AIDSinfo

A Service of the U.S. Department of Health and Human Services

# What Is an HIV/AIDS Clinical Trial?

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HIV/AIDS clinical trials are research studies in which new therapies and prevention strategies for HIV infection and AIDS are tested in humans. These studies are conducted by physicians and other health care professionals and can help determine the usefulness of experimental drugs and vaccines in treating or preventing HIV infection. Carefully conducted clinical trials are the fastest and safest way to help find treatments and prevention strategies that work.

New therapies are tested in humans only after laboratory and animal studies show promising results. In Phase I clinical trials, the experimental therapies are given to small numbers of people to help determine safe doses. Larger groups of patients may then receive the therapies in Phase II trials to help measure side effects and preliminary effectiveness. The treatments may then be used in even larger Phase III studies to compare the new treatment to ones already in use or to help estimate other effects of the drug.

## What is a clinical trial protocol?

A clinical trial protocol is a detailed plan of how the trial will be conducted. Potential clinical trial participants learn details about the clinical trial protocol in a process called *informed consent.*

Informed consent is the process of learning key facts about a clinical trial before deciding whether or not to participate. To help someone decide whether or not to participate, study staff explain the details of the trial. 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 also explained in the document. The participant then decides whether or not to sign the document. Informed consent is an ongoing process and the participant may withdraw from the trial at any time.

## Benefits of participating in an HIV/AIDS clinical trial:

- Participants may gain access to new treatments not yet available to the public.
- Participants may receive expert medical care at leading health care facilities.
- Participants have a chance to help others by contributing to medical research.
- Experimental drugs are often provided free of charge.

## Risks of participating in an HIV/AIDS clinical trial:

- Experimental drugs may not have any benefits or may even be harmful.
- New drugs may have unanticipated side effects.
- Protocols may require a lot of the participant's time and frequent trips to the study site.

## What questions should I ask?

If you are interested in participating in a clinical trial, you may want to ask:

- What is the purpose of the study?
- What are the drug's side effects?
- What other treatment options do I have?
- Will I have to be in the hospital?
- How often will I have study visits?
- How long will the study last?
- Who will provide my medical care after the study is completed?
- What other drugs can I take if I participate in the study?
- What treatments must I avoid while participating in the study?
- Who will pay the costs of the study?
- How will my confidentiality be protected?

## How do I find more information about HIV/AIDS clinical trials?

*AIDSinfo* provides free, up-to-date information on clinical trials evaluating experimental HIV/AIDS drugs and vaccines. Callers can speak with experienced health information specialists who can answer questions concerning a clinical trial's purpose, location, eligibility requirements, names and telephone numbers of the contact persons, and more. Bilingual specialists are available to talk with Spanish-speaking callers.

To contact *AIDSinfo* toll free from the United States or Canada, call: 1-800-HIV-0440 (1-800-448-0440)
Fax: 1-301-519-6616
International: 1-301-519-0459
TTY: 1-888-480-3739
E-mail: **ContactUs@AIDSinfo.nih.gov**
Web site: **http://aidsinfo.nih.gov**

In addition, the National Library of Medicine offers online access to information on HIV/AIDS clinical trials through the *ClinicalTrials.gov* database. To search the database, go to **www.ClinicalTrials.gov**.