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# Understanding Clinical Trials

*Last updated: April 3, 2024*

*Together, we can change the course of the HIV epidemic...one woman at a time.*

#onewomanatotime

[www.thewellproject.org](http://www.thewellproject.org)

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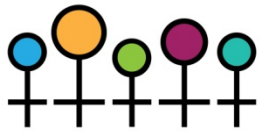


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# What Are Clinical Trials?

*Clinical trial:* Describes many different types of **research studies on people (“human subjects”)**





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# Five Main Types of Clinical Trials

## **Treatment trials** study ...

- New drugs, combinations of existing drugs, or types of therapies

## **Prevention trials** look for ...

- Better ways to prevent disease, with drugs or behavior changes

## **Diagnostic trials** test ...

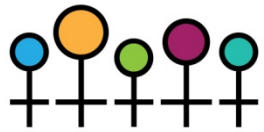
- Best way to find disease or changes within the body

## **Natural History trials** study ...

- Natural course of disease in the human body

## **Quality of Life trials** study ...

- Ways to improve aspects of life for people living with illnesses

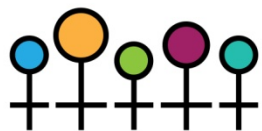


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# Clinical Trials to Find an HIV Cure

## *HIV cure (HIV remission) trials* study ...

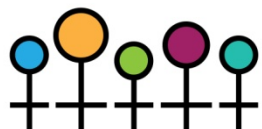
- Ways to control HIV over a long period without HIV drugs
- Remission: a person no longer shows signs or symptoms of a disease



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# Basic Components of Clinical Trials

- **Investigators:** the scientists and/or healthcare providers managing clinical trials
- **Participants** (may also be called **volunteers** or **study subjects**): people who join clinical trials
- ***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 laws
- Each clinical trial has a **study protocol**, which describes:
  - Goals of the study
  - How long the study will last
  - Who is allowed to participate (**inclusion and exclusion criteria**)
  - What tests and procedures are required of each participant



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# Inclusion and Exclusion Criteria

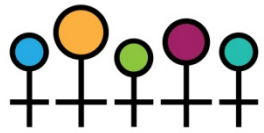
- **Inclusion criteria:** Requirements a person must meet to participate; may include:
  - Never having taken HIV drugs, CD4 cell count, viral load, age
- **Exclusion criteria:** Factors that prevent a person from participating:
  - For his or her safety
  - To make it easier to understand study results
  - Advocacy may challenge these criteria
    - E.g., people living with HIV were first excluded from COVID-19 vaccine trials, but included after community members' advocacy



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# Informed Consent

- Participants must sign an “informed consent” form
- Consider taking the form with you and talk about it with your healthcare provider, family, friends
- Ask if translation is available if your native language is not the one spoken by the people describing the study
- Important that you truly understand the study and what you will be asked to do
- Ask study staff any questions
  - Their job is to make sure that you understand what you are agreeing to do when you sign this document.

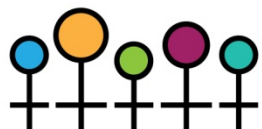


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# Compensation

- You may be paid for travel expenses to and from the study site and for your time
- Childcare may also be provided
- You can ***choose to leave (drop out of) a study*** at any time, for any reason



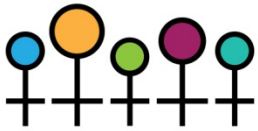


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# Stages of Treatment Trials

Four stages (phases) of treatment trials:

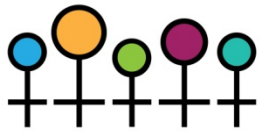
- ***Phase I: Is the drug safe?***
  - Tests drug in small number of participants (usually <100) to find a safe dose, document side effects
  - Usually short (a few days to a few weeks)
- ***Phase II: Is the drug effective?***
  - Tests drug in larger number of participants (usually 100-300) to see if it works
  - May test different doses to find the best one
  - Continues to evaluate drug safety
  - Usually lasts 6 months - 1 year



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# Stages of Treatment Trials

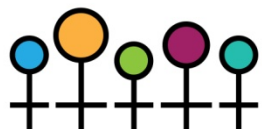
- ***Phase III: Is the drug safe and effective in larger groups of people for longer periods of time?***
  - Tests drug in very large group of participants (typically 1,000 -3,000)
  - Gathers more information about drug's safety, effectiveness by comparing it to an existing treatment
  - Generally lasts 2-3 years
- ***Phase IV or Post-Marketing studies: What are the long-term results of using the drug?***
  - Done after drug has been approved for sale
  - Gets more information about drug's best use
  - Further examines long-term side effects



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# Stages of Treatment Trials

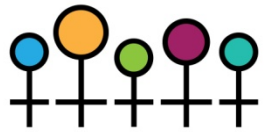
- Company submits study data to the drug regulation authority (FDA in the US) for approval once drug has completed first three phases of research
- Because need for HIV treatments is so great, drug can get **accelerated** approval (in some countries) if it offers something new or meets a need for people living with HIV
  - Accelerated approval may put special restrictions on how drug can be used
- Even with accelerated approval, drug company must continue to do long-term research on the drug for it to get full approval



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# Clinical Trials and Women Living with HIV

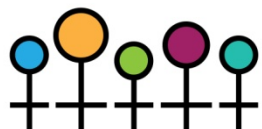
- More information is needed on issues such as:
  - Correct drug doses for women
  - How opportunistic infections, gynecologic problems affect women living with HIV
  - What side effects are more likely to affect women
  - How do drugs fit into women's lifestyles?
  - Whether HIV increases risk of certain cancers
  - Does a diet and exercise program work in women with HIV?
- Previously, women could not participate in many trials
  - Now they can participate freely, but few women do so



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# Clinical Trials and People Living with HIV

- **Important for people – and especially women – living with HIV to be involved early in research**
  - Results more useful when people affected by what is being studied are included in designing the study
  - Reveals important information for researchers to know before study begins signing up participants
- **2020 study on HIV cure trial participation**
  - Men and women consider different factors when deciding to participate in a clinical trial



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# Should I Participate in a Clinical Trial?

Choosing to participate in a clinical trial is a big decision

## **Risks:**

- May experience side effects
- May be asked highly personal questions
- May need to stop all current drugs, including HIV drugs
- May receive a placebo (a pill containing no medication)
- No guarantee experimental drug will be effective for you

## **Benefits:**

- Potential health benefits from new treatment not yet publicly available
- Potential free lab tests, expert medical care, drugs at no cost (for purpose of study)
- Contributing to development of a new medication or increasing understanding of HIV



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# Important Lessons from HIV Clinical Trials

- Enhanced effectiveness of combined HIV drugs compared to one drug for HIV treatment
- ART for the prevention of vertical (mother-to-child) HIV transmission
- Treatment as prevention
  - U=U
- Effectiveness of PrEP
- Benefits of early treatment regardless of CD4 cell count



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# Reasons to Participate in Clinical Trials

- 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\*\*

*\*\* Many decisions about women's HIV care and treatment are based on research studies in men*





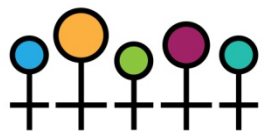
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# Important for Women to Participate in Research

- Women aren't just smaller versions of men
- HIV and some of the HIV drugs act differently in women's bodies

***Only way to discover this information is for more women living with HIV to join clinical trials***

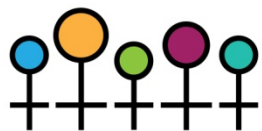
- Clinical trial in US that included many women: GRACE



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# Where to Find a Clinical Trial

- Various clinical trial registries:
  - [ClinicalTrials.gov](https://clinicaltrials.gov)
  - [HIV and AIDS Clinical Trials at HIVinfo](https://www.hivinfo.org/)
  - [AIDS Clinical Trials Group \(ACTG\)](https://www.actg.org/)
  - [HIV Prevention Trials Network \(HPTN\)](https://www.hptn.org/)
  - [HIV Vaccine Trials Network](https://www.hivvaccine.org/)
  - [Microbicide Trials Network \(MTN\)](https://www.mtn.org/)
  - [International Clinical Trials Registry Platform](https://www.clinicaltrials.gov/)



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## Learn More!

- To learn more, please read the full fact sheet on this topic:
  - [Understanding Clinical Trials](#)
- For more fact sheets and to connect to our community of women living with HIV, visit:
  - [www.thewellproject.org](http://www.thewellproject.org)
  - [www.facebook.com/thewellproject](https://www.facebook.com/thewellproject)
  - [www.twitter.com/thewellproject](https://www.twitter.com/thewellproject)
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