

About Clinical Trials

What is a clinical trial?

A clinical trial is a highly-organized method to look at new ways to prevent, detect, or treat disease and to advance medicine. The purpose of a clinical trial is to determine if a new test, drug, or treatment is safe and works, and it involves participation from people like you to help answer these important questions. Treatments could involve a new, or a combination of, drugs or imaging agents, new surgical procedures or devices, or new ways to use existing treatments and imaging agents. Clinical trials can also look at other aspects of care, such as improving the quality of life for people with chronic illnesses. The idea for a clinical research trial—also known as a clinical study—often starts in the laboratory and in animal studies before moving into human trials. Clinical trials follow a specific series of steps, or “phases,” established by the US Food and Drug Administration (FDA). Based on the result of the information collected during a study phase, the FDA may decide to stop the study or approve it to move forward through the clinical research process.

Phases of Clinical Trials

Each phase has a different purpose and answers different questions:

- **Phase I:** Researchers test an experimental drug or treatment in a small group of people (20–80) for the first time. The purpose is to evaluate its safety and identify any side effects.
- **Phase II:** The experimental drug or treatment is administered to a larger group of people (100–300) to determine its effectiveness and to further evaluate its safety.
- **Phase III:** The experimental drug or treatment is administered to large groups of people (1,000–3,000) to confirm its effectiveness, monitor side effects, compare it with standard treatments, and collect information that will allow the experimental drug or treatment to be used safely.
- **Phase IV:** After a drug is approved by the FDA and made available to the public, researchers track its safety, seeking more information about a drug or treatment’s risks, benefits, and optimal use.

Before a study begins, it is reviewed scientifically and ethically to ensure that the benefits and risks are appropriate to the treatment, drug or device being studied. Many “checks and balances” are in place to monitor the trial, and researchers provide reports on all side effects noted during the study. Clinical trials can be done at a single institution or at multiple facilities – even involving sites around the world.

People agree to participate in clinical trials for a variety of reasons. Healthy volunteers often join a study to help others and hopefully contribute to advances in medicine. Study participants – those with an illness or disease – also wish to help others, but also may be interested in possibly receiving the newest treatment available as well as the additional care and attention that is associated with a clinical trial. Some people may be hesitant to join a clinical trial because they do not want to be a ‘guinea pig’ or receive a placebo, or sugar pill. FDA requires that a new treatment be tested against the currently accepted treatment. In some cases where there is no effective treatment known, some participants may receive a placebo for a short period. Following this double-blind phase, study



participants are given access to the study treatment. Participation in a clinical study is usually the only way to receive new medicine. At no time will seriously ill patients go without treatment. Trials provide hope for many people and an opportunity to help researchers find better treatments for others in the future.

About SNMMI

The Society of Nuclear Medicine (SNMMI) is an international and medical organization dedicated to raising public awareness about nuclear and molecular imaging and therapy and how they can help provide patients with the best health care possible. With more than 18,000 members, SNMMI has been a leader in unifying and optimizing nuclear medicine and molecular imaging since 1954.

The material presented in this pamphlet is for information only and is not intended as a substitute for discussions between you and your physician. Be sure to consult with your physician or the nuclear medicine department where the treatment will be performed if you want more information about this or other nuclear medicine procedures.

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