services/financial-assistance-for-cancer-patients/>

Lazarex Cancer Foundation

Contact: 877-866-9523 or 925-820-4517

Other language(s): Spanish, Mandarin, Korean

Helps cancer patients navigate clinical trial options by offering financial assistance (such as lodging and transportation costs) for participation in FDA-approved clinical trials; call for eligibility details. Also provides community outreach and education.

Clinical Trial Finders

21st Century C.A.R.E.

Get immediate financial assistance for incidental expenses related to active cancer treatments. Must be referred by a physician to be considered for assistance.

Applications are processed without delay. Once the application is approved, then you are eligible for financial assistance for incidental expenses related to: transportation to and from treatments, follow-up visits related to cancer-care, childcare during treatment, temporary housing due to geographical distance from the treatment center, medical supplies, and much more.

Medicare and the National Cancer Institute provides information on Medicare coverage for clinical trials.

Contact: 1-800-633-4227 or 1-877-486-2048 for hearing impaired

CenterWatch offers online tools to:

- Search clinical trials
- Receive email notifications about specific clinical trials
- Review results from completed clinical trials
- Search drug information
- Learn about the informed consent process
- Read an overview of the clinical trials process
- Find disease-specific health associations and other educational resources

UNDERSTANDING CLINICAL TRIALS:

A JARGON BUSTER GUIDE

By: Marie Ennis-O'Connor



When it comes to cancer treatment, you or a loved one may be considering participating in a clinical trial as a treatment option.

Clinical trials are designed to evaluate the safety and effectiveness of a treatment. They may involve researchers administering drugs, taking blood or tissue samples, or checking the progress of patients as they take a treatment, according to a study's protocol.

Learning about clinical trials can be a steep learning curve – not the least because the process comes with a lot of new terms, acronyms, and jargon. To help you, we've put together this list of the most common terms you will find when you are researching clinical trial information. This is not an exhaustive list, but it is a helpful starting point. At the end of this article, you will see links to find more information.

ADVERSE EFFECTS (AE)

Also called Adverse Events, or Adverse Drug Reaction, AEs are any harmful event experienced by a person while they are having a drug or any other treatment or intervention. In clinical trials, researchers must always report adverse events, regardless of whether or not the event is suspected to be related to or caused by the drug, treatment, or intervention.



ARM

Subsection of people within a study who have a particular intervention.

BIAS

Bias is an error that distorts the objectivity of a study. It can arise if a researcher doesn't adhere to rigorous standards in designing the study, selecting the subjects, administering the treatments, analyzing the data, or reporting and interpreting the study results. It can also result from circumstances beyond a researcher's control, as when there is an uneven distribution of some characteristic between groups as a result of randomization.

BLINDING

Blinding is a method of controlling for bias in a study by ensuring that those involved are unable to tell if they are in an intervention or control group, so they cannot influence the results. In a single-blind study, patients do not know whether they are receiving the active drug or a placebo. In a double-blind study, neither the patients nor the persons administering the treatments know which patients are receiving the active drug.

COMPARATOR

When a treatment for a specific medical condition already exists, it would be unethical to do a randomized controlled trial that would require some participants to be given an ineffective substitute. In this case, new treatments are tested against the best existing treatment, (i.e., a comparator). The comparator can also be no intervention (for example, best supportive care).

COMPLETED

A trial is considered completed when trial participants are no longer being examined or treated (i.e., no longer in follow-up); the database has been "locked" and records have been archived.

CONTROL

A group of people in a study who do not have the intervention or test being studied. Instead, they may have the standard intervention (sometimes called "usual care") or a dummy intervention (placebo). The results for the control group are compared with those for a group having the intervention being tested. The aim is to check for any differences. The people in the control group should be as similar as possible to those in the intervention group, to make it as easy as possible to detect any effects due to the intervention.

EFFICACY

How beneficial a treatment is under ideal conditions (for example, in a laboratory), compared with doing nothing or opting for another type of care.

A drug passes efficacy trials if it is effective at the dose tested and against the illness for which it is prescribed.

ELIGIBILITY CRITERIA/INCLUSION AND EXCLUSION CRITERIA

Eligibility criteria ensures patients enrolling in a clinical trial share similar characteristics (e.g., gender, age, medications, disease type, and status) so that the results of the study are more likely due to the treatment received rather than other factors.

FOLLOW-UP

Observation over a period of time of participants enrolled in a trial to observe changes in health status.

INFORMED CONSENT

A process (by means of a written informed consent form) by which a participant voluntarily agrees to take part in a trial, having been informed of the possible benefits, risks and side effects associated with participating in the study.

INTERVENTION

The treatment (e.g., a drug, surgical procedure, or diagnostic test) being researched. The intervention group consists of the study participants that have been randomly assigned to receive the treatment.

INVESTIGATOR

A person responsible for the conduct of the clinical trial at a trial site. If a trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the principal investigator (PI).

MULTICENTER TRIAL

A clinical trial conducted according to a single protocol but at more than one site, and therefore, carried out by more than one investigator.

NUMBER NEEDED TO TREAT (NNT)

The average number of patients who need to receive the treatment or other intervention for one of them to get the positive outcome in the time specified.

OUTCOME MEASURES

The impact that a test, treatment, or other intervention has on a person, group, or population.

PLACEBO

A fake (or dummy) treatment given to patients in the control group of a clinical trial. Placebos are indistinguishable from the actual treatment and used so that the subjects in the control group are unable to tell who is receiving the active drug or treatment. Using placebos prevents bias in judging the effects of the medical intervention being tested.

POPULATION

A group of people with a common link, such as the same medical condition or living in the same area or sharing the same characteristics. The population for a clinical trial is all the people the test or treatment is designed to help.

PROTOCOL

A plan or set of steps that defines how something will be done. Before carrying out a research study, for example, the research protocol sets out what question is to be answered and how information will be collected and analyzed.

Randomized Controlled Trial (RCT)

A study in which a number of similar people are randomly assigned to two (or more) groups to test a specific drug, treatment, or other intervention. One group has the intervention being tested; the other (the comparison or control group) has an alternative intervention, a placebo, or no intervention at all.

Participants are assigned to different groups without taking any similarities or differences between them into account. For example, it could involve using a computer-generated random sequence. RCTs are considered the most unbiased way of assessing the outcome of an intervention because each individual has the same chance of having the intervention.

RELIABILITY

The ability to get the same or similar result each time a study is repeated with a different population or group.

SAMPLE

People in a study recruited from part of the study's target population. If they are recruited in an unbiased way, the results from the sample can be generalized to the target population as a whole.

SUBJECTS

In clinical trials, the people selected to take part are called subjects. The term applies to both those participants receiving the treatment being investigated and to those receiving a placebo or alternate treatment.

TRIAL SITE

The location where trial-related activities are conducted.