

Clinical Trials and Lupus: Frequently Asked Questions

What is a Clinical Trial?

Clinical trials are studies that research medications, vaccines, devices or procedures to determine if they are safe and work in people who have diseases such as lupus. These studies may show which medical approaches work best for certain groups of people. People who participate in clinical trials are always volunteers.

Who Can Participate in a Clinical Trial?

All clinical trials have guidelines about who can participate. Researchers use inclusion/exclusion criteria to determine if someone is eligible to enroll in a clinical trial. The factors that allow someone to participate in a clinical trial are called "inclusion criteria" and those that disallow someone from participating are called "exclusion criteria".

These criteria are based on such factors as age, gender, the type and stage of a disease, previous treatment history, and other medical conditions. Before joining a clinical trial, a participant must qualify for the study. Some research studies seek participants with illnesses or conditions to be studied in the clinical trial, while others need healthy participants. It is important to note that inclusion and exclusion criteria are not used to reject people personally. Instead the criteria are used to identify participants and help ensure that researchers will be able to answer the questions they plan to study.

Are There Different Types of Clinical Trials?

Yes, types of clinical trials include:

- ▣ **Screening trials:** These trials test the best ways to detect certain diseases or health conditions.
- ▣ **Diagnostic trials:** These trials attempt to find better tests or procedures for diagnosing a disease or condition.
- ▣ **Prevention trials:** These trials look for better ways to prevent disease, lessen its severity, or avoid the complications associated with a disease.
- ▣ **Treatment trials:** These trials test new therapies, devices, combinations of drugs, or approaches to treatment.
- ▣ **Quality-of-life trials:** These trials evaluate ways to improve comfort and quality of life for people with chronic illness.

What Happens During a Clinical Trial?

The clinical trial process depends on the kind of trial being conducted. Clinical trials also have a research team that is led by a research/study coordinator and may include doctors, nurses, social workers and other healthcare professionals. They check the health of the participant at the beginning of the trial, give specific instructions for participating in the trial, monitor the participant carefully during the trial, and stay in touch after the trial is completed. Some clinical trials involve more tests and doctor visits than the participant would normally have for an illness or condition. For all types of trials, the participant works with a research team. The clinical trial can only be successful if the protocol is carefully followed and there is frequent contact with the research staff.

What Are the Benefits of Participating in a Clinical Trial?

Clinical trials allow participants to:

- ▣ Play an active role in their own health care.
- ▣ Gain access to new research treatments before they are widely available.
- ▣ Obtain expert medical care during the trial.
- ▣ Receive compensation, in some instances, for their participation.
- ▣ Help others by contributing to medical research.

What Are the Risks of Participating in a Clinical Trial?

There are potential risks to clinical trials.

- ▣ There may be unpleasant, serious or even life-threatening side effects to experimental treatment.
- ▣ The experimental treatment may not be effective for the participant.

- ▣ The protocol may require more time and attention than would a non-protocol treatment, including trips to the study site, more treatments, hospital stays or complex dosage requirements.

How is the Safety of the Participant Protected?

The ethical and legal codes that govern medical practice also apply to clinical trials. In addition, most clinical research is federally regulated with built-in safeguards to protect the participants. The trial follows a carefully designed protocol, a study plan which details what researchers will do in the study. As a clinical trial progresses, researchers report the results of the trial at scientific meetings, to medical journals, and to various government agencies. Individual participants' names will remain private and will not be mentioned in these reports.

What is Informed Consent?

Informed consent is the process of learning the key facts about a clinical trial before deciding whether or not to participate. It is also a continuing process throughout the study to provide information for participants. To help someone decide whether or not to participate, the doctors and nurses involved in the trial explain the details of the study. If the participant's native language is not English, translation assistance can be provided. Then the research team provides an informed consent document that includes details about the study, such as its purpose, duration, required procedures, and key contacts. Risks and potential

benefits are explained in the informed consent document. The participant then decides whether or not to sign the document. Informed consent is not a contract, and the participant may withdraw from the trial at any time.

What Should I Consider Before Agreeing to Participate in a Clinical Trial?

You should know as much as possible about the clinical trial and feel comfortable asking the members of the research team questions about it, the care expected while in a trial, and the cost, if any, of participating in the trial.

The decision to participate in a clinical trial should not be taken lightly. If you would like to participate, you should have a clear understanding of the nature and aims of the study and your role in it. Ask the research team questions about anything that is unclear.

Can I Leave a Clinical Trial After it Has Begun?

Yes. You can leave a clinical trial at any time. When withdrawing from the trial, you must let the research team know about it and your reasons for leaving the study.

Where Can I Find Out About Upcoming Clinical Trials?

For more information about clinical trials in your area, visit the National Resource Center on Lupus: Resources.Lupus.org/Entry/Search-For-Clinical-Trials

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