



Clinical Trials: FACT SHEET

People Helping to Shape Science Through Clinical Trials

Lupus research has been greatly advanced by the pioneering studies of brilliant scientists – *and* the caring people who participate in clinical trials. In these studies, scientists and laypeople work together to find safer, more effective methods to diagnose, prevent, treat, and ultimately cure diseases.

Those thinking about joining clinical trials often face a myriad of concerns – from basic questions, to those of a more complex nature: *“What are clinical trials?” ... “How do they work?” ... “Are they safe?”... “Where can I obtain the information I need to make an informed decision?”*

While the Alliance for Lupus Research (ALR) does not monitor, substantiate, or endorse clinical trials, we recommend that anyone interested in joining a lupus trial should speak with their doctor first. The purpose of this publication is to help answer some of the most frequently asked questions about clinical trials.

What are clinical trials ... and why are they so important?

Clinical trials are generally considered to be health-related research studies in human beings and one of the last steps in the development of a new drug or treatment for diseases like lupus.

These studies are done to find out if the drug, therapy, procedure, or medical device is safe and effective for people to use – which must be determined *before* they can be made available to the public. This is why patient participation is so important.

Recently, research has brought to light many promising avenues in the treatment of lupus – and a number of them are in clinical trial phases today. The people who participate in them are helping researchers develop better treatments and ultimately even find a cure for lupus. Clinical trials are usually orchestrated and sponsored by a government organization or a pharmaceutical or biotechnology company.

From the development of new techniques to better diagnose the disease ... to the creation of new therapies ... to the lessening of harsh side effects – clinical trials are addressing lupus on many fronts. Go to www.lupusresearch.org for more information about lupus and the ALR.

How do clinical trials work?

Because patient safety is a paramount concern, drug approval can cost hundreds of millions of dollars and take decades to complete. The process is complex and is conducted in the following four phases:

- **Phase I** determines safety and dosage.
- **Phase II** evaluates effectiveness and safety levels.
- **Phase III** involves many more patients and volunteers, allowing scientists to determine effectiveness for the general population.
- **Phase IV** collects further information after FDA approval.

If you are thinking about joining a clinical trial, please see the reverse side for guidelines and sources of additional information.



Are clinical trials safe?

Every precaution is taken to make trials as safe as possible. Even before patients can become involved in a clinical trial, satisfactory data must be compiled and presented to the Food and Drug Administration (FDA) for approval. Only after the FDA deems that the therapy is safe to test in humans, can a clinical trial begin.

The researchers who conduct trials must work in accordance with strict rules set by the federal government.

But clinical trials do not come without risks:

- Treatment side effects could be mildly unpleasant to life threatening.
- The treatment may not be effective.
- The protocol (clinical trial procedures) may require more time and attention than a non-protocol treatment.

Who sponsors this work?

Clinical trials can be funded by a variety of organizations, medical institutions, a pharmaceutical or biotechnology company, or a federal agency, such as the National Institutes of Health (NIH).

Why do people volunteer for clinical trials?

People who volunteer in clinical trials have the satisfaction of knowing that they are taking an active role in their health. Participants have access to a potential new treatment that may improve their conditions. Many view their involvement as a way of helping others — today and in the future.

The ALR is the world's largest private funder of lupus research. We are proud to be a catalyst for increased attention to lupus research and will continue to aggressively pursue new therapies until effective treatments reach people with lupus.

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Choosing to join a clinical trial is one of the most important decisions an individual can make. For more information please visit us at www.lupusresearch.org or the NIH website at www.nih.gov.

Who is eligible to participate in a clinical trial?

A participant must qualify for the study and the criteria specific to the trial. Criteria is generally based on such factors as age, gender, the stage of the disease, previous treatment history, and other medical conditions.

What do I need to know before I decide to volunteer?

The following is a list of questions that may be useful in helping you decide:

What is the study trying to find out?

What "phase" is the trial testing? (See reverse for an explanation of phases.)

What kinds of tests might I have to take?

How much time is involved?

Will I be hospitalized?

What are the costs to me?

Who will pay if clinical trial funds don't cover these costs?

What are my other treatment choices?

How do they compare with the treatment being studied?

What side effects, if any, can I expect?

How long will the trial last?

If I change my mind about participating, can I leave the trial when I want?

