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Understanding Clinical Trials

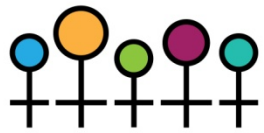
Last updated: January 13, 2021

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

#onewomanatatime

www.thewellproject.org

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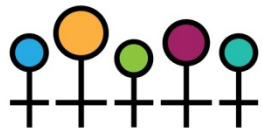


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What Are Clinical Trials?

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 ...

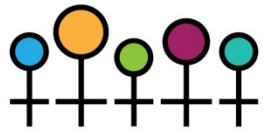
- Best way to find disease or changes within the body

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

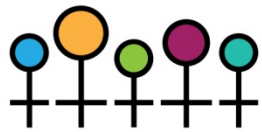


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Clinical Trials to Find an HIV Cure

HIV cure or (HIV remission) trials study ...

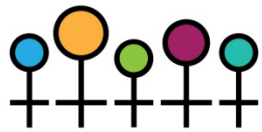
- Ways to control HIV over a long period of time without HIV drugs



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Basic Components of Clinical Trials

- **Investigators:** the scientists and/or health care 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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Basic Components of Clinical Trials

- **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
 - People might be excluded for having liver problems, or if they have already taken a drug that is being studied
- Each participant in a clinical trial must sign an **informed consent**
 - Signing means you understand details of study, agree to participate



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Before you Decide to Participate

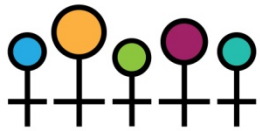
- Consider taking the consent form with you; talk about the study with your health care provider, family, friends
- Ask if translation is available if your native language is not the one spoken by the people describing the study
- Important that you truly understand the study and what you will be asked 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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Basic Components of Clinical Trials

- 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

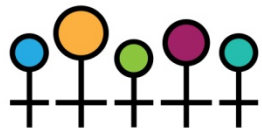


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Stages of Treatment Trials

Four stages (phases) of treatment trials:

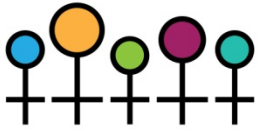
- ***Phase I: Is the drug safe?***
 - Tests drug in small number of participants (usually <100) to find a safe dose, document side effects
 - Usually short (a few days to a few weeks)
- ***Phase II: Is the drug effective?***
 - Tests drug in larger number of participants (usually 100-300) to see if it 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

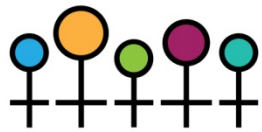
- ***Phase III: Is the drug safe and effective in larger groups of people for longer periods of time?***
 - Tests drug in very large group of participants (typically 1,000 -3,000)
 - Gathers more information about drug's safety, effectiveness by comparing it to an existing treatment
 - Generally lasts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



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Stages of Treatment Trials

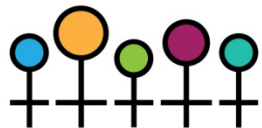
- Company submits study data to the drug regulation authority (FDA in the US) for approval once drug has completed first three phases of research
- Because need for HIV treatments is so great, drug can get **accelerated** approval (in some countries) if it offers something new or meets a need for people 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 People Living with HIV

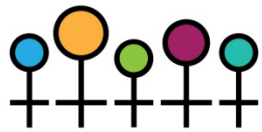
- Worldwide, women represent half of all people living with HIV
- In the past, women could not participate in many types of clinical trials
 - Now they can participate freely, but few women do so
 - Represent only 1 in 5 participants in trials for FDA-approved drugs from 2000 to 2008
- Globally, women's participation in prevention studies, including vaccine studies and behavioral methods, appears higher



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Clinical Trials and People Living with HIV

- **Extremely important for people – and especially women – living with HIV to be involved at every level of research**
 - Results more useful and successful when people impacted by what is being studied are included in designing the study
 - Reveals important information for researchers to know before study begins recruiting (signing up) participants



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Should I Participate in a Clinical Trial?

Choosing to participate in a clinical trial is a big decision - risks and benefits to consider:

Risks:

- May experience unpleasant or serious side effects
- May be asked possibly uncomfortable personal questions
- May have to stop all current medications, including any HIV medications
- May receive a placebo (a pill containing no medication)

Benefits:

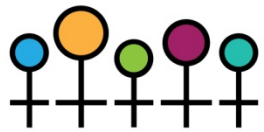
- Potential health benefits from new treatment not yet publicly available
- Potential free lab tests, expert medical care, drugs at no cost (for purpose of study)
- Contributing to development of a new medication or increasing understanding of HIV



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What Have We Learned About HIV in Women?

- **Women are not small men**
 - Risk, co-morbidities, medication side effects and dosing
- **Research in men \neq research in women**
 - Clinical outcomes
 - HIV care continuum
 - Prevention
 - The context of women's lives
- **Research in women benefits HIV research as a whole**



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Important Lessons from HIV Clinical Trials

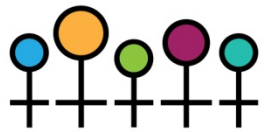
- Enhanced effectiveness of the HIV “cocktail” compared to one medication for HIV treatment
- ART for the prevention of vertical (mother-to-child) HIV transmission
- Treatment as prevention
 - U=U



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Important Lessons from HIV Clinical Trials

- The effectiveness of PrEP
 - IPrEX
 - Partners PrEP
- The benefits of early treatment regardless of CD4 Cell count
 - START Trial

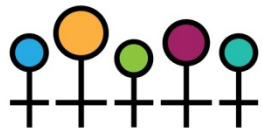


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Reasons to Participate in Clinical Trials

- 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*

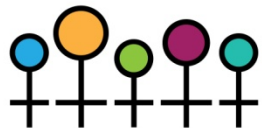


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Important for Women to Participate in Research

- HIV and some of the HIV drugs act differently in women's bodies
- More information is needed on issues such as:
 - Correct drug doses for women
 - Differences in lab tests such as CD4 cells and viral load
 - How opportunistic infections, gynecologic problems affect women living with HIV
 - What side effects are likely to affect women

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



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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
 - www.facebook.com/thewellproject
 - www.twitter.com/thewellproject