MTN-003c / VOICE-C
Ancillary proposal

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VOICE-C Collaboration

VOICE-C is the result of the close collaboration between the following MTN Working Groups:

- Community Working Group (CWG)
- Behavioral Research Working Group (BRWG)
Community Working Group (CWG)

- The goal of the MTN CWG is to conduct community preparedness and engagement activities to ensure successful conduct of microbicide studies and has the following aims
Community Working Group Aims

- To ensure community input into science generation and the research process of the MTN
- To build capacity for local communities to provide input into research at the site level
- To develop mechanisms for sharing experiences, lessons learned, and best practices for community involvement in MTN research
Behavioral Research Working Group

- Provide behavioral science support for the development of all of the MTN protocols
- Develop innovative techniques to capture critical behavioral data in clinical studies
- Develop the tools, including questionnaires, to capture behavioral data in MTN protocols
VOICE-C - The Big Picture

- Achieving high level of adherence in VOICE is KEY to being able to estimate the protective effect of the products against HIV
- We need to understand not just how much use (or non-use) there is in VOICE, but WHY
- VOICE-C aims to qualitatively explore factors beyond the individual that influence product use and non-use among VOICE participants
# VOICE-C Study Population

<table>
<thead>
<tr>
<th>Group</th>
<th>Description</th>
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<tbody>
<tr>
<td>Group 1</td>
<td>VOICE participants</td>
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<tr>
<td>Group 2</td>
<td>Male partners of VOICE participants</td>
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<tr>
<td>Group 3</td>
<td>Members of Community Advisory Boards (CABs)</td>
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<td>Group 4</td>
<td>Key community stakeholders in the community surrounding VOICE-C sites</td>
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VOICE-C Study Design

- Exploratory sub study of VOICE using qualitative research methods, including focus group discussions (FGDs) and in-depth interview (IDI) at participating VOICE-C sites.

- **Descriptive component**: qualitative exploration of barriers and facilitators of product adherence

- **Strategic component**: issues identified through the descriptive component will be brought back to the VOICE protocol team, and a decision will be made about the modification or implementation of new adherence strategies across all VOICE sites
Primary Objectives

- To explore socio-cultural and contextual factors at the **household level** (i.e. relationship with partner, poverty) and at the **community level** (i.e., stigma against HIV, rumors about the trial) that participants identify as **influencing product use** (and non-use) in VOICE.

- To determine if factors identified by participants as influencing product use (and non-use) are different between the women who are randomized to the **vaginal product arm vs. oral product arm**.

- To elicit VOICE participants’ perceptions of the **importance of adherence**, and its **barriers and facilitators** as identified by them.
Secondary Objectives

Descriptive

☐ To elicit “external” perspectives on the trial, its acceptance at the household level and in the community, and views on adherence-related issues among the following groups:
  - Male partners of study participants (Group 2)
  - CAB members (Group 3)
  - Key community stakeholders (Group 4)

Strategic

☐ To solicit the input of external stakeholders on developing and implementing strategies to improve product adherence in the trial.

☐ To collect feedback on experience with these implemented strategies through specific questions in the exit FGDs with VOICE participants and their male partners.
Socio-Ecological Model of Factors Affecting Adherence in VOICE

Community
- HIV
- Organizational
- Trial clinic
- Norms/traditions
- Information flow/beliefs

Household
- Male partner
- Life events
- Resources
- Family
- Membership to various groups

Individual adherence

Community Resources
Qualitative Methods

- Quantitative methods (survey questionnaires):
  - Best to measure a behavior (product use): how much, how often and characteristics of who is adherent

- Qualitative methods:
  - Seek to understand WHY people practice certain behaviors (use or non-use of product)
  - Provides information on how people experience the topic of interest (i.e. being adherent) in their own words
  - Help identify intangible factors (i.e. norms, gender roles, religion, culture) affecting product use
  - Can describe variation and explain relationships between phenomena (i.e. work may be associated with non-use, because erratic schedule prevents taking products at the same time each day)
Sample Size and Study Procedures

At each VOICE-C participating site (N=approximately 270)

- **VOICE participants- randomly selected N~140**
  - Exit FGD (8 FGD; 4 per arm ~100 ♀)
  - Monthly IDI (1♀/arm/month during accrual=36 ♀)

- **Male partners-systematically selected N~65**
  - Exit FGD (4 FGD; 2 per arm ~50 ♂)
  - Quarterly IDI (1♂/arm/quarter during accrual = 14)

- **CAB- purposively selected N~15**
  - Biannual FGD (5 groups with same 15 members)

- **Key Community Stakeholders- purposively selected N~50**
  - Biannual FGD (5 groups with 10 different participants each time)
Timeline for VOICE-C Data Collection

**Group 1: VOICE ppts**
- IDIs: XXX*
- Exit FGDs: XXX

**Group 2: Male partners**
- IDIs: X*
- Exit FGDs: XXX

**Group 3: CAB members**
- FGDs: X

**Group 4: Community Stakeholders**
- FGDs: X

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<tr>
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<th>Study Accrual Period</th>
<th>Follow-up Period</th>
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<tr>
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<td>start</td>
<td>mo3</td>
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<tr>
<td><strong>Group 1: VOICE ppts</strong></td>
<td>XXX*</td>
<td>XXX</td>
</tr>
<tr>
<td><strong>Group 2: Male partners</strong></td>
<td>X*</td>
<td>X</td>
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<tr>
<td><strong>Group 3: CAB members</strong></td>
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*"X" refers to one data collection round. "XXX" refers to three monthly IDIs in that quarterly interval.*
Socio-behavioral & Community Activities in other PrEP studies

- **FEM-PrEP:**
  - Site preparedness (community mapping; IDI & FGDs with community members and stakeholders)
  - IDIs during trial implementation
    - IDIs and FGDs with community stakeholders
    - Quarterly IDIs with 5% of participants
  - Intervention planning protocol (preparation of post trial activities)
  - Community engagement activities (building partnerships with CABs, and other civil society stakeholders; ethics training)

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- PrEP Botswana trial (CDC)
  - Community monitoring survey to assess rumor/perceptions and awareness of trial (ongoing)
  - IDI with community members knowledgeable about the trial and with HIV+ patients
  - Qualitative substudy with trial participants (in development)

K. Chillag Personal communication
Acknowledgements

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