Community Involvement in MTN Studies: Community Preparedness

Charles Chasakara
UZ-UCSF
Harare
Zimbabwe

cchasakara@uz-ucsf.co.zw
Presentation Outline

- Network Overview
- Study Overview
- Roles and Responsibilities of the Clinical Research Site (CRS) in Community Preparedness
Network Overview

- Mission
  - Reduce the sexual transmission of HIV through the development & evaluation of products that reduce the transmission of HIV when applied topically to mucosal surfaces or when taken orally.

- Goal
  - Work in a highly efficient manner & conduct scientifically rigorous & ethically sound clinical studies of microbicides safety & effectiveness

chasakara@uz-ucsf.co.zw
Network Overview Cont...

- Location of Clinical Research Sites
  - India, Malawi, USA, South Africa, Uganda, Zambia & Zimbabwe
MTN 003 Study Overview

- **Study Objectives**
  - To compare the safety and efficacy of oral versus topical Pre-Exposure Prophylaxis (PrEP) for prevention of sexual transmission of HIV in women.

- **Study Design**
  - Phase 2B, five-arm, double-blinded, placebo-controlled, multi-site, randomized, controlled trial

ccchasakara@uz-ucsf.co.zw
Study Overview Cont…

- **Duration**
  - 4 year study

- **Study Population & Study Size**
  - HIV negative women, 18 - 45 yrs
  - 5000 participants

- **Clinical Research Sites**
  - Uganda (1)
  - South Africa (11)
  - Zimbabwe (3)

cchasakara@uz-ucsf.co.zw
Community Involvement at CRS

- Roles and Responsibilities of Research Staff in Community Preparedness
  - Facilitated CAB participation in MTN 003 protocol & IEC material development.
  - Ensured CWG & CAB representation at all MTN training meetings.
  - Attended all CAB meetings to give study updates & get community feedback
Community Involvement at CRS Cont…

- **Ensured Stakeholders Involvement**
  - Trained the media on MTN protocols & updated them on MTN activities
  - Invited the media to local & international MTN conferences
  - Engaged male focused groups for male involvement
  - Gave study overviews at stakeholders & general community meetings
  - Sensitized the community at national & international events

- **Organized Trainings for CAB on**
  - Engaging the Media in Research
  - Promoting Community Advocacy and Awareness
  - Basics of Research & Research Terminology
Best Practices

- Best Practices for Community Preparedness
  - Male involvement in women’s research
  - Community Mapping & Community involvement
    - CAB involvement in protocol developments & community engagement
    - CAB training & support for community activities
    - Community engagement & awareness programs
  - Worked closely with CABs & stakeholders

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Conclusion

“You can either include the community & hear from them directly, or exclude them from the process & hear from them indirectly!”

*Quote – IAVI*

We owe our successes thus far to a greater extent to the critical role played by community involvement.

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