LUNG CANCER TREATMENTS



What you need to know about...

clinical trials patient-assisted research studies















foreword

About LUNGevity

LUNGevity is the largest national lung cancer-focused nonprofit, changing outcomes for people with lung cancer through research, education, and support.

About the LUNGevity PATIENT EDUCATION SERIES

LUNGevity has developed a comprehensive series of materials for patients/survivors and their caregivers, focused on understanding how lung cancer develops, how it can be diagnosed, and treatment options. Whether you or someone you care about has been diagnosed with lung cancer, or you are concerned about your lung cancer risk, we have resources to help you.

The medical experts and lung cancer survivors who provided their valuable expertise and experience in developing these materials all share the belief that well-informed patients make their own best advocates.

In addition to this and other brochures in the LUNGevity patient education series, information and resources can be found on LUNGevity's website at www.LUNGevity.org, under "About Lung Cancer" and "Support & Survivorship."

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introduction

Clinical trials offer an important treatment option for people affected by lung cancer. They are important to consider from the time of diagnosis and are available for people with all stages of cancer.

New lung cancer treatments and other medical approaches are being developed through clinical trials. Clinical trial participants receive the best available standard of care and may have access to the very newest treatment approaches. They also contribute to knowledge about whether new lung cancer treatments are safe and effective and work better than current treatments. Studying how new treatments work in a representative group of people with lung cancer ultimately results in more and improved options for everyone, helping people live longer and better lives with the disease.

This brochure will help you:

- Learn about clinical trials
- Consider whether participating in a clinical trial might be right for you
- Locate resources to help you find a clinical trial that might be right for you

YOU'LL FIND A GLOSSARY TOWARD THE END OF THIS BROCHURE. Words included in the glossary appear **blue** the first time that they are used in the text.



clinical trials

"Clinical trials are my new hope, my new best friend. At first I was terrified of them; now I'm excited to have options. Hope is a chance!"

-LINNEA DUFF, Diagnosed stage IV adenocarcinoma, 2005

The goal of **clinical trials** is to find out whether new medical approaches that are being developed are safe and effective and better than those currently being used. Most drugs or medical procedures that are available for patients today went through clinical trial testing. This phase of research is only possible if patients who have the condition that is being studied participate, so a better name for clinical trials would be "patient-assisted research studies." Clinical trials are an important option for patients thinking about lung cancer treatments because the newest treatment approaches are being tested in them.

Clinical trials are sometimes also called:

- Clinical research trials
- Clinical research studies

What is a clinical trial?

Clinical trials are research studies in people that take place in a medical (clinical) setting. These studies test new medical approaches for their safety and **efficacy** among a group of volunteer participants.

For people affected by lung cancer, clinical trials test new ways to:

- Find and diagnose lung cancer
- Treat lung cancer
- Manage the symptoms of lung cancer or the side effects of treatment
- Prevent lung cancer in the first place (through **chemoprevention**, for example)

New lung cancer treatments are always tested in volunteers with the type (**histology** and/or **molecular profile**) and **stage** of lung cancer for which the new treatment is intended. Clinical trials are vital for adding to medical knowledge that can improve the care given to patients. The results of these research studies determine whether new treatments are approved for prescribing by doctors for patients outside of clinical trials. In the United States, the Food & Drug Administration (FDA) is the regulatory organization that makes this approval decision.

Note: Participants in treatment-focused clinical trials receive either a new treatment, a combination of treatments, or the treatment that is currently considered the "gold standard," which is the best currently-available proven treatment. A clinical trial participant will <u>never</u> be treated with less than the standard of care.

Each clinical trial has its own **protocol**, or study plan. The protocol outlines every aspect of how the clinical trial is to be conducted, including:

- The reason for doing the trial
- Who can join the trial (called "eligibility requirements," or "inclusion criteria" and "exclusion criteria")
- Possible benefits
- Risks and possible side effects
- How long the study will last
- What treatment is given, how the treatment is given, and how often the treatment is given (for studies of new treatments)
- What medical tests will be done to measure whether the treatment is working
- What types of information will be collected about the patients taking part in the trial

Where do clinical trials take place?

There is no one standard location for where clinical trials take place. Some are available in just a few places; others have sites at hundreds of locations—across the United States and in many other countries. They may take place in doctors' offices, community hospitals and clinics, cancer centers, veterans' and military hospitals, or at the National Institutes of Health Clinical Center. When you talk with your doctor about treatment options, ask about clinical trials. There may be one that is right for you and is taking place at your doctor's office or nearby.

What are the phases of a clinical trial?

Clinical trials to test new cancer treatments involve a series of steps, called phases. There are 3 main phases of clinical trials. If a new treatment is successful in one phase, it will move on to further testing in the next phase. A drug or device usually has to demonstrate success in the first 3 phases before it is approved by the FDA for broader use.

However, the FDA also has a number of programs to support faster development and review of new drugs for areas of unmet medical need, like lung cancer. These programs include:

- Breakthrough therapy designation
- Fast track designation
- Accelerated approval
- Priority review

When a treatment is developed through one of these programs, a drug may be approved after strong phase 2 success, for example, and then monitored closely afterwards. The following table shows the numbers of patients who take part and the goal of each phase.

Phase	Purpose	Patient Population
Phase 1	 To find a safe dose of a new treatment To decide how the new treatment should be given (by mouth, in a vein, etc.) To see how the new treatment affects the human body (whether it causes side effects) 	 15-30 people May be a mix of people with different cancers
Phase 2	 To find out if the new treatment has an effect on a certain type of cancer, like lung cancer To see whether the new treatment causes any side effects 	 Fewer than 100 people All the same kind of cancer
Phase 3	 To compare the efficacy of the new treatment (or new use of a treatment) with the current standard treatment 	 From 100 to several thousand people All the same kind of cancer

PHASES OF A CLINICAL TRIAL IN CANCER

Some researchers design trials that combine two phases (phase 1/2 or phase 2/3 trials) in a single protocol. In this combined design, there is a seamless transition between trial phases. This may allow research questions to be answered more quickly or with fewer patients.

Note: Before a treatment is studied in humans, it is studied in the pre-clinical research phase. During this phase, the treatment is generally studied in laboratory animals for safety and efficacy.

You may also hear the term "phase 4"-this is also called postmarketing surveillance. The goal of this phase is to monitor the long-term effectiveness and safety of an approved treatment after it's on the market with FDA approval.

How are people assigned to different treatments in clinical trials?

In some phase 2 and all phase 3 clinical trials, participants are assigned to groups that receive different treatments. The assignments are made randomly, usually by a computer, so that neither the researchers nor the participant knows which group the participant is in. In the most basic trial design, one group receives the new treatment. This group is called the **investigational group**. The other group receives the current standard therapy. This group is called the control group.



TREATMENT GROUPS

When are placebos used in clinical trials?

In lung cancer clinical trials, participants are never given a placebo instead of an effective standard treatment.

Note: A placebo is a substance designed to look like the medicine being tested, but it is not an active drug.

In fact, placebos are rarely used in cancer treatment clinical trials. They are only used:

- When there is <u>no</u> standard treatment
- In a clinical trial that compares standard treatment plus a new treatment against standard treatment plus a placebo, as in the image below



PLACEBO

Using a placebo in this way can help prevent patients and their doctors from figuring out which treatment group the patients were assigned to.

Note: You will always be told if a clinical trial uses a placebo.

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What happens after a clinical trial is over?

The clinical trial's research team should remain in contact with the participants and will let them know about the trial's findings and conclusions. They may ask participants to continue to provide information about their health, either through surveys or actual health examinations. This is in addition to the regular care provided by the participants' usual medical team.

RESOURCE FOR MORE INFORMATION ABOUT THE DIFFERENT TYPES OF CLINICAL TRIALS:

 National Cancer Institute (NCI): www.cancer.gov/clinicaltrials/learningabout/what-are-clinical-trials/types

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participating in a clinical trial

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participating in a clinical trial

Clinical trials provide a great opportunity to gain access to cuttingedge treatments and also to contribute to the progress of lung cancer research. Factors to consider when deciding whether to participate in a clinical trial include whether or not you are eligible, possible benefits and risks of participating, and also how the clinical trial fits into your overall healthcare.

Who can participate in a clinical trial?

Each clinical trial defines who is eligible to take part. Each trial must include only people who fit the patient traits for that study (also known as the eligibility criteria). Criteria for who can take part in a trial may include:

- Specific age range
- Gender
- Type of lung cancer—this may be described by histology and/or molecular profile
- Stage of lung cancer

participating in a clinical trial **LUNG**EVITY FOUNDATION

- Site of **metastases**—for example, whether someone has brain metastases or other central nervous system (CNS) metastases
- Previous treatment history—the type of treatment or the number of different types of treatment
- Medical history
- Current health status

"I am about to begin my second clinical trial. I choose to participate because I'm hopeful that the trial will provide me with more time with my loved ones, and also because my participation can help researchers determine what will and will not work."

 MELISSA CROUSE, Diagnosed stage IA adenocarcinoma, 2005, with recurrence of metastatic disease (stage IV), 2008



Criteria such as these help reduce the medical differences among participants in the clinical trial. When patients taking part in a trial are alike in key ways, researchers can be more certain that the results are due to the treatment being tested and not to other factors.

Also, some patients have health problems besides lung cancer that could be made worse by the treatments in a trial. If you are interested in joining a trial, you will receive medical tests to be sure that you are fit for the trial.

The factors that allow someone to participate in a clinical study are called inclusion criteria, and the factors that disqualify someone from participating are called exclusion criteria.

How are participants in clinical trials kept safe?

People who take part in clinical trials are protected in a number of ways. In fact, the federal government has rules in place to help ensure both the safety and the ethics of clinical trials. Ways to keep patients safe include:

- Informed consent process
- Review of the clinical trial protocol (plan) by an institutional review board (IRB)
- Ongoing monitoring of the clinical trial

"There are two reasons I've participated in clinical trials: first, because doing so could save my life, but also because I hope that my experience can benefit someone else down the line."

 —KIMBERLY MITCHELL, Diagnosed stage IV ALK-positive non-small cell lung cancer (NSCLC), 2006



Informed consent process

Researchers must provide patients who are thinking about joining a clinical research study with detailed information about the study. This includes enough information about the trial's purpose and possible benefits and risks, so that each patient can decide whether to take part. This information must be given in writing and may be discussed with the doctors and nurses or the research team. If a patient decides to take part in a study, he or she will be given an informed consent document to sign, confirming understanding of this information.

Note: The informed consent document is not a contract. Participants always have the right to leave a clinical trial at any time, even if it is not complete.

Review of the clinical trial protocol (plan) by an institutional review board (IRB)

There is an institutional review board (IRB) at every healthcare facility that does clinical research. This board includes doctors, researchers, and community members. The IRB's role is to ensure that the clinical trial protocol is ethical, and that the rights and welfare of the patients who take part are being protected.

Ongoing monitoring of the clinical trial

Once the clinical trial is under way, it continues to be monitored by the:

- Institutional review board (IRB)
- Research team conducting the trial
- Data and Safety Monitoring Board (DSMB), for the phase 3 portion of a clinical trial. The DSMB decides whether a trial should be changed or closed. The DSMB is made up of doctors, statisticians, and others who are independent of the people, organizations, and institutions that are sponsoring, organizing, and conducting the clinical trial. DSMB members are experts in clinical research and clinical trials
- FDA, which meets with researchers and inspects clinical trial sites
- Sponsor of the trial

Clinical research trials may be sponsored—developed and supported by a number of different organizations and entities, including:

- Academic medical centers
- Community hospitals
- Government agencies, such as the National Institutes of Health and the U.S. Department of Defense
- Patient advocacy groups
- Pharmaceutical or biotechnology companies
- Physicians

How does a clinical trial fit in with a person's overall healthcare?

The research protocol (plan) for the clinical trial determines how often a participant receives a drug treatment and what exactly that treatment will be. Most often, a patient taking part in a clinical trial will continue to receive the rest of his or her healthcare from their usual doctors. This is true whether or not the patient is receiving the study treatment in the same location as where they receive their regular care. The researchers and usual doctors can work together to ensure that the clinical trial protocol will not conflict with any other drugs or treatments that the patient is taking.

Note: As the patient, you should be proactive in making sure your primary care doctors and other specialists are aware of your clinical trial medications. You also need to make sure your clinical trial team knows about any changes in your other healthcare and clears the addition of any other new medications.

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What are the benefits and risks associated with participating in a clinical trial?

Like all treatment options, there are both benefits and risks for patients who take part in a clinical trial. Before deciding to take part, you should carefully consider both.

Note: If you are thinking about taking part in a clinical trial, ask your doctors and the research team conducting the trial as many questions as you need to feel satisfied that you understand exactly what is involved. There is a list of suggested questions at the back of this brochure.

Possible benefits of participating in clinical trials

The possible benefits of participating in a clinical trial include:

- You may have access to a new treatment that is not otherwise available, reflecting the latest thinking in lung cancer research and treatment
- The research team will monitor your health closely, providing excellent care
- If the treatment being studied is more effective than the standard treatment, you may be among the first to benefit from the treatment
- Even if you do not directly benefit, the information gathered during the clinical trial will still add to knowledge about lung cancer and can help other patients

Possible risks of participating in clinical trials

The possible risks of participating in a clinical trial include:

- The new treatment may not be better than, or even as good as, the standard treatment
- New treatments may have side effects that doctors do not expect or that are worse than those of the standard treatment
- You may be required to make more visits to the doctor, or have more hospitalizations, than if you were receiving standard treatment
- You may need extra tests, and some of these may be uncomfortable or time-consuming
- Even if a new treatment benefits some patients, it may not benefit you
- Health insurance may not cover all patient care costs in a trial. In addition, you may have extra expenses related to extra doctor visits, such as travel and child care costs
- You may have to travel to the place the research treatment is being given

How do participants pay for clinical trials?

As you think about taking part in a clinical trial, you will face the issue of how to cover the costs of care. There are two types of costs associated with a clinical trial:

- Patient care costs
- Research costs

Patient care costs

Patient care costs are costs related to treating your cancer, whether you are in a clinical trial or receiving standard therapy. These costs

must be covered by most health insurance under the Patient Protection and Affordable Care Act. They include:

- Doctor visits
- Lab tests
- Hospital stays
- X-rays and other imaging tests

Research costs

Research costs are those related to taking part in a clinical trial. Often, these costs are not covered by health insurance, but they may be covered by the trial's sponsor. Examples include:

- The drug or treatment being studied
- Lab tests performed purely for research purposes
- Additional X-rays and imaging tests performed solely for the trial

Also, when you take part in a trial, you may have extra doctor visits that you would not have with standard treatment. These extra visits can add costs for transportation and child care. A number of resources have been established to help navigate extra costs associated with clinical trials, or with cancer care in general.

RESOURCES TO HELP YOU MANAGE THE EXTRA COSTS ASSOCIATED WITH CLINICAL TRIALS:

- The clinical trial research coordinator or research nurse
- CancerCare:
 www.cancercare.org
- Cancer Financial Assistance Coalition: www.cancerfac.org
- Patient Advocate Foundation: www.patientadvocate.org

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03

resources and information on clinical trials

resources and information on clinical trials

Numerous resources are available to help you find the right clinical trial. These include your healthcare team, which is a valuable source of information for all of your healthcare needs, especially when it comes to your participation in a clinical trial.

"I have been on three clinical trials—the first two were chemotherapy, and they worked for me long enough to get me to the next option. Four years ago, I entered a phase 1 immunotherapy trial of a drug that didn't even have a name yet.

I was on the treatment for two years, and it's working for me. Today, I am eternally grateful.

-DAVID GOBIN, Diagnosed stage IV squamous cell lung cancer, 2008



Finding a clinical trial that might be right for you

If you are considering participating in a clinical trial, start by asking your healthcare team whether there is one that might be a good match for you in your geographic area. In addition, there are several resources to help you find one that may be a good match.

Information about available clinical trials may be found through the resources detailed below. The first is a comprehensive resource, with trained experts who help you navigate clinical trials. The next three include trials for all cancers, not just lung cancer. The last three focus on patients with **genetic mutations**.

RESOURCES TO HELP YOU NAVIGATE YOUR CLINICAL TRIALS SEARCH:

- EmergingMed: www.emergingmed.com/ networks/LUNGevity
 - LUNGevity partners with this free clinical trials matching service to help you with the decision of whether to participate in a clinical trial
 - EmergingMed helps you identify lung cancer clinical trials for which you may be eligible
 - Clinical trial navigators are available Monday through Friday from 8:30am to 6:30pm ET at 800-698-0931
- U.S. National Institutes of Health: www.clinicaltrials.gov
 - Includes publicly and privately supported clinical studies of human participants conducted in the U.S. and 186 other countries around the world in all different disease states

RESOURCES TO HELP YOU NAVIGATE YOUR CLINICAL TRIALS SEARCH (CONTINUED):

- National Cancer Institute (NCI): www.cancer.gov/clinicaltrials/search
 - This site has all of the 12,000+ clinical trials in the U.S. in all cancer types
- Coalition of Cancer Cooperative Groups: www.cancertrialshelp.org/cancer-trial-search
 - This site gets its information from www.clinicaltrials.gov, but organizes the search and results in a different way
- My Cancer Genome:

www.mycancergenome.org

- Managed by a team of doctors at Vanderbilt University
- My Cancer Genome gives up-to-date information on what mutations make cancers grow and related treatment options, including available clinical trials
- Lung Cancer Mutation Consortium (LCMC):
 - www.golcmc.com
 - Composed of 16 leading cancer centers across the country
 - LCMC's goal is to examine the tumors of patients who have a type of advanced (stage IIIB or IV) non-small cell lung cancer called adenocarcinoma and match those patients to the best possible therapies, including clinical trials
- Lung Cancer Master Protocol (Lung-MAP): www.lung-map.org
 - For patients with squamous cell carcinoma
 - Lung-MAP is a collaboration of many research sites across the country. They use a unique approach to match patients to one of several drugs being developed

In addition, if you are interested in a specific drug or other treatment that is being developed, you can often find information about studies for that drug on the website of the company developing it.

QUESTIONS TO ASK YOUR HEALTHCARE TEAM IF YOU ARE CONSIDERING A CLINICAL TRIAL:

- How do I know if I am a possible candidate for a clinical trial?
- Are clinical trials only for people who have failed all other options?
- If I am a candidate to receive an approved standard therapy, why should I participate in a clinical trial?
- Are clinical trials safe?
- What are some of the benefits and risks of participating in a clinical trial?
- What is the goal of this trial? Who is sponsoring it?
- What is known about the investigational drug being studied? Has it worked in previous trials? Is it the same as chemotherapy?
- How will I be given the drug? How often and for how long?
- Are there tests to determine if I am eligible for this trial?
- What types of tests, scans, or other procedures are required during the trial, and how frequently will they need to be performed?
- What side effects might I experience if I'm given the investigational drug? Are the side effects reversible, and how can they be managed?

QUESTIONS TO ASK YOUR HEALTHCARE TEAM IF YOU ARE CONSIDERING A CLINICAL TRIAL (CONTINUED):

- Are the side effects from the investigational drug worse than those I might experience with standard treatment? How severe could these side effects be?
- Will I lose my hair?
- Will I be able to continue working or go about my daily routine?



glossary

Chemoprevention—The use of drugs, vitamins, or other agents to try to reduce the risk, or delay the development or recurrence, of cancer

Clinical trial—A type of research study that tests how well new medical approaches work in people. These studies test new methods of screening, prevention, diagnosis, or treatment of a disease. Also called clinical research trial or clinical study

Control group—In a clinical trial, the group that does not receive the new treatment being studied. This group is compared with the group that receives the new treatment to see if the new treatment works

Data and Safety Monitoring Board (DSMB)—An impartial group that oversees a clinical trial and reviews the results to see if they are acceptable. This group determines if the trial should be changed or closed

Efficacy—The ability of an intervention (for example, a drug or surgery) to produce the desired beneficial effect

Genetic mutation—Any change in the gene sequence of a cell. Mutations may be caused by mistakes during cell division, or they may be caused by exposure to gene-damaging agents in the environment. Certain mutations may lead to cancer or other diseases

Histology—The study of tissues and cells under a microscope

Imaging test—Any test that uses a form of energy, such as X-rays, ultrasounds, radio waves, or radioactive substances, to make detailed pictures of areas inside the body. Imaging tests include CT scans, MRI scans, and nuclear medicine tests

Informed consent process—A process in which patients are given important information, including possible benefits and risks, about a medical procedure or treatment, a clinical trial, or genetic testing. This is to help them decide if they want to be treated, tested, or take part in the trial. Patients are also given any new information that might affect their decision to continue. Also called consent process

Institutional review board (IRB)—A group of scientists, doctors, clergy, and patient advocates that reviews and approves the detailed plan for every clinical trial. Institutional review boards are meant to protect the patients who take part in clinical trials. They check to see that the trial is well designed, legal, and ethical, does not involve unneeded risks, and includes a safety plan for patients. There is an institutional review board at every healthcare facility that does clinical research

Investigational group—In a treatment clinical trial, the group that receives the new treatment being studied. This group is compared with the group that does not receive the new treatment, to see if the new treatment works

Metastasis—The spread of cancer from the primary site, or place where it started, to other places in the body

Molecular profile—The genetic characteristics, as well as any other unique biomarkers, found in a person's cancer. For example, ALKpositive or EGFR-positive

Mutation—See genetic mutation

Phase 1 clinical trial or research study—Researchers test a new drug or treatment in a small group of patients for the first time to evaluate its safety, determine a safe dosage range, and identify side effects

Phase 2 clinical trial or research study—The drug or treatment is given to a larger group of patients to see if it is effective and to further evaluate its safety

Phase 3 clinical trial or research study—The drug or treatment is given to large groups of patients to confirm its effectiveness, monitor side effects, compare it with commonly used treatments, and collect information that will allow the drug or treatment to be used safely. Once phase 3 is completed, the drug or treatment can be submitted to the U.S. Food and Drug Administration (FDA) for approval

Protocol—A detailed plan of a scientific or medical experiment, treatment, or procedure. In clinical trials, it states what the study will do, how it will be done, and why it is being done. It explains how many patients will be in the study, who is eligible to take part in it, what study drugs or other interventions will be given, what tests will be done and how often, and what information will be collected

Stage—The extent of a cancer in the body

Stage O lung cancer in situ—Abnormal cells found in the lining of the airways. These abnormal cells may become cancer and spread into nearby normal tissue

Stage I lung cancer—The lung tumor has grown through the innermost lining of the lung into deeper lung tissue. The tumor is no more than 5 centimeters across. Cancer cells have not spread to nearby tissues or lymph nodes

Stage II lung cancer—The lung tumor is smaller than 7 centimeters across, and cancer cells have spread to lymph nodes on the same side as the tumor. Or, the lung tumor is more than 5 centimeters across and the cancer has not spread to the lymph nodes, but it did invade nearby tissues, such as the chest wall, diaphragm, pleura, main bronchus, or tissue that surrounds the heart. More than one tumor may be found within the same lobe of the lung

Stage III lung cancer—The lung tumor can be any size, and more than one tumor may be within the same lung. Cancer cells may have spread to lymph nodes on either side of the chest or the neck. The tumor may have invaded nearby organs, such as the heart, esophagus, or trachea

Stage IV lung cancer—Lung tumors are found in both lungs. Or, the lung cancer has spread to other parts of the body, such as the brain, bones, liver, or adrenal glands

X-ray—A type of radiation used in the diagnosis and treatment of cancer and other diseases. In low doses, X-rays are used to diagnose diseases by making pictures of the inside of the body. In high doses, X-rays are used to treat cancer



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CHICAGO OFFICE

228 S. WABASH AVENUE, SUITE 700 CHICAGO, IL 60604 **PH:** 312.407.6100 **F:** 312.464.0737

BETHESDA OFFICE

6917 ARLINGTON ROAD, SUITE 352 BETHESDA, MD 20814 **PH:** 240.454.3100 **F:** 240.497.0034

EMAIL: INFO@LUNGEVITY.ORG

www.LUNGevity.org

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