

Glossary of Lung Cancer Clinical Trial Terms



The following glossary was prepared to help patients with lung cancer and their families become familiar with many of the common terms used in lung cancer clinical trials.

Adenocarcinoma

A form of cancer that originates from cells in the lining of the walls of many different organs of the body, such as the lungs, colon, and pancreas. When adenocarcinoma develops in the lungs' air sacs, it is called bronchioalveolar adenocarcinoma.

Adjuvant therapy

The use of chemotherapy, radiation, and/or other therapy following initial treatment.

Adverse reaction (adverse event)

An unwanted effect caused by the administration of drugs. The reaction may occur suddenly or develop over time. See also side effects.

Antiemetics

Drugs that prevent or reduce nausea and vomiting.

Approved drugs

In the United States, the Food and Drug Administration (FDA) must approve a drug before it can be used in patients. The approval process involves several steps including preclinical laboratory and animal studies (testing that takes place before the drug is studied in humans), clinical trials that help determine safety and effectiveness, filing of a New Drug Application (NDA) by the manufacturer of the drug, FDA review of the application, and FDA approval/rejection of the application.

Arm

A treatment group in a clinical trial. A single-arm clinical trial is a study that involves one treatment group. A randomized clinical trial is a study that can have 2 or more arms.

Baseline

Information about the health and condition of a patient that is gathered at the beginning of a study. Clinical trial investigators use baseline information to measure differences that occur in a patient throughout a trial.

Benign

Not cancerous. A benign tumor does not invade nearby tissue, nor spread to other parts of the body.

Biomarker

A substance sometimes found in an increased volume in the blood, other body fluids, or tissues, which may signify that a certain type of cancer is in the body. Also called a tumor marker.

Biopsy

Removal of a tissue sample for examination under a microscope by a pathologist (a doctor who specializes in the study and diagnosis of disease through examination of organs, tissues, body fluids, and whole body).

Blind

A clinical trial is "blind" if participants are unaware of what drug they are receiving (either the experimental or control drug) during the study; it can also be referred to as "masked." See also single-blind study and double-blind study.

Cancer

A group of diseases in which cells divide and grow uncontrollably. Cancer cells can invade nearby tissues and can spread through the bloodstream and lymphatic system (the body's immune system that is made up of bone marrow, the spleen, thymus, and lymph nodes) to other parts of the body.

Carcinoma

Cancer that arises from the epithelium cells, which are cells that cover or line internal and external body surfaces.

Chemoprevention agents

Substances that could potentially repair damage to genes (sequences of DNA that determine an individual's characteristics) before cancer develops.

Chemotherapy

Treatment with a chemical, or combination of chemicals, that kills rapidly dividing cells or cells that grow quickly, including cancer cells. Chemotherapy is a systemic treatment, which means it flows through the bloodstream, reaching every part of the body.

Clinical investigator

A medical researcher who helps carry out a clinical trial.

Clinical trial

A research study that attempts to answer specific questions about new therapies or new ways of using existing treatments. Clinical trials (also called medical research and research studies) are used to determine whether new drugs or treatments are both safe and effective.

Cohort

A group of individuals with common characteristics, such as disease severity or past medical history. For example, all patients in one cohort may receive the same type of cancer treatment.

Complete remission

When a patient's cancer can no longer be detected after treatment, using tests which may include imaging tests.

Computed tomography scan

Computed tomography, also known as CT or CAT scan, is an instrument that uses a computer to create a 2-dimensional scan from a series of X-ray images. These images may be of tissue at the cancer site. CT scans show much more detail than X-rays, and can indicate where the cancer is, the size of the tumor(s), and if and where the cancer has spread.

Consolidation therapy

Treatment given to patients after initial therapy that attempts to prolong remission, the period of time when the patient is cancer-free.

Confidentiality regarding trial participants

Refers to maintaining the confidentiality of all trial participants, including their personal identity and all personal medical information.

Contraindication

A specific circumstance when the use of certain treatments could be harmful to patients.

Control

A standard against which experimental observations may be evaluated. In clinical trials, one group of participants is given an experimental drug, while another group (ie, the control group) is given either a commonly accepted treatment for the disease or a placebo.

Data Safety and Monitoring Board (DSMB)

An independent committee, composed of clinical scientists, physicians, and/or patient representatives or advocates, that reviews data while a clinical trial is ongoing to make sure that participants are not exposed to unnecessary risk. A DSMB may recommend that a trial be stopped if there are safety concerns or if the trial objectives have been achieved.



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Dose-ranging study

A clinical trial in which 2 or more doses of a treatment are tested against each other to determine which works best and is least harmful.

Double-blind study

A clinical trial in which neither the participating individuals, physician, nor the study staff knows which participants are receiving the experimental drug and which are receiving a placebo or another therapy. Double-blind trials are thought to produce objective or unbiased results, since the expectations of the doctor and the participant about the experimental drug do not affect the outcome. See also blind study, single-blind study.

Drug-drug interaction

A modification of the effect of a drug when administered with another drug. Effects may include an increase or a decrease in the action of either substance, or an adverse effect not normally seen when either drug is administered alone.

Dyspnea

Difficulty breathing or shortness of breath.

Efficacy

The ability of a treatment to be effective. A drug is “efficacious” if it is effective at the dose being tested and against the illness.

Eligibility criteria

Conditions for participant selection in a clinical trial; includes inclusion and exclusion criteria.

Empirical

Based on experimental data, not on a theory.

Enrolling

Signing up participants into a study. Generally, this process involves evaluating a participant with respect to the eligibility criteria of the study and obtaining consent. See also informed consent.

Expanded access

Refers to any of the FDA procedures with an investigational new drug (IND) that make experimental drugs available to participants who have no other treatment options for their condition, and are unable to participate in ongoing clinical trials.

Experimental drug

A drug that is not FDA-approved for use in humans or as a treatment for a particular condition. See also off-label use.

FDA

The United States Food and Drug Administration is an agency of the US Department of Health and Human Services that is responsible for ensuring the safety and effectiveness of all drugs, biologics, vaccines, and medical devices. The Internet address is: <http://www.fda.gov>.

Five-year survival rate

The number of patients who live at least 5 years after a diagnosis of cancer, regardless of whether or not they are undergoing treatment for their disease.

Genetics

Pertaining to a person’s genes. Genes are components of deoxyribonucleic acid (DNA), which is found in every cell in the body. Damage to genes, which can occur through aging, cell division, or as an effect from chemicals or radiation, may lead to cancer.

Hemoptysis

Coughing up blood, usually originating in the respiratory tract.

Immunotherapy

Treatment using a person’s immune system to fight infection and disease, or to lessen side effects that may be caused by some cancer treatments. Also called biological therapy.

Inclusion/exclusion criteria

A set of factors, such as age, gender, type and stage of disease, and medical history, that is used to determine whether a person may or may not be allowed to enter or enroll in a clinical trial. It is important to note that inclusion and exclusion criteria are not used to reject patients, but rather to identify appropriate participants and keep them safe.

Induction therapy

The initial course of chemotherapy designed to induce or bring about a remission of cancer.

Informed consent

The process of learning key information about a clinical trial before deciding whether or not to participate. It is also a continuing process throughout the study to provide information for participants.

Informed consent document

A document that describes the rights of study participants, and includes details about the study, including its purpose, duration, required procedures, and key contacts. Risks and potential benefits are explained in the informed consent document. The participant then decides whether or not to sign the document. Informed consent is not a contract, and the participant may withdraw from the trial at any time.

Institutional Review Board (IRB)

A committee consisting of physicians, other scientists, and/or patient representatives or advocates that ensures that a clinical trial is ethical and that the rights of study participants are protected. All clinical trials in the United States must be approved by an IRB before they begin.

Intent to treat

Analysis of clinical trial results that includes all of the data from participants in the groups to which they were randomized or assigned to by chance, even if they never received the treatment.

Invasive cancer

Cancer that has spread beyond the layer of tissue in which it originally developed, and is growing into surrounding tissue. Also called infiltrating cancer.

Investigational new drug (IND)

A new drug that is used in a clinical investigation. It may also include products used in vitro (in a test tube or artificial environment) for diagnostic purposes.

Lobectomy

Surgery that removes the lobe (a portion) of the lung that contains the tumor. The right lung is divided into 3 lobes; the left lung has 2 lobes.

Lymph nodes

Small oval structures located throughout the lymphatic system (the body’s immune system made up of bone marrow, the spleen, thymus, and lymph nodes) that act as filters to keep foreign bodies from entering the bloodstream. They also produce a type of white blood cell called lymphocytes, which are components of the immune system.

Maintenance therapy

A treatment that is designed to help the original treatment succeed. Maintenance chemotherapy may be given to patients with cancer in remission to prevent a relapse.

Malignant cancer

A cancer that invades nearby tissues or spreads to other parts of the body.

Metastasis

The spread of a disease from one organ or part of the body (primary growth) to another nonadjacent organ or part of the body.

Micrometastases

The spread of a disease that is too small to be detected by routine screening tests such as an X-ray.

Magnetic resonance imaging (MRI)

Magnetic resonance imaging is an imaging test, similar to a CT scan, that uses a magnetic field instead of X-rays to create an image.

Neoadjuvant therapy

The use of chemotherapy and/or radiation therapy before surgery in order to shrink the size of a tumor and/or destroy distant micrometastases that may cause the cancer to come back following local therapy.

New Drug Application (NDA)

An application submitted by the manufacturer of a drug to the FDA—after clinical trials have been completed—for a license to make the drug available and promote it to treat a specific indication.

Non-small cell lung cancer (NSCLC)

A diverse group of cancers that grow and spread less rapidly than small cell lung cancer.

Off-label use

A drug prescribed to treat conditions other than those approved by the FDA.

Oncology

The field of medicine that treats and researches cancer.

Open-label trial

A clinical trial in which every patient in the trial gets the experimental drug.

Palliation

The use of therapy to relieve symptoms (including physical pain) without providing a cure.

Partial remission

A response to therapy that involves a decrease in the size of the tumor by more than 50%, which is measured by various tests, including imaging tests.

Peer review

Review of a clinical trial by experts who are chosen by the study sponsor (the person or organization responsible for financing a study). These experts review the trial for scientific value, participant safety, and ethical considerations.

Performance status

Criteria used by doctors and researchers to evaluate a patient's general well-being or ability to function to determine whether he/she can receive treatment.

Pharmacokinetics

In a living organism, the processes of the absorption, distribution, metabolism, and elimination of a drug or vaccine.

Phase I trials

Studies that determine how a drug reacts in humans, evaluate the drug's side effects, and show early evidence of the drug's effectiveness. These trials may include healthy participants.

Phase II trials

Studies that evaluate the effectiveness of a drug in patients with the disease or condition that is being studied, and determine the common short-term side effects and risks.

Phase III trials

Longer controlled and uncontrolled studies that demonstrate the effectiveness of a drug against the usual standard of care. These trials are intended to gather additional information to evaluate the overall risk-benefit relationship of a drug (the risk to participants versus the potential benefits).

Phase IV trials

Studies that provide additional information on the risks, benefits, and best use of drugs already approved for commercial use.

Placebo

A placebo is an inactive pill, liquid, or powder that has no treatment value. In cancer clinical trials, experimental treatments are often compared with standard therapies, and not placebos, to assess the treatment's effectiveness. See also placebo-controlled study.

Placebo-controlled study

A trial in which an inactive substance (the placebo) is given to one group of participants, while the experimental drug is given to another group. The results obtained in the 2 groups are then compared to see if the experimental treatment is more effective in treating the condition. This would not be conducted in a patient with active disease.

Placebo effect

A physical or emotional change that is seen after an inactive substance is taken or administered. The change may be beneficial, reflecting the expectations of the participant and, often, the expectations of the person giving the substance.

Pleura

The membrane that lines the inner surface of the chest wall and also covers the lungs.

Pneumonectomy

The surgical removal of an entire lung.

Positron-emission tomography (PET) scan

Positron-emission tomography is a scan that examines a cancer's rapidly dividing cells to help doctors make a diagnosis. Radiologists give the patient a radioactive sugar substance that will be absorbed more by the cancer than by normal tissues due to the cancer cells' increased need for energy. The PET scan records the areas where the radioactivity is focused.

Preclinical

Refers to the testing of experimental drugs in a test tube or in animals, ie, the testing that occurs before clinical trials in humans may be carried out.

Prognosis

The likely outcome or course of a disease; the chance of recovery.

Protocol

A study plan that is carefully designed for each clinical trial to safeguard the health of participants as well as answer specific research questions. A protocol describes what types of patients may participate in the trial; the schedule of tests, procedures, medications, and dosages; and the length of the study. See also inclusion/exclusion criteria.

Quality of life trials (or supportive care trials)

Refers to trials that explore ways to improve the comfort and quality of life for individuals with a chronic illness.

Radiation therapy

The use of high-energy radiation from X-rays, neutrons, and other sources to kill cancer cells and shrink tumors. Radiation therapy affects cancer cells in a targeted area.

Randomization

A method based on chance by which study participants are assigned to a treatment group. Randomization minimizes the differences between groups by equally distributing participants with specific characteristics among all of the trial arms. The researchers do not know which treatment is better. From what is known at the time, any one of the treatments chosen could be beneficial to the participant.

Randomized trial

A study in which participants are randomly (ie, by chance) assigned to 1 of 2 or more treatment arms of a clinical trial.

Recurrence

The return of cancer after it has been treated or removed.

Recruiting

The period during which a trial is attempting to identify and enroll participants. Recruitment activities can include advertising and other ways of generating interest from possible participants. See also recruitment status, enrolling.

Recruitment status

Indicates whether patient recruitment for the trial is planned, ongoing, or completed.

Remission

The disappearance of the signs and symptoms of cancer. A patient may be in partial or complete remission, and that remission may be temporary or permanent.

Resection

The surgical removal of part of an organ.

Risk-benefit ratio

The risk to individual participants versus the potential benefits. The risk-benefit ratio may differ depending on the condition being treated.

Screening trials

Refers to trials that test the best way to detect certain diseases or health conditions.

Side effects

Any undesired actions or effects of a drug or treatment. Negative or adverse effects of certain treatments may include headache, nausea, hair loss, skin irritation, or other physical problems. Experimental drugs must be evaluated for both immediate and long-term side effects. See also adverse reaction.

Single-blind study

A study in which either the investigator or participant, but not both, is unaware of what medication the participant is taking; also called single-masked study. See also blind, double-blind study.

Small cell lung cancer (SCLC)

A type of lung cancer characterized by aggressive, rapid growth of cancer starting in a normal lung cell. This type of lung cancer cell appears small and round when viewed under a microscope.

Spiral computerized tomography (spiral CT) scan

The spiral (or helical) CT scan is a CT scan that can image the lungs within the time it takes for a patient to hold his/her breath once. The newest helical or spiral scans are even more sensitive than regular CT scans.

Sputum

A phlegm-like substance brought up from the lungs that contains mucus, cells, microorganisms, blood, and/or pus.

Staging

An attempt to pinpoint where the cancer is in the body and if it has spread to other parts of the body. Staging involves knowing the size of the primary tumor and determining if the lymph nodes are involved.

Standard treatment

A treatment currently in wide use and approved by the FDA that is considered effective in the treatment of a specific disease or condition.

Standards of care

Treatment standards for disease management and patient care.

Study endpoint

An outcome used to judge the effectiveness of a treatment.

Synergy

A process in which 2 drugs enhance the effect of one another so that when they are combined, they produce a higher response than would be expected based on their activity alone.

Systemic

Affecting the entire body.

Targeted therapies

Drugs that are specifically designed to interfere with the formation or functioning of cancer cells. These drugs can block specific substances involved in cancer cell growth, or they can cause cancer cells to die.

TNM

Staging of tumors according to 3 basic components: primary tumor (T), lymph node status (N), and metastases (M).

Toxicity

An adverse effect produced by a drug that is harmful to the participant's health.

Treatment trials

Refers to trials that test new treatments, new combinations of drugs, or new approaches to surgery or radiation therapy.

Tumor

An abnormal mass of tissue that results from uncontrolled cell division. Tumors perform no useful bodily function, and may be either benign (not cancerous) or malignant (cancerous).

Tumor marker

A substance sometimes found in an increased volume in the blood, other body fluids, or tissues, which may signify that a certain type of cancer is in the body. Also called a biomarker.