



SCLC & NSCLC LUNG CANCER CLINICAL TRIAL CORNERSTONE DIRECTORY



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WHAT ARE THE GOALS OF LUNG CANCER CLINICAL TRIALS?

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

TIPS FOR LEARNING ABOUT & FINDING CLINICAL TRIALS

- Know your lung 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 lung cancer include combinations of:

Targeted Therapy: Targeted therapy is commonly referred to as a treatment for patients who have specific tumor abnormalities that can be found through biomarker testing. Testing checks for abnormalities including the EGFR, ALK, ROS-1, NTRK, MET, RET and BRAF V600E markers.

Immunotherapy: Immunotherapy uses the patient's own immune system to fight against the cancer cells. Lung cancer immunotherapy types include:

- Adoptive T-cell therapy
- Cancer vaccines
- Checkpoint inhibitors

WHAT TYPE OF TREATMENTS ARE USED IN A CLINICAL TRIAL?

Radiation Therapy: Radiation therapy for lung cancer uses powerful, high-energy X-rays or other methods to kill cancer cells or to slow down the growth of cancer cells. Radiation therapy types for lung cancer include:

- Brachytherapy
- External beam radiation
- Intensity modulated radiation therapy (IMRT)
- Stereotactic radiosurgery (SRS)
- Stereotactic body radiation therapy (SBRT)
- Stereotactic ablative radiotherapy (SABR)

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.

Surgery: Early stage and non-small lung cancer sometimes use surgery as a treatment option. Feasibility of surgery depends on the type, location, and stage of the lung cancer as well as other medical conditions.

RESOURCES TO FIND CLINICAL TRIALS

NIH National Cancer Institute provides a list of NCI-sponsored lung cancer clinical trials for different stages and subtypes of lung cancer.

[ClinicalTrials.gov](https://clinicaltrials.gov) provides a searchable database of clinical trials that can be filtered by lung cancer, country, trial status, and additional terms.

American Lung Association provides a list of U.S. clinical trials for lung conditions that can be filtered by state and by lung condition.

Source: <https://www.lung.org/lung-health-diseases/lung-disease-lookup/lung-cancer/patients/treatment/types-of-treatment>

SMALL CELL LUNG CANCER (SCLC) VS. NON-SMALL CELL LUNG CANCER (NSCLC)

Small cell lung cancer (SCLC) has some key differences from non-small cell lung cancer (NSCLC).

How are SCLC clinical trials different from NSCLC trials? SCLC differs from NSCLC in that SCLC begins in the bronchi and grows and spreads more quickly to other areas of the body, often involving the lymph nodes. For these reasons, SCLC clinical trials are given a separate clinical trial category due to the studies being carried out at a quicker pace.

What clinical trials are available for SCLC patients? Here's a selection of currently available SCLC clinical trials.

Testing Maintenance Therapy for Small Cell Lung Cancer in Patients with SLFN11-Positive Biomarker

This phase II trial studies whether atezolizumab in combination with talazoparib works better than atezolizumab alone as maintenance therapy for patients with SLFN11-positive extensive-stage small cell lung cancer.

SMALL CELL LUNG CANCER (SCLC) VS. NON-SMALL CELL LUNG CANCER (NSCLC) CONT.

Immunotherapy with monoclonal antibodies, such as atezolizumab, may help the body's immune system attack the cancer, and may interfere with the ability of tumor cells to grow and spread. PARPs are proteins that help repair damage to DNA, the genetic material that serves as the body's instruction book.

Changes (mutations) in DNA can cause tumor cells to grow quickly and out of control, but PARP inhibitors like talazoparib may keep PARP from working, so tumor cells can't repair themselves, and they stop growing.

Giving atezolizumab in combination with talazoparib may help lower the chance of extensive-stage small cell lung cancer growing and spreading compared to atezolizumab alone.

SMALL CELL LUNG CANCER (SCLC) VS. NON-SMALL CELL LUNG CANCER (NSCLC) CONT.

Chemoradiation with or without Atezolizumab in Treating Patients with Limited Stage Small Cell Lung Cancer

This phase III trial studies how well chemotherapy and radiation therapy (chemoradiation) with or without atezolizumab works in treating patients with limited stage small cell lung cancer.

Drugs used in chemotherapy, such as etoposide, cisplatin, and carboplatin, work in different ways to stop the growth of tumor cells, either by killing the cells, by stopping them from dividing, or by stopping them from spreading. Radiation therapy uses high energy x-rays to kill tumor cells and shrink tumors. Immunotherapy with monoclonal antibodies, such as atezolizumab, may help the body's immune system attack the cancer, and may interfere with the ability of tumor cells to grow and spread. Giving chemoradiation with or without atezolizumab may work better in treating patients with limited stage small cell lung cancer.

SMALL CELL LUNG CANCER (SCLC) VS. NON-SMALL CELL LUNG CANCER (NSCLC) CONT.

Testing Whether the Use of Brain Scans Alone Instead of Brain Scans plus Preventive Brain Radiation Affects Lifespan in Patients with Small Cell Lung Cancer

This phase III trial studies magnetic resonance imaging (MRI) surveillance and prophylactic cranial irradiation (PCI) to see how well they work compared to MRI surveillance alone in treating patients with small cell lung cancer.

MRI scans are used to monitor the possible spread of the cancer with an MRI machine over time. PCI is radiation therapy that is delivered to the brain in hopes of preventing spread of cancer into the brain. The use of brain MRI alone may reduce side effects of receiving PCI and prolong patients' lifespan.

Monitoring with MRI scans alone (delaying radiation until the actual spread of the cancer) may be at least as good as the combination of PCI with MRI scans.

SMALL CELL LUNG CANCER (SCLC) VS. NON-SMALL CELL LUNG CANCER (NSCLC) CONT.

Testing the Addition of Radiation Therapy to the Usual Immune Therapy Treatment (Atezolizumab) for Extensive Stage Small Cell Lung Cancer, The RAPTOR Trial

This phase II / III trial compares the effect of adding radiation therapy to the usual maintenance therapy with atezolizumab versus atezolizumab alone in patients who have already received atezolizumab plus chemotherapy for the treatment of small cell lung cancer that has spread outside of the lung or to other parts of the body (extensive stage).

Immunotherapy with monoclonal antibodies, such as atezolizumab, may help the body's immune system attack the cancer, and may interfere with the ability of tumor cells to grow and spread. Radiation therapy uses high energy x-rays to kill tumor cells and shrink tumors. Giving radiation therapy in addition to atezolizumab may extend the time without extensive small cell lung cancer growing or spreading compared to atezolizumab alone.

SMALL CELL LUNG CANCER (SCLC) VS. NON-SMALL CELL LUNG CANCER (NSCLC) CONT.

Randomized Trial of Topotecan With M6620, an ATR Kinase Inhibitor, in Small Cell Lung Cancers and Small Cell Cancers Outside of the Lungs

This phase II trial studies how well M6620 works when given in combination with topotecan hydrochloride (topotecan) compared with topotecan alone in treating patients with small cell lung cancer that has come back (relapsed), or small cell cancer that arises from a site other than the lung (extrapulmonary).

Drugs used in chemotherapy, such as topotecan hydrochloride, work by damaging the DNA (deoxyribonucleic acid) in tumor cells, causing those cells to die and the tumor to shrink. However, some tumor cells can become less affected by chemotherapy because they have ways to repair the damaged DNA. The addition of M6620 could help topotecan hydrochloride shrink the cancer and prevent it from returning by blocking enzymes needed for DNA repair.

SMALL CELL LUNG CANCER (SCLC) VS. NON-SMALL CELL LUNG CANCER (NSCLC) CONT.

A Study of ABBV-011 Alone and in Combination With Budigalimab (ABBV-181) in Participants With Relapsed or Refractory Small Cell Lung Cancer

This is a multicenter, open-label, Phase 1 study of ABBV-011 given as a single agent and in combination with budigalimab (ABBV-181) in participants with relapsed or refractory small cell lung cancer (SCLC).

The study consists of 4 parts: Part A is a single-agent ABBV-011 dose regimen finding cohort; followed by Part B, a single-agent ABBV-011 dose expansion cohort; and then Part C, an ABBV-011 and budigalimab (ABBV-181) combination escalation and expansion cohort; Part D, single-agent ABBV-011 dose-evaluating cohort for Japan.

SMALL CELL LUNG CANCER (SCLC) VS. NON-SMALL CELL LUNG CANCER (NSCLC) CONT.

A Phase 1 / 2 Study of CYT-0851, an Oral RAD51 Inhibitor, in B-Cell Malignancies and Advanced Solid Tumors

This clinical trial is an interventional, active-treatment, open-label, multi-center, Phase 1 / 2 study. The study objectives are to assess the safety, tolerability and pharmacokinetics (PK) of the oral RAD51 inhibitor CYT-0851 in patients with relapsed / refractory B-cell malignancies and advanced solid tumors and to identify a recommended Phase 2 dose as a monotherapy and in combination with chemotherapy for evaluation in these patients.

A Study of XmAb[®]20717 in Subjects With Selected Advanced Solid Tumors

This is a Phase 1, multiple dose, ascending dose escalation study to define a MTD / RD and regimen of XmAb20717, to describe safety and tolerability, to assess PK and immunogenicity, and to preliminarily assess anti-tumor activity of XmAb20717 in subjects with selected advanced solid tumors.

SMALL CELL LUNG CANCER (SCLC) VS. NON-SMALL CELL LUNG CANCER (NSCLC) CONT.

A Study of XmAb[®]23104 in Subjects With Selected Advanced Solid Tumors (DUET-3).

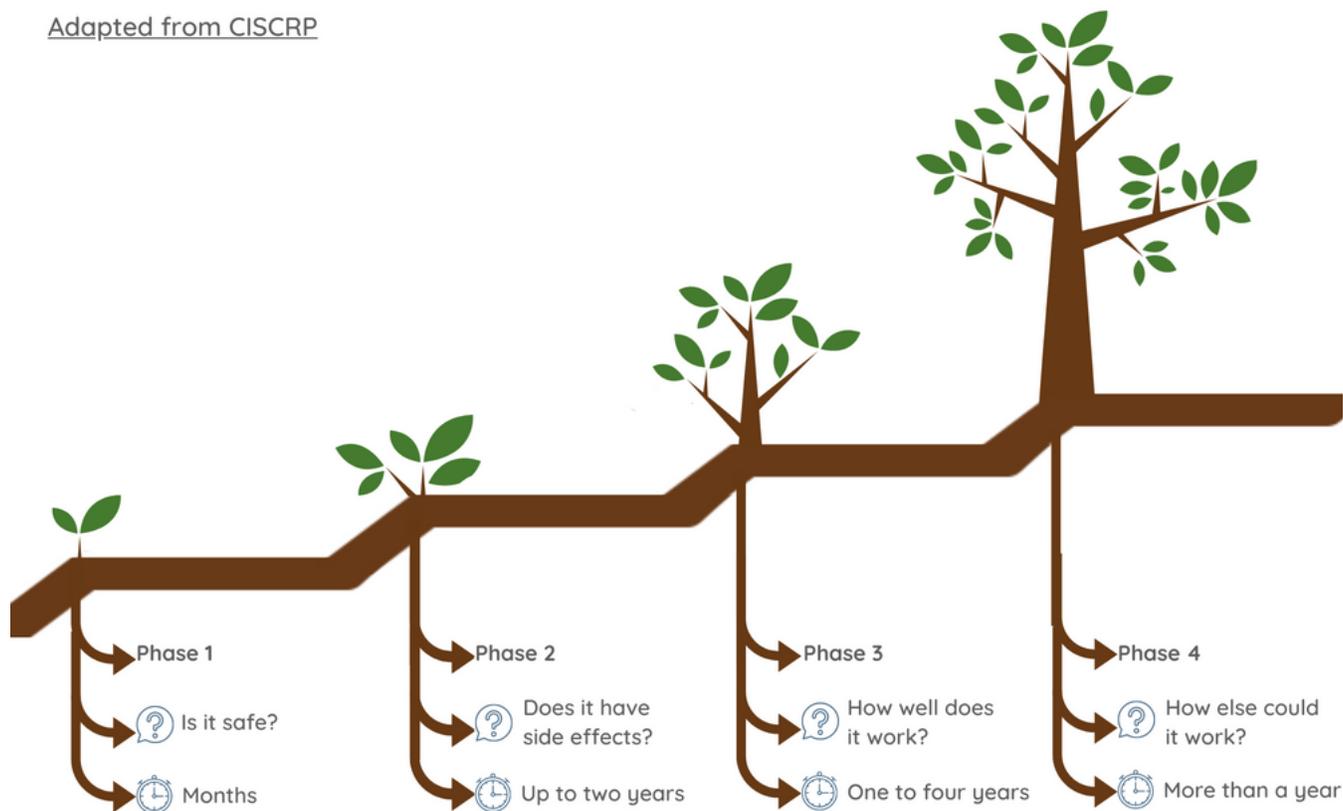
This is a Phase 1, multiple dose, ascending dose escalation study to define a MTD / RD and regimen of XmAb23104, to describe safety and tolerability, to assess PK and immunogenicity, and to preliminarily assess anti-tumor activity of XmAb23104 monotherapy and combination therapy with ipilimumab in subjects with selected advanced solid tumors.

A Study of XmAb[®]22841 Monotherapy & in Combination w / Pembrolizumab in Subjects w / Selected Advanced Solid Tumors

This is a Phase 1, multiple dose, ascending-dose escalation study and expansion study designed to define a maximum tolerated dose and / or recommended dose of XmAb22841 monotherapy and in combination with pembrolizumab; to assess safety, tolerability, pharmacokinetics, immunogenicity, and anti-tumor activity of XmAb22841 monotherapy and in combination with pembrolizumab in subjects with select advanced solid tumors.

CLINICAL TRIALS & PHASES

Adapted from CISCRP



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.

OVERCOMING KNOWN DISPARITIES AND ACCESS FOR LUNG CANCER PATIENTS



For cancer patients, multiple studies have shown that there are some known barriers to equitable access to care. The overall clinical trials participation rate is only about 5 percent of adult cancer patients. Some of the disparities show lower clinical trial participation rates for adolescent and young patients, patients over age 65, women in non-sex-specific cancers, and patients who earn \$50,000 or less annually.

And though study results were somewhat mixed about whether participation rates have increased for Black, Indigenous, and People of Color (BIPOC) communities, it's vital for BIPOC patients to increase their clinical trial participation rates as the percentages of BIPOC populations continue to rise in the overall U.S. population.

To increase lung cancer clinical trial participation for underrepresented groups, there are several strategies to improve rates.

OVERCOMING KNOWN DISPARITIES AND ACCESS FOR LUNG CANCER PATIENTS

These strategies include:

- Starting discussions about clinical trials early in the patient journey, beginning with diagnosis and continuing to discuss throughout their testing process up until discussions start about treatment decisions.
- Making special efforts to connect BIPOC patients and young patients with advocates targeted to their underrepresented group to help patients feel more connected and trusting about clinical trials.
- Connecting non-native English speakers to translators early in their lung cancer journey to ensure patients understand clinical trial options.
- Continuing and extending reimbursement of food and transportation costs as part of clinical trial participation.
- Patients from underrepresented lung cancer clinical trial groups sharing their experiences about clinical trials to increase education about trials.
- Patient advocacy websites and other resources including clinical trials as part of their foundational content for patients and caregivers.
- Continuing telemedicine as a viable option for initial entry into lung cancer clinical trials.

OVERCOMING KNOWN DISPARITIES AND ACCESS FOR LUNG CANCER PATIENTS



Educating lung cancer patients about clinical trials is an important piece of continuing effective clinical trials.

If efforts can continue to reach lung cancer patients who are underrepresented in clinical trials, these efforts will help to improve care for lung cancer patients receiving care currently and for those who will need treatment years in the future.

As researchers receive more data on the lung cancer treatments under study, lung cancer treatments will continue to be refined for subtypes and other factors for optimal lung cancer care and quality of life for each patient.

LUNG CANCER: DONNA'S CLINICAL TRIAL PROFILE



PLAY



Patient-to-Patient Diverse Clinical Trial Profiles

"What you have experienced or endured at the time, during a clinical trial and expressing it, it can only help the next person. But, in essence, I think the clinical trial is not in that only to help someone else, but it's also to help you...I think the knowledge of just knowing that you're a part of something that could be enhanced or approved or just help you with your health is a plus."

LUNG CANCER: GINA'S CLINICAL TRIAL PROFILE



Lung cancer survivor and non-smoker Gina was shocked after receiving her diagnosis at age 38. Watch as she shares her lung cancer journey including her diagnosis, treatment, clinical trial experience, and advice to other patients. In Gina's words, "So what I've learned is that clinical trials are really the best and newest care for patients, and I feel like all patients should have access and have the experience of a clinical trial."

WHAT ARE SOLUTIONS TO LUNG CANCER CARE BARRIERS?



You are watching a Patient Empowerment Network program

What are some solutions to lung cancer care barriers? Experts Dr. Nicole Rochester and Dr. Olugbenga Okusanya share key advice for working to overcome care barriers for optimal care.

HOW CAN LUNG CANCER PATIENTS ENSURE QUALITY CARE NO MATTER LOCATION?



You are watching a Patient Empowerment Network program

Now that lung cancer patients have access to in-person and telemedicine visits, how can they ensure quality care no matter location?

Experts Dr. Nicole Rochester and Dr. Olugbenga Okusanya share their advice on maximum travel times to in-person providers, when telemedicine visits make sense, and how to ensure you get the best fit for you as a patient.

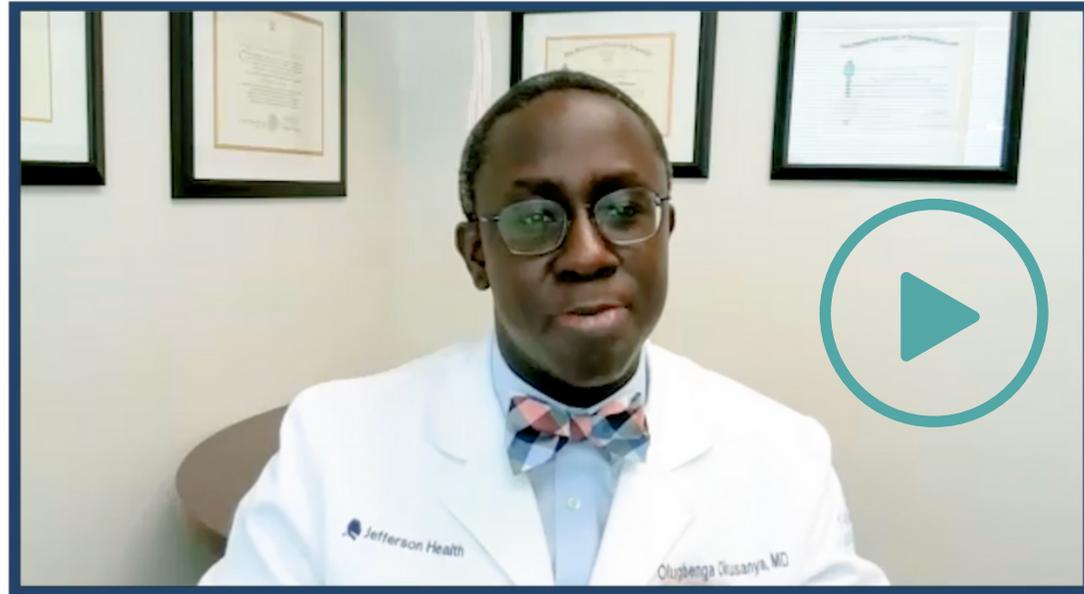
DECIDING ON A TREATMENT PLAN: WHERE DO CLINICAL TRIALS FIT IN?



Could a clinical trial be right for your lung cancer? Dr. Jessica Bauman, a specialist in lung cancer, discusses where clinical trials fit into the treatment plan and the role that trials play in the future of lung cancer care.

Dr. Jessica Bauman is assistant professor in the department of hematology/oncology and as associate program director of the hematology/oncology fellowship training program at Fox Chase Cancer Center in Philadelphia.

EMPOWERING LUNG CANCER PATIENTS TO INCREASE THEIR TREATMENT OPTIONS



You are watching a Patient Empowerment Network program

How can lung cancer patients be empowered to increase their treatment options?

Experts Dr. Nicole Rochester and Dr. Olugbenga Okusanya explain ways to improve access to lung cancer treatments and to process information more completely for the best care.

HOW CAN LUNG CANCER PATIENTS TAKE A MORE ACTIVE ROLE IN THEIR CARE?



You are watching a Patient Empowerment Network program

As a lung cancer patient, how can someone take a more active role in their care?

Experts Dr. Nicole Rochester and Dr. Olugbenga Okusanya provide advice for patients to empower themselves and questions to ask themselves about their lung cancer care team members for their best care.

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 **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.