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

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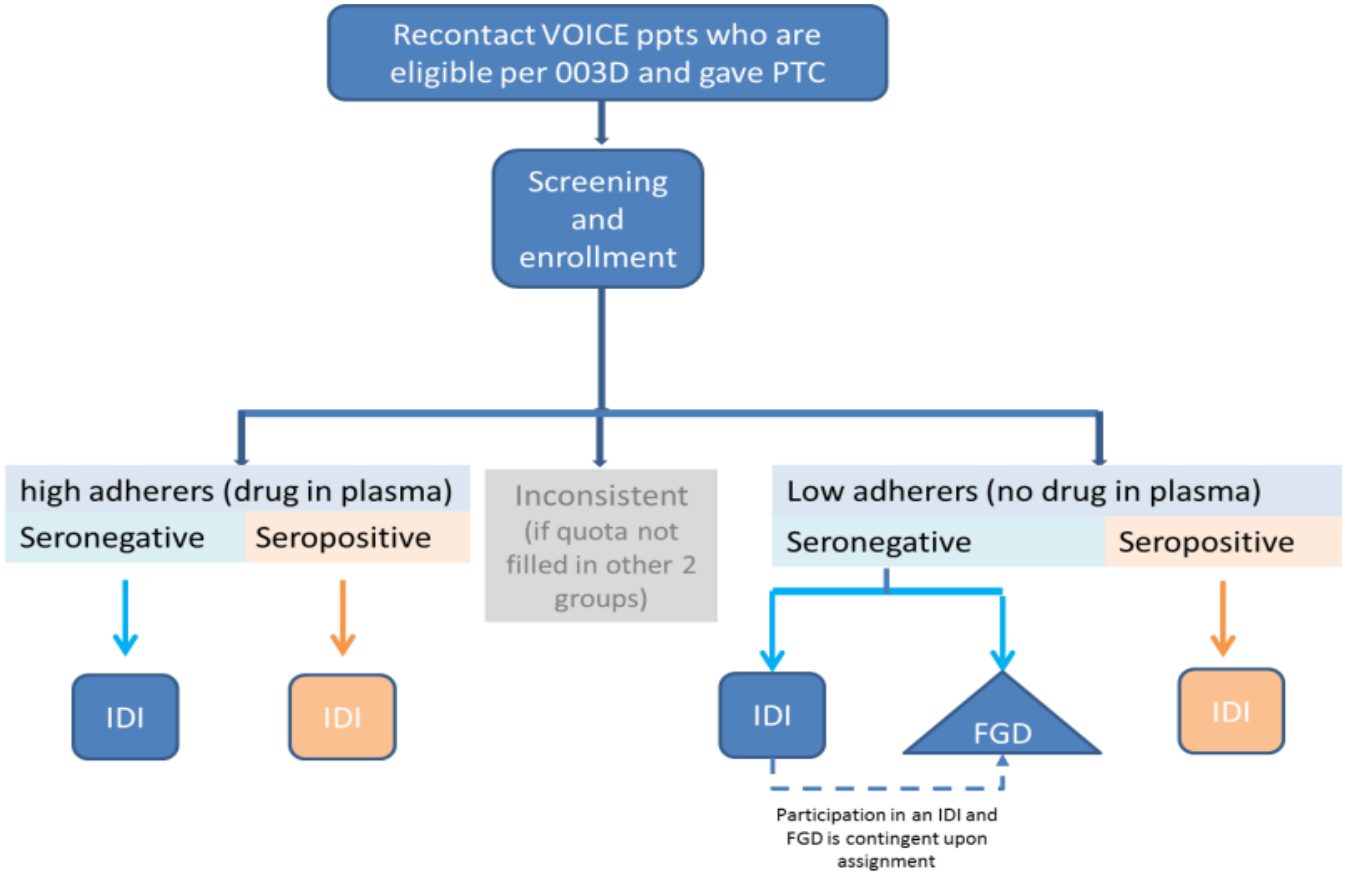
Accrual Targets per Site

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

⌂ 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



Recruitment Lists

- 8 Recruitment Lists will be generated by SCHARP

1G:	1T:	2G:	2T:
• Gel participants • HIV-negative • Low drug detection	4 IDI 2 FGD	4 IDI	• Tablet participants • HIV-negative • High drug detection
3G:	**3T:**	**4G:**	**4T:**
• Gel participants • HIV-positive • Low drug detection	2 IDI	• Gel participants • HIV-positive • High drug detection	• Tablet participants • HIV-positive • High drug detection

Recruitment List Example

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

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

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

[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

Site	PTID Range	FGD # Range
MRC Isipingo	1001-1099	101-199
MRC Overport	2001-2099	
UZ-UCSF	3001-3099	301-399
MUJHU	4001-4099	401-499

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

Name: **Date:**

	Open-Ended Question/Statement	Required Points of Comprehension	✓	Comments
1	Please tell me your understanding of the purpose of the study.	To better understand VOICE participant's use of study product		
		To better understand VOICE participant's sexual behavior		
2	How long will the study last?	There may be ~~only~~ one interview and it will take about 3 hours		
		There may be one focus group discussion that will take about 3 hours		
3	What are participants being asked to do in this study?	Answer interview questions that will be written on a form		
		Answer interview questions that will be audio-recorded		
		May be chosen to take part in group discussion		
		Questions will include information about different ways women used study product during VOICE. Will receive VOICE results and own product use test results. ~~and sexual behaviors, including anal sex~~		
4	What are the possible risks for participants in the study?	Questions may cause embarrassment		
		Others may find out about participation in the study		
		Loss of confidentiality		
5	What will happen if women decide not to join the study?	Free to make her own decision about joining the study		
		No change to her access to health care whether she joins the study or not		
6	How will information about participants in the study be protected?	Information about participants is confidential, private, and locked away		
		Only people working on the study have access to the information		
7	What are the possible benefits for participants in the study?	There are no direct benefits		
		Information provided may help researchers improve counseing materials		
8	What should participants do if they have questions or concerns about their health or about what is happening in the study?	*Must state how to contact study staff*		

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):_____

Staff Signature:

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)

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?