Understanding Clinical Trials

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

#onewomanatatime

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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
Clinical Trials to Find an HIV Cure

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

- Ways to control HIV over a long period 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
  - 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
- Each participant in a clinical trial must sign an **informed consent**
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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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 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
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?

• In the past, women could not participate in many types of clinical trials
  – Now they can participate freely, but few women do so
• Extremely important for people – and especially women – living with HIV to be involved at every level of 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
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
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• Effectiveness of PrEP
• Benefits of early treatment regardless of CD4 cell count
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

• 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
  • HIV and AIDS Clinical Trials at HIVinfo
  • AIDS Clinical Trials Group (ACTG)
  • HIV Prevention Trials Network (HPTN)
  • HIV Vaccine Trials Network
  • Microbicide Trials Network (MTN)
  • International Clinical Trials Registry Platform

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• 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