Patient Education

CLINICAL TRIALS 101

What is a Clinical Trial?

A clinical trial is a research study involving human volunteers to evaluate new ways to prevent, diagnose, or treat diseases. Clinical trials help determine if experimental treatments are safe, effective, or better in some way than standard treatments.

Are There Different Types of Clinical Trials?

Clinical trials have four distinct steps, or "phases" that are designed to answer different questions:

Phase I: Is the treatment safe? These are usually the first studies of a new drug in people. Safety is the main concern at this point, and investigators are trying to find the best way to give a new treatment, as well as the highest and safest dose.

Phase II: Does the treatment work? After determined to be safe, the new treatment must be proven effective. These trials are typically longer and involve more people than Phase I trials.

Phase III: Is it better than what is already available? Typically, in this stage of large-scale testing, several thousand participants may be "randomized" to receive either the standard treatment or experimental treatment. If the drug is shown to be better than standard care, the drug may be submitted to the U.S. Food and Drug Administration (FDA) for approval.

Phase IV: What else do we need to know? At this stage, investigators will ask questions about the full effects of a new treatment, including such issues as cost-effectiveness, long-term effectiveness, or how a drug affects a patient's quality of life.

Why are Clinical Trials Important?

Clinical trials are essential to the advancement of medicine. By participating in a trial, you may have access to a new treatment that is better than the standard treatment. You are also helping others who may benefit from the trial's findings—both today and in the future.

Because disease affects everyone—but not in the same way—it is important to have people of all races, ages, backgrounds, and genders participate in clinical trials, so that researchers can find the best ways of preventing, diagnosing, and treating every kind of disease for every kind of person.

Should You Participate in a Clinical Trial?

Participation in a clinical trial is completely voluntary, and your health-care provider can help you weigh your options. See the **SIDEBAR** for some questions to help guide your discussion with your health-care provider. Remember, *no question about your care is unimportant.*

Before participating in a clinical trial, you must be provided with an Informed Consent document explaining the risks and potential benefits of the trial. Be sure to read over this information carefully. It is important to fully understand the purpose of the trial and what to expect.

Are Clinical Trials Safe?

Before an experimental treatment can be applied to people, it is carefully studied in the laboratory to determine its effectiveness and safety. Clinical trials are reviewed at both the national level (by the FDA) and at the local level (by an institutional review board or "IRB").

Clinical trials are conducted according to a plan or protocol, which describes the types of patients who may enter the study; outcomes that will be measured; and schedules of tests and procedures, drugs, dosages, and length of study.

Possible participants are also carefully screened – by thorough analysis of a patient's medical history, physical examinations, and possibly other tests – to ensure that they are the best possible candidates for the experimental treatment. During the trial, patients are carefully monitored to track how the treatment is affecting their condition. Since participation in a clinical trial is voluntary, a patient can stop at any time for any reason.

Where Can You Find a Clinical Trial?

There are many websites that list current clinical trials for a variety of diseases and conditions. ASH recommends the following:

- *ClinicalTrials.gov*
- *Cancer.gov/clinicaltrials*
- *CenterWatch.com*

You may be eligible for several different studies at the same time. Speak with your health-care provider about which clinical trial is right for you.

Questions to Ask Your Health-Care Provider

- What is the purpose of the trial?
- Who can participate in this clinical trial?
- What type of tests or procedures will be done (i.e., biopsies or blood draws)?
- Do I have to pay for any of the treatments or tests?
- Will I be able to see my own doctor? Who will monitor my care and safety?
- How much time is involved in participating? Will it fit with my work schedule and personal life?
- How does the treatment I would receive in this trial compare with other treatment choices?
- How will the treatment and its possible side effects affect my daily life?
- Who can I speak with about questions I have during and after the trial?
- How will my health information be kept private?

Sources

- American Cancer Society. "Clinical Trials: What You Need to Know." *www.cancer.org/treatment/treatmentsandsideeffects/clinicaltrials/whatyouneedtoknowaboutclinicaltrials/index.htm*
- American Society of Hematology. "Clinical Trials." *www.hematology.org/Patients/Trials.aspx*
- National Heart, Lung, and Blood Institute. "What Are Clinical Trials?" *www.nhlbi.nih.gov/studies/clinicaltrials*

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