Understanding Clinical Trials for Lung Cancer

LUNG CANCER RESEARCH FOUNDATION
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What is a clinical trial?

Clinical trials are research studies that test new and promising treatments directly with patients. **In fact, today's gold standard treatment options were once studies in a clinical trial.** These studies may also test new ways to prevent or diagnose diseases such as lung cancer. Clinical trials may include new ways to take medicine, radiation therapy, or surgery. Clinical trial teams make sure you receive the safest and best care.

If you are recently diagnosed, you do not need to wait to consider a clinical trial for your treatment. No matter where you are in your treatment process, a clinical trial could be a good option for you.

FYI: You can stop at any time you choose, for any reason, and return to the gold standard treatment.

> **Our philosophy is simple: scientific discoveries lead to improved outcomes for patients. LCRF strongly supports the role that research and clinical trials play in advancing lung cancer treatments."**
>
> - Brendon M. Stiles, MD
> Chief, Division of Thoracic Surgery & Surgical Oncology, Montefiore-Einstein Medical Center; Vice Chair, LCRF Board of Directors & LCRF Scientific Advisory Board

Trusting clinical trials: protections are in place

For some people, the thought of participating in a research study is uncomfortable. They may have trust issues about the treatment they will receive. They may worry about the ways they will feel included in the process.

Over time, researchers have learned many valuable lessons about the importance of trust. Decades ago, trial staff did not share the information participants needed to know about issues such as safety or goals. This was a serious issue for diverse communities and influences recruitment efforts to this day. As a result, the rules were changed to make sure everyone is given information but also ensure the information was understood.

Today, researchers design clinical trials to make certain that:

- Participants receive all the information they need through a process called Informed Consent before they agree to join the research effort.
- Trial staff strive to enhance diversity and remove barriers about issues including participation and access such as help with transportation or support services.
- Community representation is a priority. For the research to be most helpful, trials must include the patients who are more vulnerable to the health condition.

Why should I consider a clinical trial?

Benefits:

People choose to participate in clinical trials for a variety of reasons. The top motivators include:

- **Potential Access to Tomorrow's Treatments**
  Participants may have access to promising new treatments
- **Increase in Treatment Options**
  Participation may help expand your possibilities
- **Additional Healthcare Oversight & Guidance**
  Participants find the guidance of additional teams and support to be helpful

Risks:

People choose not to participate in clinical trials if they have concerns about the risks. All benefits and risks will be communicated to you so you can make the best decision for yourself. Risks may include:

- Unknown side effects
- There is no guarantee the new treatment may work for you
- Important to know that Insurers may not cover all costs of the clinical trial

Your participation helps others. Even if the clinical trial does not meet its goals, you will have played a role in important cancer research.

Lung cancer treatment trials

Although there are multiple types of clinical trials, this resource is about treatment trials. Lung cancer trials study how new treatments can be developed and how existing treatments can be improved. Clinical trials can help inform the lung cancer patient community about new:

- Medications
- Advances in types of surgery or radiation therapy
- New combinations of treatments, such as oral pills combined with infusion sessions.

> **"The treatment I'm on today would not exist without clinical trials. When I participate in a trial, I'm paying it forward for the patients who will come after me. And the patients in trials for newer medications help me by receiving the latest treatment that I'll need someday to keep on living with lung cancer."**
>
> - Patient, Stage 4 lung cancer on the benefits of participating in a clinical trial

NO MATTER WHAT, YOU'LL GET TREATMENT

Clinical trials may include new ways to take medicine, radiation therapy, or surgery. Clinical Trial teams make sure you receive the safest and best care. You will either receive the current "gold standard" of treatment or the new medication.

In non-cancer trials, patients might receive a "sugar pill" called a placebo, which would mean they are not receiving treatment. If a placebo is ever used in a cancer clinical trial, all patients will know ahead of time.

Phases of trials

Have you ever wondered how we all know to "take 2 pills and call the doc in the morning"? It's because somewhere along the way, researchers studied just how much of medication a person should take at a time. Clinical trials are designed to make sure:

- the treatment is safe and offered at a healthy dose, the most effective way
- the treatment works
- the treatment is better than what is currently out there on the market

Patient volunteers play key roles in helping researchers understand the role treatments play in the body, not just a lab. Depending on which phase you are placed into, your trial participation could vary. For example, you may have more appointments or fill out more surveys than someone else in the same trial.

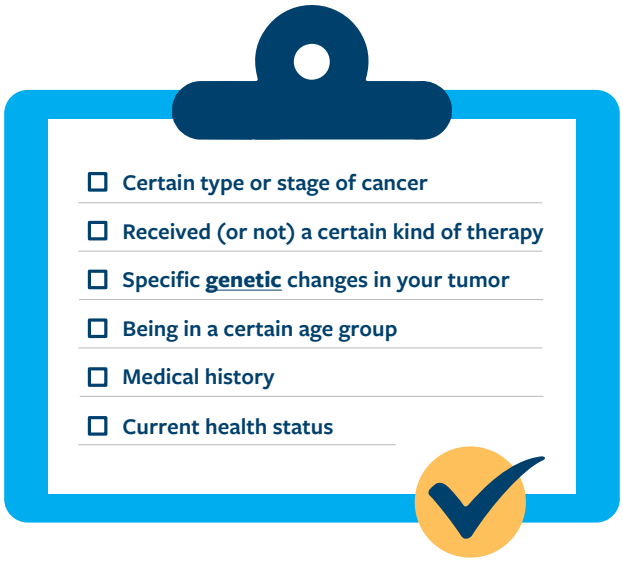
Eligibility & finding a trial

Every clinical trial has a study plan that is also known as it's protocol. Every protocol describes how the trial will work and the requirements that patients must meet to be eligible to participate. These requirements are called **eligibility criteria**.

You can search for clinical trials and their eligibility criteria at the following websites:

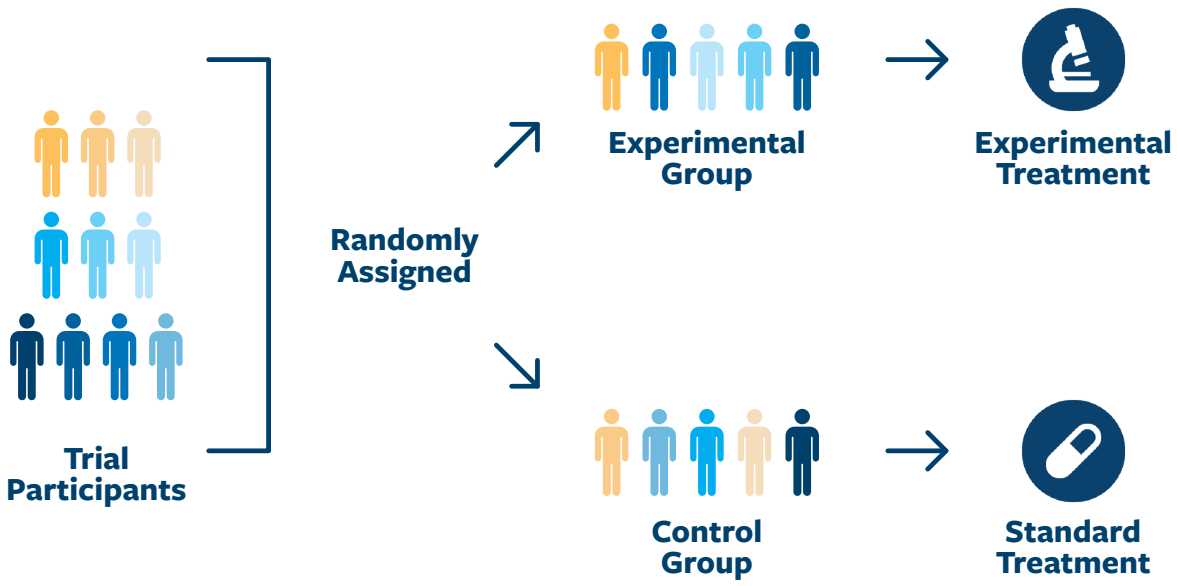
www.clinicaltrials.gov

https://www.nih.gov/health-information/nih-clinical-research-trials-you/finding-clinicaltrial



Randomization

You may hear the term “randomization” in regard to your clinical trial. This term refers to the placement process. There is a new treatment group and a current treatment group, which are also known as “arms”. The process gets its name from the chance or randomness in which group you join. Issues like age, gender or medical history will not be part of the selection process. A computer will “toss a coin” to determine group placement.



Blinding

When you read about clinical trials, you may see trials referred to as blind, or in some cases, doubleblind.

- A blinded clinical trial is when the participant does not know if they are in the gold standard group (arm) or the new treatment group.
- A double-blind clinical trial is one in which both the participant and the Trial team do not know the group placement.

You will find out through the Informed Consent process (outlined below) if your study is a blinded one or not.

Decentralized Clinical Trials

One of the many ways that clinical trials are evolving to meet the needs of patients is to be conducted virtually. These trials use technology and supplies to guide the patient safely through the trial and all the required communications. By meeting patients where they are, more people can get involved and help move the promising treatments to the market.

Informed consent

An essential communication tool in the clinical trials process is the informed consent form. This plan reviews every aspect of the clinical trial, so you best understand the goals, risks, benefits, and expectations as a participant.

The Informed Consent document will include:

- Research goals
- Expected participation time commitment
- Description of the trial medical procedures
- Potential risks or discomforts
- Potential benefits from participation
- Disclosure of appropriate alternative procedures or courses of treatment
- Confidentiality of records
- Compensation information if part of trial
- Contact information for all research-related questions and concerns
- A formal statement that participation is voluntary and without penalty
- Any additional costs from participation in the research such as travel and/or accommodations
- Expected total number of participants involved in the trial
- Funding support information

REMEMBER: INFORMED CONSENT IS NOT A CONTRACT. YOU CAN DISCONTINUE THE STUDY AT ANY TIME.

Employer communications

- If you choose to share your diagnosis with your employer, then it's likely you have shared how your treatment schedule may or may not impact work. With clinical trials, it's no different. If you are participating in a clinical trial, that process is your treatment. Here are some tips for communicating with your employer about trial participation.
- If your trial requires more time for office visits or tests, you may want to explain to your employer it is because of your new clinical trial treatment plan. They may need to hear that the additional time commitments do not mean your health has gotten worse, but it's a different treatment requiring more follow-up with your healthcare team.
- If changes need to be made, ask your healthcare team for their recommendations on what type of work schedule is best for you and present that to your employer.
- Take notes about all conversations you have with your employer about your health and its relation to your work productivity. This will help you establish expectations and can be used to inform your healthcare team or your Human Resources office about any issues.
- Remember that there are laws in place that can protect you and provide access to certain benefits due to your cancer diagnosis. For more information about this, see https://www.eeoc.gov/laws/guidance/cancer-workplace-and-ada

Talking with family & friends

Clinical trials can be challenging to talk to loved ones about because of the complexity of the process and uncertainty of the treatment. Some people in your life may want to understand everything and others may be easily overwhelmed or anxious by any changes.

When discussing your decision to take part in a clinical trial, consider these issues to have a supportive and productive conversation:

- Set aside time. Clinical trials are complicated and require the listener's full attention and understanding. Bringing it up as a separate issue gives it the weight it deserves so questions can be asked and answered.
- Customize the conversation as much as you can for whomever you are speaking with about your plan. If clinical trials are too scientific of a subject for your loved one, focus on what they will understand such as the fact that you are taking a promising new drug before other cancer patients.
- If you are explaining risks of the trial, it's important to also highlight the benefits and why you are making this decision. Hearing that you have thought this through, and you know what you have signed on for may help them feel less anxious about the unknown.

Ask away!

Your healthcare team will be able to answer your questions about your cancer and possible treatment options. Your Clinical Trial team will be able to address all of your concerns related to trial participation. It is important to ask as many questions as you need to ask, no matter the team. Here are several suggested questions to help you get started.

Questions for your Healthcare Team

- What type of cancer do I have?
- What stage of cancer do I have?
- Where can I get a second opinion?
- Are there any biomarkers I should be tested for? Could that help me qualify for a clinical trial or for other therapies?
- What are my treatment options?
- What trials are available for the type of cancer I have?
- How will I know if the treatment is working?
- How will my medical records be shared?
- Will my family be informed of my treatment and progress?

Notes

Questions for Clinical Trials Team

- Who is my point person for all my questions throughout the trial?
- What treatments will I have as part of this trial?
- Will I know if I am getting the new treatment?
- What phase is the trial in? (e.g., Phase 1, 2, or 3?)
- What are the expected side effects of the new treatment?
- What benefit might I get from participating in this trial?
- What additional tests will I need to have, and how often will I need to have them?
- Can I stop participating in the study at any time?
- What happens if my health gets worse during the study?
- How will the study affect my everyday life?
- What costs will my health insurance cover?
- What costs will I have?
- Can I continue my treatment for other health problems?
- Who will be in charge of my care while I am in the study?
- What will be my primary physician's role?
- What happens once the study ends?

Notes

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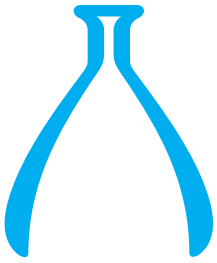
Help make future research possible: LCRF.org/getinvolved



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