

# Lupus Update with Dr. Robert Katz

## What are Clinical Trials

Although there are many definitions of clinical trials, they are generally considered to be biomedical or health-related research studies in people that follow a pre-defined protocol or procedure. A clinical trial is a research study to determine the value and safety of a new medication for a specific disease.

Clinical trials are important in the development of new treatments for lupus patients. The first new lupus drug in 56 years, Benlysta, was approved by the FDA in March, 2011. The drug was approved after a long process including an international clinical trial study to determine effectiveness and safety.

There have been relatively few clinical trials for lupus to attempt to get Food and Drug Administration (FDA) approval until recently. There are several lupus specific studies in process now. (to find out go to:

<http://www.lupus.org/clinicaltrials/> or

<http://www.clinicaltrials.gov/ct/search;jsessionid=E08B6BAB985B53C138F6968D76EC17C6?term=lupus&submit=Search>)

Currently, new medications being tested in clinical trials are similar to Benlysta and include antagonizing certain white blood cells in the body called b-lymphocytes. B-lymphocytes are responsible for making antibodies, including the lupus antibody.

Clinical trials happen in 3 stages. Stages 1 and 2 determine the safety, effectiveness and dosage of the drug or treatment. Stage 3 is designed to gain approval from the FDA by testing the drug or treatment on human subjects. Stage 3 clinical trials require large studies with many participants.

Most of the stage 3 clinical trials have a placebo – meaning some study participants will receive the drug being tested and some will receive a pill with no drug. Some participants who are on placebo initially will get access to the drug

eventually.

Stage 3 clinical trials also have set criteria for individuals looking to participate. The criteria is generally strict so not everyone will be eligible to participate in every study.

Benefits of clinical trials for participants include:

Access to new potentially effective treatments, such as monoclonal antibodies

Care and testing by health care professionals throughout the study at no cost to the participant

A chance to help others who have lupus if the medication is approved.

Disadvantages to participating in a clinical trial include:

1. participant could get placebo treatment

2. if the treatment is successful and the study ends, the drug may not be available to the participant until after the FDA has approved the drug.

Prior to beginning a clinical trial, you will meet with a study coordinator, nurse or doctor who will explain the study to you in detail. You will be allowed to ask questions before deciding to participate. Sometimes, studies offer a modest stipend for travel and/or participation. If you decide to participate in a clinical trial you can choose to drop out at any time during the study.

For more information on clinical trials, go to:

CISCRP, an organization dedicated to educating the public about clinical trials.

<http://www.ciscrp.org/>

The federal government's clinical trials website:

<http://clinicaltrials.gov>