



Health Awareness

Clinical Trials—What Are They?

(NAPSA)—Though many people read about clinical trials, not all know exactly what they are or who participates in them.

Clinical trials are actually research studies to answer specific questions about new therapies or new ways of using known treatments. Clinical trials are used to make sure new medicines or treatments are both safe and effective. Carefully conducted clinical trials are the fastest and safest way to find treatments that work in people. Today, they take place in a variety of locations such as hospitals, universities, doctors' offices or community clinics.

A Brief History

Clinical trials go back further than many people realize. Probably the first actual clinical trial was conducted in 1747 by James Lind on board the British ship *Salisbury*. Lind took 12 patients, separated them into pairs of two and tried different remedies on each pair to try and find a remedy for scurvy. It was here that he determined that fresh oranges and lemons were the effective treatment.

Before joining a clinical trial, a participant must qualify for the study and meet certain criteria, such as age, gender, the type and stage of a disease and previous treatment history. Some research studies seek participants with illnesses or conditions to be studied in the clinical trial, while others need healthy participants. The criteria help ensure that researchers will be able to answer the questions they plan to study.

Clinical trials that are well designed and well executed are the best treatment approach for patients to play an active role in their own health care and gain access to new research treatments before they are widely available.

There are risks to clinical trials. Federal law insists that, before any medicine is given to humans, its safety is first tested in the laboratory and in animals. But sometimes, serious or even life-threatening side effects to treatment are seen. And sometimes, the new medicine may prove ineffective for the participant.

Many trials use a placebo,



Clinical trials are the bedrock of medical progress. Patients joining a clinical trial have a chance to receive tomorrow's best medicines.

which is an inactive pill, liquid or powder that has no treatment value. In clinical trials experimental treatments are often compared with placebos to assess the treatment's effectiveness. In some studies, the participants in the control group will receive a placebo instead of an active drug or treatment. If a medical condition is life-threatening, however, patients are not given placebo if a remedy already exists.

In the U.S., clinical trials are regulated by the Food and Drug Administration. Doctors and researchers running a clinical trial develop a written plan detailing exactly how the trial will be conducted. This plan, called a protocol, explains how the trial will be run, what information will be gathered and what researchers hope to learn. Each plan has to be approved before the trial begins.

For the most part, the study drugs used in clinical trials are provided at no cost to the study participants. In addition, Medicare now covers all routine patient care associated with clinical trials. Volunteers also often receive free medical check-ups during the trials.

Patients can learn about clinical trials from many sources, ranging from their doctor to the Internet. To learn more about clinical trials visit www.clinicaltrials.gov. To find out some of the drugs developed through trials, visit www.pfizer.com.