

MTN-003D Stage 2 FGD Visit Procedures

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FGD Individual Visit Checklist

Stage 2 FGD Individual Participant Visit Checklist

MTN-003D PTID:		FGD No.:	Visit Date:
Initials	Procedures		
Participant Arrival, IC & Data Collection			
Confirm participant identity			
<i>[If participant has not already participated in a Stage 2 IDI:]</i>			
Explain, conduct, and document informed consent process per site SOPs:			
<input type="checkbox"/> Willing and able to provide written informed consent ⇒ CONTINUE, have participant sign ICF, collect signed form, and offer a copy for participant to take home.			
<input type="checkbox"/> NOT willing and able to provide written informed consent ⇒ STOP, provide participant reimbursement and thank her for her time. Document in PSF and participant file notes.			
Confirm eligibility criteria:			
<input type="checkbox"/> ELIGIBLE ⇒ CONTINUE.			
<input type="checkbox"/> NOT ELIGIBLE ⇒ STOP. Document in Participant Status Form (PSF) and participant file notes.			
<i>[If participant has not already participated in a Stage 2 IDI:]</i>			
<ul style="list-style-type: none"> • Administer Demographic Information Form (DEM) • Conduct sections A-B of the discussion guide • Complete PK Discussion Response on the PSF (Q 8) 			
Post FGD (Immediately following FGD)			
Complete PSF			
Comments: <i>Initial and date all comments.</i>			

- Step-by-step guide to individual visit procedures for the FGD participants
- Each line to be completed (or write “NA”)

FGD Group Visit Checklist

Stage 2 FGD Group Visit Checklist

FGD No.:		Visit Date:
Initials	Procedures	
Preparation		
Audio-recorder checked (power supply, extra batteries, etc.)		
Supplies gathered: pen and stationery for note-taking, consent forms, PSFs, discussion guide, refreshments (if applicable), reimbursements		
Verification of participant status (PK results and study product group)		
Participant Arrival, IC & Data Collection		
Greet participants and offer refreshments		
Complete procedures with all individual FGD participants as outlined on the FGD Individual Participant Visit Checklist.		
Review FGD ground rules: <ul style="list-style-type: none"> • No right or wrong answers • Use pseudonyms when providing responses • Information shared remains confidential • Cell phone off 		
Conduct sections A & C of Stage 2 Discussion Guide		
Thank and reimburse the participants		
Post FGD (Immediately following FGD)		
Check audio recording to verify that the session was properly recorded.		
Expand notes and complete debriefing report		
Comments: <i>Initial and date all comments.</i>		

- Step-by-step guide to FGD group visit procedures
- Each line to be completed (or write “NA”)

FGD Preparation

- ✓ Time confirmed with participants
- ✓ Appropriate space for discussion identified and reserved
- ✓ Current versions of ICF, discussion guide, other tools (e.g. PK visuals, theme cards, etc.) and checklists
- ✓ Audio-recorder charged, has batteries, and tested that day for functionality
- ✓ **Verify all participants' status (i.e. PK results, study product group)**



Outline of Individual Visit Procedures

- Confirm identity
- Informed consent
- Confirm eligibility
- Demographic Information (DEM) form
- Conduct sections A-B of guide
- Fill out/note PK Response for/on Participant Status Form (PSF)
- [*Switch to FGD group procedures*]
- Complete PSFs for all individuals



Outline of FGD Group Procedures

- Conduct sections A & C of discussion guide with FGD group
- Thank and reimburse participants



FGD Procedures: the Beginning

- Greet participants
- Offer refreshments
- Review FGD ground rules



FGD Procedures: the Middle

- Discussion will follow guide
 - Primary research *topics* numbered and appear in gray
 - Primary research *questions* in bold
 - Probes bulleted
- Notes to be taken on separate sheets of paper
 - Separate sheets must be labeled with all participant PTIDs, date, and staff initials



FGD Procedures: the Middle

- The guide is a guide, not a script.
Interview should flow naturally and flexibly
 - Acceptable to jump around
 - Acceptable to probe on spontaneous, relevant issues
 - Acceptable to rephrase probes
- However...
 - Ensure primary research topics/questions are addressed

(Re-)Conduct Section A

Section A. Use the following talking points as a guide for IDI participants and during both the individual consent period and the group discussion for FGD participants.

1. **Impression of the VOICE Results**

(For women from Stage 1: emphasize that we are still trying to understand VOICE, and that at the time when she was interviewed previously we did not have blood test results).

English: **We would like to understand why so many women in VOICE did not take their products consistently so we can design products that women can take and improve future studies for HIV prevention. Since YOU are the expert, please help us by explaining your experience in VOICE.**

Translation:

Additional Probes (Get feedback on the following specific points):

- Neither of the two tablets (Truvada or tenofovir) nor the gel were found to be effective in preventing HIV in VOICE
- When researchers looked at VOICE participants' blood tests they found that a majority of the women in VOICE (this means thousands of women) never had any drug from the study products in their blood.
- Because of these blood tests showing that women were not taking the products in VOICE, researchers could not determine if the products were protective against HIV.
- There are several other studies that were conducted more or less at the same time as VOICE, in Africa and other parts of the world that indicated that the products are protective against HIV, when they are taken consistently as directed.

Available tools: *e.g. MTN press release, educational sheet for study results; local press clippings*

Conduct Section C

Section C. Use the following talking points for IDI participants and FGD participants in the group discussion setting.

3. Factors influencing adherence (spontaneously derived)
(Note the importance of eliciting all the reasons the participant spontaneously mentions as influencing adherence before probing on specific topics)

English:

- [For women with **low drug** detection:] **What are all the reasons you were not able to take your products?**
- [For women with **high/inconsistent drug** detection:] **the drug data show that you took the product [some of/ most of/ all of] the time prior to coming to the study visits... What are all the reasons you were able to [some of/ most of/ all of] the time, take your products?**

Translation:

- [For women with **low drug** detection:]
- [For women with **high/inconsistent drug** detection:]

4. All other factors influencing adherence (probing topics)

- [For IDI participants]: Do key theme card exercise.
- [For FGDs]: Use cards to facilitate conversations....

Additional Probes:

[For women with low drug detection:]

- What was happening (that influenced you not taking product)?
- How did reasons for non-use change over time, or did the reasons stay the same?

[For women with high/inconsistent drug detection:]

- How much did the visit act as a reminder to take the products?
- What situations or circumstances made it easier or more difficult to take the product daily?
What was happening (that influenced you taking product)?



FGD Procedures: the End

- Thank and reimburse participants



Post-FGD Procedures

1. Complete Participant Status Form (PSF) for all participants
2. Interviewers and note-takers: check recording and expand notes, if necessary
3. Review CRFs for completeness and clarity
4. Complete FGD Debrief Report template



PSFs for Enrolled Participants

- Captures
 - MTN-003D PTID,
 - VOICE PTID,
 - Stage 1 and Stage 2 status,
 - Drug detection level and response to PK results,
 - Enrollment, interview and termination dates
 - Reason for termination
- Will differ for potential FGD sparks

Ex. 2: FGD Ppt Only

MTN-003D PTID

1 0 9 8

Date Form Initiated

23 SEP 13
dd MMM yy

MTN-003D Stage 2 Participant Status Form (PSF)			
<i>Instructions: This form is to be completed for any MTN-003D participant who is considered for Stage 2 participation.</i>			
1.	Complete VOICE PTID	1 2 3 - 0 0 6 5 0 - 8	
		Yes	No
2.	Was the participant enrolled in MTN-003D Stage 1? (If yes, PTID will remain the same as Stage 1)	<input type="checkbox"/> ₁	<input checked="" type="checkbox"/> ₂
3.	Was the participant enrolled in MTN-003D Stage 2?	<input checked="" type="checkbox"/> ₁	<input type="checkbox"/> ₂ GO TO 12
4.	Date of enrollment in MTN-003D Stage 2:	23 SEP 13 dd MMM yy	
5.	Date MTN-003D Stage 2 IDI conducted (record date or check N/A):	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> or <input checked="" type="checkbox"/> N/A	
6.	Date MTN-003D Stage 2 FGD conducted (record date or check N/A):	23 SEP 13 or <input type="checkbox"/> N/A → GO TO 8	
7.	FGD Participant Pseudonym:	Kiw	
8.	What is the participant's drug detection level classification (mark one)?	<input checked="" type="checkbox"/> ₁ Low drug <input type="checkbox"/> ₂ Inconsistent drug <input type="checkbox"/> ₃ High drug	

9.	Record your assessment of the participant's physical/emotional reaction upon hearing her PK results. <i>(Select all that apply)</i>	<input type="checkbox"/> ₁ Anger <input checked="" type="checkbox"/> ₁ Distress/ Unhappiness <input type="checkbox"/> ₁ Fear <input type="checkbox"/> ₁ Happiness <input type="checkbox"/> ₁ Sadness <input type="checkbox"/> ₁ Surprise <input type="checkbox"/> ₁ Disbelief <input type="checkbox"/> ₁ Other, specify: _____														
10.	Date of termination from MTN-003D Stage 2:	<table border="1" style="display: inline-table; border-collapse: collapse;"> <tr> <td style="padding: 2px;">2</td> <td style="padding: 2px;">3</td> <td style="padding: 2px;">S</td> <td style="padding: 2px;">E</td> <td style="padding: 2px;">P</td> <td style="padding: 2px;">1</td> <td style="padding: 2px;">3</td> </tr> <tr> <td colspan="2" style="text-align: center;">dd</td> <td colspan="3" style="text-align: center;">MMM</td> <td colspan="2" style="text-align: center;">yy</td> </tr> </table>	2	3	S	E	P	1	3	dd		MMM			yy	
2	3	S	E	P	1	3										
dd		MMM			yy											
11.	Reason for termination from MTN-003D Stage 2 <i>(mark one)</i> :	<input checked="" type="checkbox"/> ₁ Participant completed study <input type="checkbox"/> ₂ Inappropriate enrollment <input type="checkbox"/> ₃ Other, specify: _____ →END FORM														
12.	Reason for non-enrollment in MTN-003D Stage 2 <i>(mark one)</i> :	<input type="checkbox"/> ₁ Did not give permission to be contacted <input type="checkbox"/> ₂ Contacted, but refused participation, specify: _____ <input type="checkbox"/> ₃ Scheduled three times, did not show <input type="checkbox"/> ₄ Eligibility criteria not met, specify: _____ <input type="checkbox"/> ₅ Did not provide written informed consent <input type="checkbox"/> ₆ Other, specify: _____														
Comments: <hr/> <hr/>																

Ex. 2: FGD Spark Participant

MTN-003D PTID

3 2 1 4

Date Form Initiated

1 8 S E P 1 3
 dd MMM yy

MTN-003D Stage 2 Participant Status Form (PSF)	
<i>Instructions: This form is to be completed for any MTN-003D participant who is considered for Stage 2 participation.</i>	
1. Complete VOICE PTID	3 2 1 4 - 0 0 9 6 4 - 5
	Yes No
2. Was the participant enrolled in MTN-003D Stage 1? (If yes, PTID will remain the same as Stage 1)	<input checked="" type="checkbox"/> ₁ <input type="checkbox"/> ₂
3. Was the participant enrolled in MTN-003D Stage 2?	<input checked="" type="checkbox"/> ₁ <input type="checkbox"/> ₂ <small>GO TO 12</small>
4. Date of enrollment in MTN-003D Stage 2:	1 8 S E P 1 3 <small>dd MMM yy</small>
5. Date MTN-003D Stage 2 IDI conducted (record date or check N/A):	1 8 S E P 1 3 or <input type="checkbox"/> <small>dd MMM yy N/A</small>
6. Date MTN-003D Stage 2 FGD conducted (record date or check N/A):	2 3 S E P 1 3 or <input type="checkbox"/> <small>dd MMM yy N/A → GO TO 8</small>
7. FGD Participant Pseudonym:	Apple
8. What is the participant's drug detection level classification (mark one)?	<input checked="" type="checkbox"/> ₁ Low drug <input type="checkbox"/> ₂ Inconsistent drug <input type="checkbox"/> ₃ High drug
9. Record your assessment of the participant's physical/emotional reaction upon hearing her PK results. (Select all that apply)	<input type="checkbox"/> ₁ Anger <input type="checkbox"/> ₁ Distress/ Unhappiness <input type="checkbox"/> ₁ Fear <input type="checkbox"/> ₁ Happiness <input type="checkbox"/> ₁ Sadness <input type="checkbox"/> ₁ Surprise <input type="checkbox"/> ₁ Disbelief <input checked="" type="checkbox"/> ₁ Other, specify: <u>Acceptance</u>

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9.	Record your assessment of the participant's physical/emotional reaction upon hearing her PK results. <i>(Select all that apply)</i>	<input type="checkbox"/> ₁ Anger <input type="checkbox"/> ₁ Distress/ Unhappiness <input type="checkbox"/> ₁ Fear <input type="checkbox"/> ₁ Happiness <input type="checkbox"/> ₁ Sadness <input type="checkbox"/> ₁ Surprise <input type="checkbox"/> ₁ Disbelief <input checked="" type="checkbox"/> Other, specify: <u>Acceptance</u>
10.	Date of termination from MTN-003D Stage 2:	<div style="display: flex; justify-content: space-around; align-items: center;"> 2 3 S E P 1 3 </div> <div style="display: flex; justify-content: space-around; margin-top: 5px;"> dd MMM yy </div>
11.	Reason for termination from MTN-003D Stage 2 <i>(mark one)</i> :	<input checked="" type="checkbox"/> ₁ Participant completed study <input type="checkbox"/> ₂ Inappropriate enrollment <input type="checkbox"/> ₃ Other, specify: _____ →END FORM
12.	Reason for non-enrollment in MTN-003D Stage 2 <i>(mark one)</i> :	<input type="checkbox"/> ₁ Did not give permission to be contacted <input type="checkbox"/> ₂ Contacted, but refused participation, specify: _____ <input type="checkbox"/> ₃ Scheduled three times, did not show <input type="checkbox"/> ₄ Eligibility criteria not met, specify: _____ <input type="checkbox"/> ₅ Did not provide written informed consent <input type="checkbox"/> ₆ Other, specify: _____
Comments: <hr/> <hr/>		

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Debrief Report

- Purpose: To provide a summary of the participants' attitudes towards the key themes, the mood of the discussion, whether it was dominated by certain participants, unique comments, and any other important information in **REAL TIME**
- Will be discussed on study team calls and shared across sites.

MTN-003D
Stage 2 FGD Debriefing Report

Instructions: This report is to be completed on the same day as the FGD, and forwarded to RTI within one week of FGD completion. This report should be sent via email as a Word document.

Basic FGD Information:

FGD No.:	FGD Date:
PTIDs:	Facilitator #1:
Study Arm:	Facilitator #2:
CRS/CTU:	Note-taker:
FGD Venue:	Person Completing Form:

Debriefing Summary:

1. How did the FGD go today? *(Describe in detail your subjective impressions of how the participants behaved, their emotional reactions [excited, sad, laughed, bored, confused, disappointed etc.], and any other important information about the context and experience. Comment on whether the discussion was monopolized by few participants or if there was more equal contribution to the discussion from most or all participants.)*
[Redacted]
2. Overall, how did participants from this FGD react to the individually presented PK result discussions? *(Record which visual representation was used to describe results to these participants, if any, as well as details about the participants' emotional/physical reaction that expands upon the individual reactions recorded on the PSFs.)*
[Redacted]
3. What were the most important themes or ideas discussed? *(Describe in detail the most important ideas discussed within each of the main topic areas and any important issues that were raised.)*
 - a. Impression of VOICE Results:
[Redacted]
 - b. Factors Affecting Adherence *(distinguish between factors spontaneously mentioned and those discussed upon probing or based on the theme cards):*
[Redacted]
 - c. Motivation to Join/Stay in the Trial:
[Redacted]

d. Recommendations for Future Trials/Products:
[Redacted]

4. Theme identification exercise (if done):

a. New Themes *(write out any new themes identified as relevant):*
[Redacted]

b. Relevant Cards *(Record card codes or descriptions (for new themes, if applicable) in order from most relevant to least relevant, as determined by the participants):*
[Redacted]

c. Not Relevant *(record codes):*
[Redacted]

d. Not Sure/Undecided *(record codes):*
[Redacted]

5. Were there any unexpected or unanticipated findings? *(Record anything unexpected, unanticipated, or new that was learned from this FGD)*
[Redacted]



QUESTIONS?
