

# Frequently Asked Questions Concerning Clinical Trials

## 1. WHAT ARE CLINICAL TRIALS?

Clinical trials are studies performed to gather information about specific diseases or to test drugs, medical devices, or diagnostic tools. The Food and Drug Administration (FDA) requires clinical trials to be performed to prove the safety and effectiveness of a product before it can be prescribed. The information that follows primarily addresses drug trials, but much of the information applies to other types of studies.

## 2. WHY SHOULD I VOLUNTEER FOR A CLINICAL TRIAL?

Clinical trials allow patients to try new therapies before they are available to the general public. Although these treatments have great potential for advancing medical science, it must be emphasized that the purpose of these trials is to establish whether the therapy in development is both safe and effective. During the trial, patients generally receive the treatments free of charge, and some trials will even provide stipends for your time, travel, or other related expenses.

## 3. ARE THERE RISKS INVOLVED WITH CLINICAL TRIALS?

There may be risks, both known and unknown, when taking experimental therapies. Side effects to treatments can be serious or unpleasant. Also, a treatment intended to improve a condition may deliver no beneficial effects at all.

## 4. HOW DOES A CLINICAL TRIAL WORK?

Extensive laboratory and animal tests are performed before clinical tests can ever be carried out on human subjects. Once the preclinical work is complete and safety in animals established, studies in human subjects advance through 4 trial phases as regulated by the FDA:

**PHASE 1:** Evaluating safety and establishing the proper dose are the main objectives of this phase in which 20-100 subjects may participate. Sometimes these studies are performed overnight in hospitals.

**PHASE 2:** Although evaluating safety remains a priority, phase 2 studies determine whether the experimental therapy is effective. These studies are typically performed in 100-400 subjects.

**PHASE 3:** The advantages of the treatment in development as compared to existing treatments are determined in up to 3,000 volunteers. Phase 3 testing must be completed in order for the FDA to approve the treatment.

**PHASE 4:** After the drug has been approved, information on long-term side effects and effectiveness is obtained in phase 4, or “post-marketing,” studies.

## 5. WHAT SHOULD I EXPECT TO OCCUR DURING A LUPUS CLINICAL TRIAL?

**INFORMED CONSENT:** The very first activity when one is considering participation in a clinical trial is to read and discuss information about the study, experimental treatment, and methods used during the study. An informed consent form outlines all these important facts. You should have ample opportunity to read this form and ask questions. Once you fully understand the terms of the trial, you will be asked to sign the informed consent form.

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**CLINICAL VISITS:** Regularly visiting the testing site throughout the study for monitoring medical history and questionnaires: answering questions about medications you are taking, problems you have had, or other medical issues, and about the health history of family members.

**PHYSICAL EXAM:** Conducted initially and during the study to evaluate your medical state.

**SAMPLES AND LABORATORY TESTS:** Collecting of blood, urine, and possibly stool samples for testing.

**TELEPHONE UPDATES:** Receiving phone calls from medical personnel associated with the trial to check your status.

#### **6. WHO CAN PARTICIPATE IN A CLINICAL TRIAL?**

Inclusion and exclusion criteria determine who is or who is not eligible to participate in each trial. Inclusion criteria are characteristics you must have to qualify to participate in the trial and exclusion criteria are characteristics you cannot have if you want to be included in a trial. These criteria are determined before a trial begins and are not generally determined on a case-by-case basis.

#### **7. AM I ALLOWED TO QUIT A TRIAL BEFORE I HAVE COMPLETED ALL STEPS?**

You are entitled to withdraw from a study at any point without jeopardizing your future medical care. However, since enormous resources are required to perform studies, a potential participant must put a lot of thought into whether he or she wants to make the commitment.

#### **8. HOW WILL TRIAL RESEARCHERS PROTECT MY CONFIDENTIALITY?**

Investigators will never use your name in any published documents nor can they give out information that would identify you to outside sources. Although the FDA and other agencies can access your medical records for inspection, your medical information cannot be used for any other purpose.

#### **9. WHAT IS A CONTROL GROUP?**

A control group is a group of research subjects given a placebo (an inactive treatment) instead of the experimental treatment. The purpose of the control group is to better assess the good and bad effects of the experimental treatment.

#### **10. HOW DO I FIND A CLINICAL TRIAL?**

There are several ways to learn about participation possibilities in clinical trials:

**ASK YOUR DOCTOR ABOUT STUDIES**

**CALL THE MAJOR TEACHING HOSPITALS IN YOUR AREA**

**CALL YOUR LOCAL LUPUS ORGANIZATION**

**TAKE ADVANTAGE OF CLINICAL TRIAL LISTING SERVICES ON THE INTERNET**

*[www.clinicaltrials.gov](http://www.clinicaltrials.gov)  
[www.centerwatch.com](http://www.centerwatch.com)*

#### **FOR MORE INFORMATION ABOUT LUPUS RESEARCH CONTACT:**



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