Clinical Trials

GLOBAL LUNG CANCER COALITION

How Do They Work?

Once a new drug candidate has shown to have some promise after years of testing in the laboratory, scientists begin the preparation to move testing into the human population. Clinical trials are conducted in phases. This step-by-step approach allows researchers to look at how safe the new treatment is, its effectiveness, and whether the new treatment is the same as, better than, or not as good as the current "standard of care". The phrase 'standard of care' means the treatment that is currently most commonly prescribed for a particular patient population. It is important to remember that all 'standards of care' began first as a clinical trial before being approved for use with patients.

Here are the goals of the phases of clinical trials:

Phase I: These trials determine the safety of a particular treatment: how the treatment should be given, how often it should be given and what dosage is safe. A phase I trial usually enrolls only a small number of patients, sometimes as few as a dozen, and often is conducted across many types of cancer.

Phase II: Researchers continue to test safety but also begin to evaluate how well the new treatment works. These trials usually test the treatment on one particular type of cancer.

Phase III: Compares the treatment being studied with the current standard of care to determine if it works better, the same or not as well as the standard of care.

Phase IV: After a treatment has been approved and is being marketed, the drug's maker may study it further in a phase IV trial. These trials review the side effects, risks, and benefits of a treatment over a longer period of time and in a larger number of people than in phase III clinical trials. Thousands of people are involved in a phase IV trial. Phase IV trials might also be necessary when giving drugs to a healthy population for a long period of time.

What are Clinical Trials?

Clinical trials are research studies that help evaluate new cancer treatments for both early stage and advanced lung cancer patients. Additionally, clinical trials also research ways to prevent and detect lung cancer. Some studies test brand new therapies in development. Other studies test better ways to give standard treatments in hopes of improving the treatment results and lowering the side effects.

A clinical trial may involve the testing of new:

- Approaches to surgery and radiation
- Combinations of drugs
- Drugs in development
- Improvements to standard treatments
- Prevention methods (e.g., actions that can prevent cancer
- Tests to better diagnose and understand your specific tumor
- Treatment methods (such as gene therapy)

Clinical Trials

GLOBAL LUNG CANCER COALITION

Why Should I Consider Clinical Trials?

Every time you make a treatment decision, you deserve to have information about all treatment options. Too many times patients feel rushed into treatment decisions before they have had a chance to consider clinical trial alternatives. There may be a good standard of care for you—care that the experts believe is appropriate for your specific diagnosis and treatment history. However, sometimes the current standard of care is not as effective as you and your doctor would like. Sometimes the standard of care works for awhile but then stops working. Sometimes, there is no standard of care for your situation. At these times, participation in a clinical trial may be the best option available to you.

About placebos: Placebo (a substance that does not have any medical value) is rarely used in cancer clinical trials. Experimental treatments are almost always compared against a current treatment, not a placebo. If a placebo is used in a clinical trial, you will be made aware of that by the trial site before you enter the trial. Fear of placebo should not drive you away from participating in clinical trials.

When is it Appropriate to Consider Clinical Trials?

We recommend you ask about clinical trials as soon as you are diagnosed and every time you have to make a treatment decision. You need to know about studies you may be eligible for BEFORE you begin treatment.

Clinical trials are available at all stages but only enroll patients at certain times:

- Just before a biopsy
- Just prior to the first surgery or radiation treatment (called “neo-adjuvant” studies)
- Immediately after surgery or radiation treatment (called “ adjuvant” studies)
- Before starting the first treatment for lung cancer that has spread or recurred (called “first line” studies)
- Before starting the second or third treatments for lung cancer that has spread or recurred (called “second” or “third” line studies)

What is the Current Promise of Research for Lung Cancer Patients?

Over the past several years, research on all aspects of lung cancer, including prevention, early detection, and treatment, has greatly increased. Advances consist of testing drugs that may work in other cancers as well as new techniques in surgery and radiation.

Targeted treatments, referred to sometimes as personalized medicine, have become very important in lung cancer research and treatment. Targeted treatments attack cancer in more specific ways than the usual chemotherapy and radiation regimens, by blocking the factors responsible for tumor growth. Increasingly sophisticated techniques for understanding the “blueprint” of your particular tumor allow current and future treatments to deliver the right drug to the right patient at the right time. The promise of these new treatments can only be fully realized if individuals with lung cancer participate in clinical trials. Ask your doctor if a clinical trial should be considered as you review your treatment options together.