



PARTICIPATING IN A CLINICAL TRIAL

WHAT IS AN AIDS CLINICAL TRIAL?

Before new drugs can be sold, they must be proved to be safe and effective. The Food and Drug Administration (FDA) approves new drugs and other treatments based on the results of laboratory tests, animal tests, and tests in humans (clinical trials). Some medications lower viral load (see fact sheet 125.). Others treat opportunistic infections (see fact sheet 500) or raise T-cell counts (see fact sheet 124.) Clinical trials may also test vaccines to treat or prevent HIV infection.

New treatments are tested in humans only if there were good results from laboratory tests and animal studies. In the first clinical trials, the treatment is tested for safety in a small group of people. Later trials with many more participants test how well the treatment works. InfoNet Fact Sheet 105, How HIV Drugs Get Approved, has more information on the phases of clinical trials.

A clinical trial is a carefully planned medical experiment. The guidelines for a clinical trial are called a protocol. The protocol is a document that describes exactly how the trial will be carried out.

WHO CAN PARTICIPATE IN A CLINICAL TRIAL?

The protocol explains the rules for participation in a clinical trial. Each trial is different. For example, some trials require certain viral loads or CD4 cell counts.

You normally cannot participate in a clinical trial if you have any opportunistic infections, or are using any treatments that might make it difficult to measure how well the test treatment is working. You also cannot participate if the study treatment might harm you. For example, women sometimes cannot participate in trials during the first three months of pregnancy, because of the risk of birth defects for their newborn child.

Trials are carried out at different hospitals and clinics throughout the world. Some hospitals participate in many clinical trials. Others may not offer any. Some trials will

reimburse your travel costs to a study center.

WHAT ARE THE BENEFITS OF PARTICIPATING?

- You could get a new treatment before it is available by prescription.
- Your health will be watched very carefully.
- You might get some or all of your medications paid for. You might also get some lab tests or other care for free.
- You will be helping others by contributing information about new treatments.

WHAT ARE THE RISKS?

- In trials, new treatments are compared to the best available medication or to a dummy medication (a "placebo"). **You might not get the new treatment.** Patients and health care providers in these trials are not told who is getting the new treatment.
- You might have to stop taking other medications during the trial.
- Study treatments might not work.
- Study treatments might have serious side effects.
- Participating in a study might take a lot of time. It could require special record-keeping or many trips to the study location.

HOW ARE PARTICIPANTS PROTECTED?

There are strict laws on research using human participants. The main tool to protect you is called "Informed Consent." You will be given a full, written description of the clinical trial to read and sign before you agree to participate. Take your time to review the Informed Consent before you sign it. If you need an interpreter to help you understand it, ask for one. If you have questions, be sure you get the answers before you sign.

There are also local and national boards that review and monitor each clinical trial before it starts and while it is in progress. Trials can be stopped early if they are harming participants.

You can decide to drop out of a clinical trial **at any time, for any reason.**

SHOULD I PARTICIPATE?

You and your health care provider should discuss the possible benefits and risks of taking part in a clinical trial. You may want to bring a friend with you to any meeting or presentation about a clinical trial. Here are some of the questions you should consider:

- What is the purpose of the study?
- How long will it last?
- Where is it being conducted?
- How will I take the medication (pills, shots, intravenous infusion, other)?
- What else do I have to do (records to keep, office visits, etc.)?
- What will I have to pay for?
- Can I be reimbursed for travel expenses?
- Is childcare available?
- Will I be able to stay on the study treatment after the trial is over? Who will pay for it?
- What was learned in previous studies of this treatment?
- Will I have to stop any drugs or other treatments I am now using?
- Will taking part in this study exclude me from other clinical trials?

TO FIND OUT MORE ABOUT CLINICAL TRIALS:

For information about participating in clinical trials or trials availability throughout the US, call the **AIDS info Service** at 1-800-448-0440 or visit their Internet web site at <http://aidsinfo.nih.gov>

The FDA website has information on the drug development process at http://www.fda.gov/cder/handbook/dev_rev.htm

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