UNDERSTANDING SERIES

LUNG CANCER CLINICAL TRIALS

LUNG CANCER ALLIANCE

1-800-298-2436

LungCancerAlliance.org

A GUIDE FOR THE PATIENT

LUNG CANCER ALLIANCE

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THE BASICS ABOUT CLINICAL TRIALS

THE DECISION TO TAKE PART IN A CLINICAL TRIAL IS AN IMPORTANT ONE AND YOU ARE LIKELY TO HAVE QUESTIONS. WE HOPE THIS BROCHURE HELPS YOU DECIDE WHETHER A CLINICAL TRIAL IS RIGHT FOR YOU AND GUIDES DISCUSSIONS WITH YOUR FAMILY AND TREATMENT TEAM.

There are hundreds of lung cancer clinical trials going on today. By participating, you may find a treatment that works for you and also play an important role in the drug approval process. Patients who enroll in clinical trials receive high-quality cancer care and may be among the first to benefit from a new treatment that later proves to be effective.

By understanding all of your treatment options, including clinical trials, and being active in treatment decisions you may feel more in control. You may also impact future treatment options for other patients. The lung cancer treatments we have today are available because people like you participated in clinical trials.

WHAT IS A CLINICAL TRIAL?

A clinical trial is a research study to determine whether a new drug, combination of drugs, procedure or medical device is safe and effective. Sometimes clinical trials explore different ways of using treatments to make them more effective, easier to use and/or decrease side effects. Clinical trials may also be done to learn how to best use a treatment in a specific group of people.

TYPES OF CLINICAL TRIALS:

- **TREATMENT STUDIES** test new or different approaches to treatment
- **PREVENTION STUDIES** focus on preventing disease or stopping diseases from returning
- **DIAGNOSTIC STUDIES** identify new and improved tests or new procedures for diagnosing particular diseases or conditions
- **SCREENING STUDIES** test to find the best ways to detect diseases or conditions
- **QUALITY OF LIFE STUDIES** evaluate the effects of treatments on comfort and quality of life
- **POST-SURVEILLANCE STUDIES** follow the effects of an approved therapy after widespread use

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NOT ALL CLINICAL TRIALS INVOLVE DRUG TREATMENTS. FOR EXAMPLE, SOME TRIALS MAY COMPARE DIFFERENT METHODS OF SURGERY OR RADIATION.

Others may involve a new way to measure the size of a cancer tumor. Still others may explore whether one test is better than another test for detecting cancer at an earlier stage. The focus of this brochure is on treatment studies, however the information may be useful to you if you are exploring other types of trials.

PHASES OF CLINICAL TRIALS

Before a new treatment is available to the public, it usually goes through three phases of clinical trials—phase I, phase II and phase III. The new treatment continues from one phase to the next as long as it shows promising results without unacceptable side effects.

PHASE I

Phase I cancer trials test the new treatment in only a few people (less than 50) and usually only include patients whose cancer has come back or spread and standard treatments are not expected to help. In this phase, the new treatment is not expected to cure the cancer. Instead, the goals are to find out:

- whether the treatment is safe to take
- what side effects the treatment causes
- what dose can be given without causing serious side effects
- if the treatment has a negative effect on the body
- whether the treatment keeps the cancer from growing or shrinks it
- how a drug is metabolized (processed) and eliminated from the body

PHASE II

Phase II cancer trials involve more patients (usually 100-200) and explore how well the new treatment works. The goals for these studies are the same as phase I but also include learning:

- how the treatment works on particular types and stages of cancer
- more details about the treatment's side effects
- more about the best dose and how frequently the treatment should be given
- if the treatment works well enough to continue to a phase III trial

PHASE III

Phase III cancer trials involve several hundreds or thousands of patients at many different clinics and hospitals in a single country or around the world. These trials test how well the new treatment works compared to current treatment. Treatments in phase III trials have been found to be as safe as other treatments and seem to be effective during phase I and II trials. Phase III cancer trials explore:

- how long participants stay free of cancer
- the average time that participants survive with or without signs of cancer
- how well the cancer responds compared to other treatments
- whether the cancer grows more slowly with the treatment
- how the treatment affects quality of life
- more details about the treatment's side effects

Usually if a treatment is found to be safe and effective in phase III, it will be submitted to the Food and Drug Administration (FDA) for approval.

FREQUENTLY ASKED QUESTIONS ABOUT CLINICAL TRIALS

Here are questions you may have about clinical trials. If you have additional questions, please ask your healthcare team or clinical trial nurse at any time or call our Lung Cancer Clinical Trial Matching Service toll-free at **1-800-698-0931**.

Q: WHY SHOULD I CONSIDER JOINING A CLINICAL TRIAL?

Joining a clinical trial allows you to **be active in your treatment**, which may make you feel more in control. A trial **may allow you to try a new treatment before it is widely available** and to play a role in shaping future treatments and improving the lives of other patients.

Q: WHEN SHOULD I CONSIDER SEARCHING FOR CLINICAL TRIALS?

You may think that clinical trials should only be considered when no other options are available. **You should consider clinical trials each time you face a treatment decision**, whether it is as soon as you are diagnosed or after you have tried other treatments.

Q: HOW MUCH DOES IT COST TO JOIN A CLINICAL TRIAL?

Every trial is different. Some do not cover treatment related costs and not all health plans or insurance companies cover them. If there are costs associated with a particular clinical trial, **check with your health insurance company to find out what they cover before making the decision to participate.** In some studies, participants do not have to pay for treatment, medical exams or required lab tests. Travel costs and other out-of-pocket expenses related to participation may also be reimbursed.

Remember, the study team is there to help you understand any costs associated with the trial.

PLACEBOS IN CANCER CLINICAL TRIALS

While you will always receive the standard of care, you may not receive the experimental therapy. Some trials compare a group that is taking the test drug to a group that is taking **a placebo, an inactive substance or treatment that looks the same and is given in place of the treatment being tested.** The effects of the test drug are compared to the effects of the placebo. If a trial uses a placebo, it is usually combined with the standard of care. Use of a placebo in a clinical trial does not mean you will go without treatment, unless the usual course would be no treatment at all.

Q: HOW DO I JOIN A CLINICAL TRIAL?

There are many ways to learn about clinical trials including **from your doctor, the media, other patients, friends or family members.**

You can also find out about trials that you may be eligible for or learn more about a specific trial by calling our **Lung Cancer Clinical Trial Matching Service at 1-800-698-0931**. A Clinical Trial Navigator will ask you a series of questions and can send you information on the appropriate trials for you to discuss with your doctor.

Each trial has a study coordinator. To start the process, you will talk with the coordinator, who will ask about your diagnosis, past and current treatments, overall health and other questions to make sure you meet the basic requirements of the trial. You will also be able to ask questions you may have.

Q: WHAT ARE THE POTENTIAL RISKS AND BENEFITS?

Below are some potential risks and benefits that should be considered. **Remember, only you can decide if joining a clinical trial is right for you.**

BENEFITS:

- Playing a more active role in your own treatment
- Being one of the first to benefit if the new treatment is found to be helpful
- Receiving expert medical care at leading cancer centers
- Receiving frequent testing, monitoring and support from the study team
- Making a valuable contribution to lung cancer research

RISKS:

- Facing unknown side effects or risks
- Receiving a new treatment that may not work or may be less effective than the traditional approach
- Changing healthcare teams and the location of your treatment

QUESTIONS TO ASK IF YOU'RE THINKING ABOUT JOINING A CLINICAL TRIAL

- What is the purpose of the study?
- Why do researchers believe the treatment being tested may be effective?
- What kinds of tests and treatments are involved?
- How do the possible risks, side effects and benefits of the study compare with my other treatment options?
- Who will be in charge of my care?
- How long will the study last?
- How often will I have to visit the doctor's clinic/office?
- How long will the visits last?
- What will happen at these visits?
- What happens if my lung cancer gets worse?
- What other medications or drugs can I take while on this study?
- Will I have to pay for any part of the study or treatment?
- What type of follow up care is part of this study?
- What happens if I decide that I no longer want to participate in the trial?

Q: WHAT IS AN INFORMED CONSENT FORM?

Before joining a study, you will be asked to sign a document called an informed consent form. B**y signing, you agree that you understand the trial is research that you are joining of your own free will, know you have the right to ask questions and understand you can leave the trial at any time.**

Informed consent also helps to make sure you are aware of the possible risks and benefits that may be associated with the treatment being studied.

Informed consent is not a binding contract. You can change your mind and leave the study at any time.

THE INFORMED CONSENT FORM MUST INCLUDE:

- Information about the investigational treatment and why it is expected to work
- What you can expect as a trial participant, such as number of clinic visits and schedule of treatments and tests
- Possible benefits, risks and discomfort you may experience
- Other available treatments you might want to consider
- Information on any costs associated with the study

Your study team should give you time to carefully review the consent and will go through it with you to make sure you fully understand it before you sign.

HELPFUL TIP

To prepare for meeting with the study team, you may want to **ask a friend or relative to join you** for support and to help you remember what is said. Don't forget to bring along your list of questions and pen and paper to write down the answers.

Q: WHAT HAPPENS AFTER I SIGN THE INFORMED CONSENT FORM?

Once you have signed the informed consent form, **you will follow instructions of the doctor leading the study.** Even if you have met the basic requirements of the study, y**ou will likely have to go through further tests to make sure that you are able to participate.** Each trial has a different schedule that sets out how many study visits are involved and over what period of time. It also details what will happen at each visit and between visits. You will be required to take the assigned treatment as outlined in the study design, to have certain tests and check-ups and to inform your study doctor of any side effects that you notice. You may also be asked to record any side effects and/or your daily activities.

The study team is there to help. If you have questions or concerns, you should feel free to ask them.

Q: HOW IS THE SAFETY OF CLINICAL TRIALS MONITORED?

The Food and Drug Administration (FDA) has strict rules to protect patients in clinical trials and to make sure they are cared for properly and treated with respect. Before a clinical trial can begin, the study plan (also called a protocol) must be approved by an Institutional Review Board (IRB). An IRB is a committee of doctors, statisticians, patient advocates and others that reviews the study plan to make sure it is set up properly and that participants are not likely to be harmed. **Once the study has started, a Data Safety and Review Panel regularly monitors it and will stop the study if it appears to cause more harm than good.**

Q: CAN I DROP OUT OF A CLINICAL TRIAL?

Yes, taking part in any clinical trial is completely voluntary. Informed consent is not a binding contract and you may leave the study at any time without giving a reason.

There are also other times you could leave a clinical trial before the planned completion date. If the treatment is not working for you, the team may suggest you leave the trial to continue standard treatment. And, sometimes trials end early. This can happen when the new treatment does not seem to be working well enough to continue the trial. Trials can also end early when the new treatment is working so well that it should be offered to all participants.

If you leave a trial for any reason, you will be offered the best possible treatment option available for your situation.

THE DECISION IS YOURS

As with any important decision, you should take time to think through the benefits and risks of taking part in a clinical trial. You should never feel pressured into entering a study. It is your choice. To make sure you are fully informed you can:

- **Make sure all of your questions about the trial are answered**
- **Ask your health care team if they can connect you with someone who is currently enrolled or has been in a clinical trial who can share their experience**
- **Discuss the trial with friends and family**
- **Contact our Lung Cancer Clinical Trial Matching Service at 1-800-698-0931 to speak with a Clinical Trial Navigator.**

By knowing the facts, you can decide whether or not a clinical trial is right for you. Joining a clinical trial may help you and could also find new treatments for others diagnosed with lung cancer.

WHERE CAN I GO FOR MORE INFORMATION?

For more information about lung cancer and current treatments, to discuss support options or for referral to other resources, please contact us:

HELPLINE | 1-800-298-2436

CLINICAL TRIAL
MATCHING SERVICE | 1-800-698-0931

WEBSITE | lungcanceralliance.org

E-MAIL | support@lungcanceralliance.org

MAIL | 1700 K Street NW, Suite 660, Washington, DC 20006

WHAT WE DO

- Offer personalized support, information and referral services at no cost through a team of trained, dedicated staff members to help patients, their loved ones and those at risk.

- Advocate for increased lung cancer research funding and equitable access, coverage and reimbursement for screening, treatment, diagnostics and testing.

- Conduct nationwide education campaigns about the disease, risk and early detection.

LUNG CANCER ALLIANCE

SAVING LIVES AND ADVANCING RESEARCH BY EMPOWERING THOSE LIVING WITH AND AT RISK FOR LUNG CANCER

OUR COMMITMENT TO YOU

We are dedicated to helping you understand clinical trials and why they are important. To make it as easy as possible to join an appropriate trial, we partnered with Emerging-Med in 2005 to create the first ever lung cancer-specific clinical trial matching service.

LUNG CANCER ALLIANCE

This brochure is made possible by our sponsors and people like you. We are a 501 (c) (3) non-profit organization. All donations are tax-deductible to the full extent permitted by law.

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