MTN-003D Stage 2 Accrual, Screening, and Enrollment

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## Accrual Targets per Site

<table>
<thead>
<tr>
<th>Drug Detection Level**</th>
<th>Study Group</th>
<th>HIV(+)</th>
<th>HIV(-)</th>
<th>~Total IDIs/FGDs</th>
<th>~Total No. of Participants</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low drug detection per PK results</td>
<td>Gel</td>
<td>2 IDI</td>
<td>4 IDI 2 FGD⌂</td>
<td>8</td>
<td>18</td>
</tr>
<tr>
<td></td>
<td>Tablet</td>
<td>2 IDI</td>
<td>4 IDI 2 FGD⌂</td>
<td>8</td>
<td>18</td>
</tr>
<tr>
<td>High drug detection per PK results</td>
<td>Gel</td>
<td>2 IDI</td>
<td>4 IDI</td>
<td>6</td>
<td>6</td>
</tr>
<tr>
<td></td>
<td>Tablet</td>
<td>2 IDI</td>
<td>4 IDI</td>
<td>6</td>
<td>6</td>
</tr>
<tr>
<td>TOTAL</td>
<td></td>
<td></td>
<td></td>
<td>28</td>
<td>48</td>
</tr>
</tbody>
</table>

⌂ Approximately 6 participants will take part in each FGD

** Women will be drawn from Stage 1 and 003D naïve participants. If quota for low and high adherence cannot be filled we will recruit women with inconsistent adherence (some drug detected in their plasma).
Targets by Mode Assignment

Recontact VOICE pts who are eligible per 003D and gave PTC

Screening and enrollment

- High adherers (drug in plasma)
  - Seronegative
  - Seropositive

- Inconsistent (if quota not filled in other 2 groups)

- Low adherers (no drug in plasma)
  - Seronegative
  - Seropositive

IDI

FGD

Participation in an IDI and FGD is contingent upon assignment
Recruitment Lists

- 8 Recruitment Lists will be generated by SCHARP

<table>
<thead>
<tr>
<th>1G:</th>
<th>1T:</th>
<th>2G:</th>
<th>2T:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Gel participants</td>
<td>4 IDI</td>
<td>2 FGD</td>
<td>• Tablet participants</td>
</tr>
<tr>
<td>• HIV-negative</td>
<td></td>
<td></td>
<td>• HIV-negative</td>
</tr>
<tr>
<td>• Low drug detection</td>
<td></td>
<td></td>
<td>• High drug detection</td>
</tr>
<tr>
<td>3G:</td>
<td>3T:</td>
<td>4G:</td>
<td>4T:</td>
</tr>
<tr>
<td>• Gel participants</td>
<td>2 IDI</td>
<td></td>
<td>• Tablet participants</td>
</tr>
<tr>
<td>• HIV-positive</td>
<td></td>
<td></td>
<td>• HIV-positive</td>
</tr>
<tr>
<td>• Low drug detection</td>
<td></td>
<td></td>
<td>• High drug detection</td>
</tr>
</tbody>
</table>
# Recruitment List Example

<table>
<thead>
<tr>
<th>VOICE PTID</th>
<th>Stage 1 MTN-003D PTID (PTID or NA)</th>
<th>Study Arm (Gel/Tablet)</th>
<th>Drug Detection Level (A-E or %)</th>
<th>Did participant give PTC? (If no, do not contact)</th>
<th>Participant enrolled in MTN-003D Stage 2 (Y/N)</th>
<th>Staff Initials</th>
</tr>
</thead>
<tbody>
<tr>
<td>212-74374-0</td>
<td>5001 Gel</td>
<td>E</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>212-56943-8</td>
<td>NA Gel</td>
<td>E</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Accrual Process & Tips

- May recruit participants from multiple lists simultaneously
- Aim to enroll 2-3 IDIs with HIV(-), low PK level women prior to FGDs*
- Record enrollment status on RLs [and Screening/Enrollment Log]**
- Send FHI 360 updated RLs 1xweek
## Screening & Enrollment Log

<table>
<thead>
<tr>
<th>VOICE PTID</th>
<th>PTC Given</th>
<th>Screening Date</th>
<th>Scheduled Enrollment Visit Date</th>
<th>Staff Conducting Screening</th>
<th>Enrollment Date</th>
<th>MTN-003D PTID</th>
<th>Participant Name (if enrolled)</th>
<th>If not enrolled, reason for non-enrollment</th>
<th>Staff Conducting Enrollment</th>
</tr>
</thead>
<tbody>
<tr>
<td>212-74374-0</td>
<td>Y</td>
<td>23 SEP 13</td>
<td>25 SEP 13</td>
<td>MH</td>
<td>25 SEP 13</td>
<td>5001</td>
<td>NA</td>
<td>NA</td>
<td>EM</td>
</tr>
<tr>
<td>212-56943-8</td>
<td>Y</td>
<td>23 SEP 13</td>
<td>27 SEP 13</td>
<td>MH</td>
<td>27 SEP 13</td>
<td>5028</td>
<td>NA</td>
<td>NA</td>
<td>EM</td>
</tr>
</tbody>
</table>

[1] The screening date is the date the recruitment script is administered.

[2] The Enrollment date is the date the IC is administered.
Screening Process & Tips

- Review Permission to be Contacted (PTC) status
- Contact participants
  - Contact only pre-selected participants who have given PTC
  - Use VOICE locator information
  - Use Recruitment Checklist
Scheduling the Visit

- Who, when and how to schedule date and time to interview participants?
- Who, when and how to schedule date and time for focus group discussions?
- Reminder systems?
- What if participants do not turn up?
Enrollment Process & Tips

- Obtain informed consent
  - Ideally on the day of the IDI/FGD*
- Verify eligibility per inclusion and exclusion criteria
- Assign PTID
PTID Range & Assignment

- PTID ranges per site remain the same as Stage 1
- Stage 1 participants who enroll in Stage 2 will maintain same PTID
- PTIDs for Stage 1 naïve participants will begin with those not previously assigned in Stage 1
- FGDs will be numbered in order of conduct

<table>
<thead>
<tr>
<th>Site</th>
<th>PTID Range</th>
<th>FGD # Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>MRC Isipingo</td>
<td>1001-1099</td>
<td>101-199</td>
</tr>
<tr>
<td>MRC Overport</td>
<td>2001-2099</td>
<td></td>
</tr>
<tr>
<td>UZ-UCSF</td>
<td>3001-3099</td>
<td>301-399</td>
</tr>
<tr>
<td>MUJHU</td>
<td>4001-4099</td>
<td>401-499</td>
</tr>
</tbody>
</table>
Can you list all inclusion criteria for this study?
Inclusion Criteria

1. Able and willing to perform the study procedures
2. Able and willing to provide informed consent in one of the MTN-003D study languages
3. Participated in VOICE and received at least three consecutive months of study product at any time during VOICE trial participation
4. Stage 2 participants must have PK data available

[NOTE: Women from Stage 1 who have PK data available will be considered eligible for Stage 2.]
Can you list all exclusion criteria for this study?
Exclusion Criteria

1. Has any condition that, in the opinion of the Investigator of Record (IoR)/designee, would preclude informed consent, make study participation unsafe, complicate interpretation of study outcome data, or otherwise interfere with achieving the study objectives.
The “Informed Consent Process”

- Informed consent is a process by which an individual voluntarily expresses her willingness to participate in research, after having been informed of all aspects of the research that are relevant to her decision.

- It is not merely a form or a signature, but involves information exchange, comprehension, voluntariness, and documentation.
IC Reminders

- Must be obtained before performing any MTN-003D data collection activities.
- All consent procedures should be conducted in the primary language of the participant.*
- Per DAIDS policy, each step of the IC process must be documented, either using a cover sheet or an alternate method as described in the site Informed Consent SOP.
Comprehension Assessment

- Study staff are responsible for determining whether potential participants comprehend all information required to make an informed decision about study participation before proceeding to make a final enrollment decision.
- Use the MTN-003D Stage 2 Informed Consent Comprehension Checklist as a tool in this process
# IC Comprehension Checklist

**MTN-003D Enrollment Informed Consent Comprehension Checklist**

<table>
<thead>
<tr>
<th>Open-Ended Question/Statement</th>
<th>Required Points of Comprehension</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Please tell me your understanding of the purpose of the study.</td>
<td>To better understand VOICE participant's use of study product</td>
</tr>
<tr>
<td>2. How long will the study last?</td>
<td><em>There may be only one interview and it will take about 3 hours</em></td>
</tr>
<tr>
<td>3. What are participants being asked to do in this study?</td>
<td><em>There may be one focus group discussion that will take about 3 hours</em></td>
</tr>
<tr>
<td>4. What are the possible risks for participants in the study?</td>
<td>Questions may cause embarrassment</td>
</tr>
<tr>
<td>5. What will happen if women decide not to join the study?</td>
<td>Free to make her own decision about joining the study</td>
</tr>
<tr>
<td>6. How will information about participants in the study be protected?</td>
<td>Information about participants is confidential, private, and locked away</td>
</tr>
<tr>
<td>7. What are the possible benefits for participants in the study?</td>
<td>There are no direct benefits</td>
</tr>
<tr>
<td>8. What should participants do if they have questions or concerns about their health or about what is happening in the study?</td>
<td>Must state how to contact study staff</td>
</tr>
</tbody>
</table>

**Outcome**

- [ ] Demonstrated comprehension of all required points, decided to enroll in study.
- [ ] Demonstrated comprehension of all required points, decided NOT to enroll in study.
- [ ] Demonstrated comprehension of all required points, deferred enrollment decision.
- [ ] Did not demonstrate comprehension of all required points (yet), needs more time/discussion.
- [ ] Unable to demonstrate comprehension of all required points, consent process discontinued.
- [ ] Other (specify): ____________________________________________________________________

**Optional Comment Codes**

- a. Answered correctly on first try
- b. Could not answer at first but answered correctly with probing
- c. Answered incorrectly at first but answered correctly after discussion
- d. Not able to answer correctly at this time
- e. Other (describe) ____________________________________________________________________

**Staff Signature:** ____________________________
Site Discussion

- Please describe the informed consent process at your site:
  - Where will the process will take place?
  - How will you ensure confidentiality?
  - How will it differ between IDI and FGD participants?
  - What about women who participate in an IDI and an FGD?
  - Who at your site is responsible for obtaining IC?
  - How will the process be documented?
QUESTIONS?