

Understanding Clinical Trials

Clinical Trials Overview

A clinical trial is a research study conducted to answer specific questions about a new treatment or a new way of using an old treatment. Clinical trials may:

- Test new drugs
- Look at new ways to give a treatment
- See how lifestyle changes can help cancer patients
- Look for ways to prevent cancer from occurring, or
- Compare a new treatment with old ones to see which produces better results with fewer side effects

A new treatment must go through at least three trial phases before it becomes a standard therapy that is used in hospitals and clinics. Each phase is designed to find out certain information. The phases build on the information learned from the previous phase. Patients may be able to take part in different stages depending on their condition, their type and stage of cancer and the type of treatment, if any, they have already received.

Phase I

The first phase studies the best way to give a treatment and how much of it can be given safely. The treatment has been tested in a laboratory and with animals, but scientists need to see how it works with human patients. This phase has the most risks; it is usually only offered to a small number of people who have not been helped by standard treatment. Patients are watched very carefully through the treatment.

Phase II

Once a therapy is shown to be safe in Phase I, it is tested in Phase II. This phase looks at the effect of the treatment on the cancer and the patient.

Phase III

When the treatment gets to Phase III, it has been shown to be safe and effective. This phase tests the treatment on a large number of patients to confirm the results found in the first two phases. This phase also compares the new treatment with the standard treatment.

Participating in a Clinical Trial

Clinical trials may offer many benefits and risks. People in clinical trials are able to try new treatments that are not available to all patients and are monitored very closely. However, being part of the trial might mean that you receive the standard therapy. If you receive the new treatment, it may or may not be more effective than the standard one. The healthcare team studying the new treatment will explain all of the possible risks and benefits of a specific clinical trial to you.

Informed Consent

Informed consent is the process in which you learn about all of the expected risks and benefits of a clinical trial. After the healthcare team explains everything and you do not have any more questions, you will be asked to sign an informed consent form. This form lists, in writing, everything known about the risks and benefits of the study. After all of your questions have been answered and you decide to participate, you can sign the form and enroll.

Questions to Ask About Clinical Trials

Here are some sample questions you may want to ask in addition to knowing about the benefits and risks:

- What is the purpose of this clinical trial?
- Who is sponsoring it (National Cancer Institute, a cancer center, a pharmaceutical company)?
- How long is the treatment in the study?
- How could the study affect my daily life?
- Will the overall cost be more than if I received standard treatment?

Remember, you can leave a clinical trial at any time. If you leave, or if you decide not to take part, your doctor will discuss the other treatment options available to you.

Contact Us

For more information about *Getting the Facts* or information about the



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The Lymphoma Research Foundation offers a comprehensive slate of patient education and support programs including

- *Lymphoma Helpline & Clinical Trials Information Service*
- *Lymphoma Support Network*
- Publications and newsletters
- Informational teleconferences and webcasts
- In-person conferences
- National Chapter Network

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Use of Placebos ("Dummy" Pills) in Phase III Studies

Cancer trials testing a drug or therapy regimen rarely place patients into a placebo group in which they do not receive active treatment for their disease. Phase III trials usually select patients at random for the experimental group receiving the current study drug or the control group receiving the current standard treatment for their particular lymphoma. Many patients who are in the control group still benefit from the standard of care.

Cost Associated With Participating in a Clinical Trial

Clinical trials are very expensive undertakings for the study sponsor. However, the cost to the patient varies depending on the study, who is sponsoring the trial and what portion of the trial-related expenses the sponsor will cover. Some health insurance and managed healthcare providers will pay for the basic medical procedures associated with the trial, such as lab tests, scans and hospitalization when required, while others do not pay for experimental procedures. The fees vary depending on the study and the health plan. Medicare provides coverage for patient care associated with clinical trials. If a patient is taking part in a National Cancer Institute (NCI) trial being conducted at their campus located in Bethesda, Maryland, the NCI will pay for the study drug and the costs related to the study. A stipend to assist with travel, food and lodging expenses is also provided. Some cancer centers or hospitals provide financial assistance or discounted rates for room and board facilities and have special research units that will pay for study related costs. There are also organizations that will provide financial assistance for treatment related expenses.

Finding Out About Lymphoma Clinical Trials

There are many ways to find out about clinical trials.

- Your doctor may be able to tell you about some clinical trials.
- Comprehensive cancer centers in your area may also have information about clinical trials for your type of lymphoma.
- Contact the Patient Services Department at the Lymphoma Research Foundation (LRF) at (800) 500-9976 and request a clinical trial search.
- Contact the NCI's Clinical Studies Center at (888) 624-1937 or the Cancer Information Service at 800-4-CANCER.
- LRF's website lymphoma.org and the National Cancer Institute's web sites cancer.gov or clinicaltrials.gov are good on-line resources for user friendly, comprehensive clinical study listing and matching services for patients and professionals.