Understanding Clinical Trials

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

#onewomanatatime                                                            #thewellproject

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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
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
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 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
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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• **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 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.
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
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

- Enhanced effectiveness of the HIV “cocktail” compared to one medication for HIV treatment
- ART for the prevention of mother to child HIV transmission
- Treatment as prevention
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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
Clinical Trials and Women 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
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](#)

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