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Understanding Clinical Trials

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

#onewomanatatime #thewellproject

What Are Clinical Trials?

Clinical trial: Describes many different types of **research studies on 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 detect 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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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 eligible 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

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 to make sure that, when you sign, you are making an informed choice

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 drop out of a study*** at any time, for any reason

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Stages of Treatment Trials

Most common type of clinical trial in HIV is a **treatment** or **drug trial**; 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 U.S.) for approval once drug has completed first three phases of research
- Because need for HIV treatments is so great, drug can get **accelerated** approval 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 doing long-term research on the drug for it to get full approval

Reasons to Participate in Clinical Trials

- Gain access to new treatments not available to the public
- Receive expert medical care at leading healthcare facilities
- Gain 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 on men*

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 have to stop all current medications, including any HIV medications
- 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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What Have We Learned About HIV in Women?

- **Women are not small men**
  - Risk, co-morbidities, medication side effects and dosing
- **Research in men ≠ 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

- ART for the prevention of mother to child HIV transmission
- Enhanced effectiveness of the HIV “cocktail” compared to one medication for HIV treatment
- The effectiveness of PrEP
  - IPrEX
  - Partners PrEP

Important Lessons from HIV Clinical Trials

- Treatment as prevention
- The benefits of early treatment regardless of CD4 Cell count
  - START Trial
- HIV differences between men and women
  - WIHS and MACS observational studies

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Clinical Trials and Women Living with HIV

- Worldwide, women represent more than half of all people living with HIV
- In the past, women were excluded from participating in many types of clinical trials
  - Despite now being able to participate freely, number of women participating in HIV treatment trials remains low
  - 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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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