MTN 020

Qualitative Component: Update

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RTI International
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Purpose and Rationale

- To collect in-depth contextual data on ring use-experience, acceptability & adherence
  - Data collected en-route & at study’s end
- To complement ACASI and CRF data
- To offer insights into trial results and potential future use of ring in non-trial settings
ASPIRE Behavioral Measurements & Activities

- **Ring counts & collection**
  - Accountability, visual inspection, residual drug testing, (biofilm)

- **ACASI** (Bas, M3, PUEV)
  - Sensitive sex questions (anal sex)
  - Vaginal practices (detailed)
  - Ring acceptability
  - Expulsions/removals, reasons

- **CRFs; FTFI**
  - Menstrual/vaginal practices (B, SA)
  - Ring adherence (M)
  - Ring worries/concerns (B, M3, P)
  - Main partner/sexual behavior (B,Q)

- **Qualitative Component** (M3, M12, P)
All parts are working together….

- Within sites
- Across sites
Locations

- **6 CRS / 4 countries**
  - MU-JHU (Kampala, Uganda)
  - Spilhaus (Harare, Zimbabwe)
  - UNC (Lilongwe, Malawi)
  - Wits RHI (Johannesburg, RSA)
  - DTHF (Cape Town, RSA)
  - MRC/Isipingo (Durban, RSA)

Behavioral data qual+quant
Methods:
Combination of types of interviews

- Serial IDIs
  - Women randomly selected at each site
    2-3 SIDIs: Month 3, Month 12 and/or PUEV
  - A couple of women are purposively selected (special cases) by site & management team

- Single IDIs:
  - Premature product discontinuation (e.g. seroconversions, early terminations)

- Exit FGDs
  - ~2 groups per site
Sample size per site:

<table>
<thead>
<tr>
<th>Type of Qualitative Data Collection</th>
<th># of women per site</th>
<th># of interviews/FGD per site</th>
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</thead>
<tbody>
<tr>
<td>Serial IDI</td>
<td>~12-14*</td>
<td>24-42</td>
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<tr>
<td>Premature termination IDI</td>
<td>≥3**</td>
<td>3</td>
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<td>FGD</td>
<td>20</td>
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<tr>
<td><strong>Total</strong></td>
<td>~35</td>
<td>~29 - 47</td>
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</table>

(*) of those, up to 2 can be purposively selected by site staff
(**) a minimum of 3 premature terminators - and up to a maximum of all seroconverters, at a given site.
Topics of Special Interest: IDI

- Ring *acceptability*, willingness to use in future
- Adherence to ring use, *challenges* to use
- Role of *clinic environment/counseling* on ring use
- *Partner* disclosure, influence and attitudes
- *Sexual* behavior, including anal sex
- *Motivation* to join the trial & HIV risk perception
- Effect of *menses* on ring use
- *Impact* of ring use on *sexual* activity, sexual *pleasure*, *condom* use, and *intravaginal* practices
- *Change* over time (serial interviews)
- *Special issues* for case studies, (i.e. circumstances & timing of seroconversion or early study/product termination, etc.)
Topics of Special Interest: FGD

- **Community**’s perspective on HIV, RCT and ASPIRE
- **Motivations** to join the trial
- **Disclosure** and influence of others
- **Experience** in ASPIRE (incl. ppt engagement activities)
- **Experience** with the ring (incl. male partner’s views)
- **Feasibility** for future use
- **Recommendations** about ring and the trial

- **Contingent questions** if change in trial design/early stopping take place (ready to implement)
Data Management

- **Interview conducted**
- Notes expanded and debriefing report (DR) developed (2-4 pages)
- Final DR circulated to site team, MTN leadership, AWG and management team
- Interview transcribed into local language and translated into English
- English transcript reviewed by RTI and finalized
- Final transcript uploaded into qualitative management software for coding and analysis
# 020 Qual update (as of Oct 21)

<table>
<thead>
<tr>
<th>Site</th>
<th>No. Participants Interviewed</th>
<th>Total Interviews</th>
<th>Total Interviewed</th>
<th>No. Debriefing Reports Complete</th>
<th>No. Transcripts Complete</th>
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<td>SIDI 3</td>
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QUESTIONS?