Understanding Clinical Trials

Last updated: January 13, 2021

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

#onewomanatatime  #thewellproject

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What Are Clinical Trials?

Clinical trial: Describes many different types of research studies on people (“human subjects”)
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
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.
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
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
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.
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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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 ≠ research in women
  - Clinical outcomes
  - HIV care continuum
  - Prevention
  - The context of women’s lives
- Research in women benefits HIV research as a whole
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
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
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*
To learn more, please read the full fact sheet on this topic:

- [Understanding Clinical Trials](www.thewellproject.org)

For more fact sheets and to connect to our community of women living with HIV, visit:

- [www.thewellproject.org](www.thewellproject.org)
- [www.facebook.com/thewellproject](www.facebook.com/thewellproject)
- [www.twitter.com/thewellproject](www.twitter.com/thewellproject)