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## Understanding Clinical Trials

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## What Are Clinical Trials?

The term "clinical trial" is used to describe many different types of research studies on people (known as "human subjects" in research terms). There are five main types:

- **Treatment trials**

Study new medications, new combinations of existing medications, or new types of therapies

- **Prevention trials**

Look for better ways to prevent disease — sometimes with medicines, sometimes by changing people's behavior

- **Diagnostic trials**

Test the best way to find disease or changes within the body

- **Natural History trials**

Study the natural course of disease in the human body

- **Quality of Life trials**

Study ways to improve aspects of life for people living with illnesses

There are also current clinical trials that study ways to control HIV over a long period without HIV drugs – a step toward an [HIV cure](#). These are known as HIV cure trials, or HIV remission trials ("remission" means a person no longer shows signs or symptoms of a disease).

*Click above to view or download this fact sheet as a [PDF slide presentation](#)*

## The Basic Components of Clinical Trials

The scientists and healthcare providers who manage clinical trials are usually called investigators. The people who join clinical trials are usually called participants but may also be called volunteers or study subjects. ALL clinical trials are voluntary. You never have to participate in a clinical trial unless you want to; this is a human right protected by international law.

It is important that you truly understand the study and what you will be asked to do.

In 2002, the World Health Organization (WHO) released a Handbook for Good Clinical Research Practice (PDF). As of mid-2023, the WHO is working on an update . The handbook is intended to help each country develop its own laws about clinical trials. The WHO's handbook is based in part on the recommendations for good clinical practice developed by the International Conference on Harmonisation (ICH) in 1996. In the US, for example, the Food and Drug Administration (FDA), which approves drugs for public use, has adopted the ICH's recommendations for clinical trials.

### Study protocol

Each clinical trial has a written plan, or study protocol, that describes the goals of the study, how long the study will last, who can participate (also called inclusion and exclusion criteria), and what tests and procedures will be conducted for each participant.

### Inclusion and exclusion criteria

Inclusion and exclusion criteria are the guidelines for determining who can and cannot participate in a specific clinical trial.

Inclusion criteria are requirements that a person must meet to participate (such as HIV drug-naïve — never having taken HIV drugs — [CD4 cell](#) count, [viral load](#), age, or many others).

Exclusion criteria are factors that prevent a person from participating, either for his or her safety or to make it easier to understand the study results. For example, people might be excluded for having liver problems, or if they have already taken a drug that is being studied.

Beginning in early 2020, the novel coronavirus (COVID-19) swept the globe, killing millions of people and infecting millions more. HIV community members advocated for HIV to be removed from the exclusion criteria for COVID-19 vaccine trials. As a result, people living with HIV were included in some of those studies, and the vaccines appear to be safe for people living with HIV to take.

## **Informed consent**

Each participant in a clinical trial must sign a document called "informed consent." When you sign this document, it means that you understand the details of the study and you agree to participate.

You may want to take the document with you and talk about the study with your healthcare provider, family, or friends before you decide to participate. If your native language is not the language spoken by the people describing the study, ask if a translation is available.

It is important that you truly understand the study and what you will be asked to do. If you have any questions, be sure to ask the study staff. It is their job to make sure that you understand what you are agreeing to do when you sign this document.

## **Compensation**

You may be paid for travel expenses to and from the study site and for your time; this payment is sometimes called compensation. Childcare may also be provided. You can choose to leave (drop out of) a study at any time and for any reason.

## **The Stages of Treatment Trials**

The most common type of clinical trial in HIV is a treatment or drug study. These include studies of HIV drugs that can be taken in new ways, such as long-acting drugs that could be given each week, each month, or even every few months, as an injection, implant, pill, or some other method.

- **Phase I: Is the drug safe?**

A Phase I trial tests a drug in a small number of participants (usually fewer than 100) to find a safe dose and to document the [side effects](#) of the drug. Phase I trials are usually short, lasting a few days to a few weeks.

- **Phase II: Is the drug effective?**

A Phase II trial tests a drug in a larger number of participants (on average 100 to 300) to see if the drug works. Phase II trials may also test different doses of the drug to find the dose that works best. The safety of the drug also continues to be evaluated. A Phase II trial usually lasts six months to one year.

- **Phase III: Is the drug safe and effective in larger groups of people for longer periods of time?**

A Phase III trial tests a drug in a very large group of participants (typically 1,000 to 3,000). Phase III trials compare the drug to an existing medication or treatment. This lets researchers gather more information about the safety and effectiveness of the drug. Phase III trials generally last two to three years.

- **Phase IV or Post-Marketing Studies: What are the long-term results of using the drug?**

These trials are done after the drug has been approved for sale. They let researchers get more information about the drug's best use and learn more about long-term [side effects](#).

Once a drug has gone through the first three phases of research, the company that makes the drug

submits the study data to the organization that regulates drugs in that country (e.g., the FDA in the US) for approval. Because the need for HIV treatments is so great, drug companies in some countries can apply for something called accelerated, or quicker, approval if the drug offers something new or meets a need for people living with HIV.

Accelerated approval may put special restrictions on how the drug can be used. However, even if a drug gets accelerated approval, the drug company must continue to do long-term research on the drug to get full approval.

## Clinical Trials and People Living with HIV

What are the correct HIV drug dosages for women? How do [opportunistic infections](#) and [gynecologic problems](#) affect women living with HIV? What [side effects](#) are more likely to occur in women than in men? What ways of taking HIV drugs fit – and do not fit – with women's lifestyles? Does HIV increase the risk of certain cancers? Does this diet and exercise program work for weight loss in women living with HIV? Women who participate in clinical trials can help answer many questions specific to women living with HIV while also benefitting the field of HIV research as a whole.

It is extremely important for women living with HIV, and people with HIV in general, to be involved at every level of research.

Worldwide, women represent half of all people living with HIV. In the past, women could not participate in many types of clinical trials. Now they can freely take part in trials, but few women do so. A study from 2012 reported that women represented, on average, only one in five participants in clinical trials of antiretroviral drugs approved by the FDA from 2000 to 2008. The good news is that, globally, women's participation in prevention studies, including vaccine studies and behavioral studies, seems to be higher. In 2021, a third of participants in studies presented at a major AIDS conference were women.

It is extremely important for women living with HIV, and people with HIV in general, to be involved at every level of research. When a diverse range of people that will be affected by the drug or process being studied is included in designing the study rather than simply testing the product, the results will be more useful and successful.

In 2020, The Well Project was part of a group of researchers – including people living with HIV and community organizations representing them – that studied whether or not people living with HIV would be willing to participate in HIV cure trials, or switch to new forms of HIV treatment, based on potential risks and benefits. The researchers found differences in preferences and reasons for participating based on gender – which would not have been found if women (cisgender and transgender) had not been included in the study.

For example, the features that led cis and trans women to be interested in joining a clinical trial were different than for cis men. They included supports like regular nurse visits, being paid, help with transportation to the study location, and having a meal while there. Furthermore, a majority of people in the study were unlikely to switch to an HIV remission method if there were even a very small increase in the chances of transmitting HIV to a partner. This kind of information is important for researchers to know before a study even begins recruiting (signing up) participants.

## Should I Participate in a Clinical Trial?

Choosing to participate in a clinical trial is a big decision. There are risks and benefits to consider.

### Risks

- You may experience unpleasant or serious side effects

- You may get asked about sexual activity, drug and alcohol use, and other personal questions that may make you uncomfortable
- You may have to stop all current medications, including any HIV drugs
- You may receive a placebo (a pill containing no medication)
- There is no guarantee that the experimental drug will be an effective treatment for you

## Benefits

- You may experience health benefits from a new treatment that is not yet available to the general public
- Most trials provide free laboratory tests, expert medical care, and drugs at no cost for the purpose of the study
- You are contributing to the development of a new medication or increasing understanding of HIV disease

## Important Lessons from Clinical Trials

Over the past several decades, clinical trial research has helped us gain important knowledge about the treatment and prevention of HIV. Here are some highlights:

- A combination of HIV drugs (combined antiretroviral therapy) is much more effective at controlling HIV and maintaining good health than taking only one HIV drug
- Giving [pregnant people](#) HIV drugs can reduce the chances that they will pass HIV on to their babies to as low as one in 100
- [Treatment as prevention](#): For people living with HIV, taking HIV drugs can reduce their viral load, thus making them much less likely to transmit HIV to others. If their viral load is undetectable (lower than standard tests can find) and they take their HIV drugs regularly, they cannot pass the virus on to their [sexual partners](#) (known in the HIV community as [Undetectable Equals Untransmittable, or U=U](#)).
- For people who are HIV-negative, taking HIV drugs can protect them against acquiring HIV if they are exposed to the virus (e.g., [PrEP](#), or pre-exposure prophylaxis).
- People living with HIV who start treatment earlier, while their CD4 counts are still high, have a much lower risk of illness and death. This includes people living with HIV who may have no outward signs of ill health.

## Reasons to Consider Participating in a Clinical Trial

To date, women have been drastically underrepresented in HIV clinical trials. This means that many decisions about women's HIV care and treatment are based on research studies in men.

There are many reasons for participating in a clinical trial. You may:

- Get access to new treatments not available to the public
- Receive expert medical care at leading healthcare facilities
- Get access to new experimental medications
- Have a chance to help others by contributing to medical research

Women are not simply smaller versions of men; women's bodies are different. It is important to participate in research because HIV and some HIV drugs act differently in women's bodies – and taking HIV drugs affects women's lives differently as well. The only way to discover these differences is for more women living with HIV to join clinical trials.

For information on a clinical drug trial in the US that was successful in recruiting large numbers of women and people of color, see our fact sheet [Lessons from GRACE](#).

To find clinical trials that might be of interest or benefit to you, you can search the following registries:

- [ClinicalTrials.gov](#) from the US National Institutes of Health (NIH)
- [HIV and AIDS Clinical Trials](#) at HIVinfo
- [AIDS Clinical Trials Group \(ACTG\)](#)
- [HIV Prevention Trials Network \(HPTN\)](#)
- [HIV Vaccine Trials Network](#)
- [Microbicide Trials Network \(MTN\)](#)
- [International Clinical Trials Registry Platform](#) from the World Health Organization (WHO)

## Additional Resources

Select the links below for additional material related to clinical trials.

- [Clinical Trials: What Patients Need to Know \(US Food and Drug Administration\)](#)
- [Equal Partners: Recognising the Expertise of Women Living with HIV \(Salamander ...\)](#)
- [It's 2021. Where Are the Women in HIV Clinical Trials? \(TheBodyPro\)](#)
- [Women Who Make a Difference \(Cleveland AIDS Clinical Trials Unit, via YouTube\)](#)
- [Women-Only HIV Trial Hailed as Landmark \(Medpage Today\)](#)
- [Learn about Clinical Studies \(ClinicalTrials.gov\)](#)
- [Research Toward a Cure Trials \(Treatment Action Group\)](#)
- [Inside the Fight to Include HIV-Positive People in Covid-19 Vaccine Trials \(NBC...\)](#)
- [NIH Clinical Research Trials and You \(US National Institutes of Health\)](#)
- [Informed Consent for Clinical Trials \(US Food and Drug Administration\)](#)
- [HIV Clinical Trials - Search \(Power\)](#)
- [Why Including Women in HIV Research Matters \(POZ\)](#)
- [Call to Accelerate the Study of New Drugs for HIV in Pregnant and Breastfeeding...](#)
- [International Maternal Pediatric Adolescent AIDS Clinical Trials \(IMPAACT\) Netw...](#)
- [Support for Women's Inclusion in HIV-Related Clinical Research \(American Public...](#)
- [Not Counted: Clinical Trials of New HIV Treatments Are Failing Women \(aidsmap\)](#)
- [Women Are Missing From HIV Treatment Trials \(POZ\)](#)



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