

MTN-003D Stage 2 IDI Visit Procedures

Miriam Hartmann, MPH

Women's Global Health Imperative

RTI International

San Francisco, CA, USA



IDI Visit Checklist

Stage 2 IDI Visit Checklist

MTN-003D PTID:		Visit Date:
Initials	Procedures	
Preparation		
Audio-recorder checked (power supply, extra batteries, etc.)		
Supplies gathered: pen and stationery for note-taking, consent form, discussion guide, refreshments (if applicable), reimbursement		
Verification of participant status (PK results, HIV status, and study product group)		
Participant Arrival, IC & Data Collection		
Greet participant and offer refreshments		
Confirm participant identity		
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.		
Administer Demographic Information Form (DEM)		
Review IDI 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-B of the Stage 2 Discussion Guide		
Complete PK Response section of PSF or note response to PK discussion in interview notes and record on PSF immediately following IDI.		
Conduct section C of the Stage 2 Discussion Guide, including completion of the theme card exercise.		
<i>[For HIV positive participants]</i> Conduct section D of the Stage 2 Discussion Guide.		
FGD Determination Is participant HIV negative, with "low drug detection" levels, and was open about non-adherence during this IDI? <input type="checkbox"/> Yes <input type="checkbox"/> No Is participant willing to join an FGD with her peers? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A [participant did not meet above criteria]		

- Step-by-step guide to visit procedures
- Each line to be completed (or write "NA")

IDI Preparation

- ✓ Time confirmed with participant
- ✓ Appropriate space for interview 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 participant status (i.e. PK results, HIV status, study product group)**



Outline of Visit Procedures

- Confirm identity
- Informed consent
- Confirm eligibility
- Demographic Information (DEM) form
- Begin IDI
- Fill out/note PK Response for/on Participant Status Form (PSF)
- Complete IDI
- Complete PSF



IDI Procedures: the Beginning

- ❑ Greet participant
- ❑ Confirm identity
 - *How will this be done?*
- ❑ Explain, conduct and document written informed consent
- ❑ Confirm eligibility criteria
 - *What needs to be verified? How will this be done?*



Demographic (DEM) Form

- No changes from Stage 1
- Interviewer-administered prior to IDI
- Available in English and local language
- 30 questions:
 - Some new information
 - Some verbatim to VOICE CRF data to record updates/ changes since VOICE data captured



DEM Form

- CRF:
 - Complete all header and footer items: PTID, date, initials and date
 - Follow GCP in completing each question and making corrections (initial and date)
 - Use blue or black ink
 - Question guide on the reverse side

--	--	--	--

--	--

dd

--	--	--

MMM

--	--

yy

MTN-003D Demographic Information Form (DEM)

INTERVIEWER READS: The following are some basic questions regarding your background to help us know what type of people participated in the discussion for this study. All the information you provide will be kept confidential and will not be shared with anyone else besides the research study staff.

1.	What is your date of birth?	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> or dd MMM yy If unknown, record age: <input type="text"/> <input type="text"/>
2.	How many children have you had who were alive at birth?	<input type="text"/> <input type="text"/>
3.	How many total children are you currently taking care of (i.e. children, grandchildren, etc.)?	<input type="text"/> <input type="text"/>
4.	What is your ethnic group or tribe? (<i>mark ethnic group/tribe code</i>)	<input type="text"/> <input type="text"/> Ethnic Tribe Code <input type="checkbox"/> ₉₉ Other, specify: _____
5.	What is the language most spoken at home? (<i>mark language code</i>)	<input type="text"/> <input type="text"/> Language Code <input type="checkbox"/> ₉₉ Other, specify: _____
6.	Do you currently earn an income of your own?	<input type="checkbox"/> ₁ Yes <input type="checkbox"/> ₂ No → If No, go to item 8
7.	How do you earn your current income? (<i>mark all that apply</i>)	<input type="checkbox"/> ₁ Formal employment <input type="checkbox"/> ₂ Self-employment <input type="checkbox"/> ₃ Other, specify: _____

8.	What is your highest level of education? (<i>mark one</i>)	<input type="checkbox"/> ₁ No schooling <input type="checkbox"/> ₂ Primary school, not complete <input type="checkbox"/> ₃ Primary school, complete <input type="checkbox"/> ₄ Secondary school, not complete <input type="checkbox"/> ₅ Secondary school, complete <input type="checkbox"/> ₆ Attended college or university
9.	What is your religion? (<i>mark one</i>)	<input type="checkbox"/> ₁ Christian <input type="checkbox"/> ₂ Muslim <input type="checkbox"/> ₃ Other specify: _____ <input type="checkbox"/> ₄ None → If None, go to item 11
10.	How many times a week do you attend religious services? (<i>mark one</i>)	<input type="checkbox"/> ₁ More than once a week <input type="checkbox"/> ₂ Once a week <input type="checkbox"/> ₃ Less than once a week <input type="checkbox"/> ₄ Never
11.	Name of area/location where you currently live:	_____
12.	For how long have you lived in this location/area? (<i>mark one</i>)	<input type="text"/> <input type="text"/> or <input type="text"/> <input type="text"/> months years
13.	Do you consider this your home?	<input type="checkbox"/> ₁ Yes <input type="checkbox"/> ₂ No, <i>specify</i> _____
14.	Do you, or does someone in your family, own the household you are currently living in?	<input type="checkbox"/> ₁ Yes <input type="checkbox"/> ₂ No

15.	How many rooms are in the household you are currently living in?	<input type="text"/> <input type="text"/>
16.	Does your household have:...? (<i>read options and mark all that apply</i>)	<input type="checkbox"/> ₁ Electricity <input type="checkbox"/> ₂ A radio <input type="checkbox"/> ₃ A television <input type="checkbox"/> ₄ A mobile telephone <input type="checkbox"/> ₅ A non-mobile telephone <input type="checkbox"/> ₆ A refrigerator
17.	What kind of toilet facility does your household have? (<i>mark toilet facility code</i>)	<input type="text"/> <input type="text"/> Toilet Facility Code <input type="checkbox"/> ₉₉ Other, specify: _____
18.	What is the main source of drinking water for members of your household? (<i>mark water source code</i>)	<input type="text"/> <input type="text"/> Water Source Code <input type="checkbox"/> ₉₉ Other, specify: _____
19.	Do you own a mobile phone?	<input type="checkbox"/> ₁ Yes <input type="checkbox"/> ₂ No
20.	Are you currently married?	<input type="checkbox"/> ₁ Yes → if Yes, go to item 22 <input type="checkbox"/> ₂ No
21.	Do you currently have a primary sex partner? By primary sex partner, I mean a person you have sex with on a regular basis or who you consider to be your main partner.	<input type="checkbox"/> ₁ Yes <input type="checkbox"/> ₂ No → if No, go to 29
22.	Is your [husband/primary sex partner] the same partner you had when you <u>exited</u> VOICE?	<input type="checkbox"/> ₁ Yes <input type="checkbox"/> ₂ No

23.	For how long have you had this partner? (<i>mark one</i>)	<input type="text"/> <input type="text"/> or <input type="text"/> <input type="text"/> months years
24.	How old is your [husband/primary sex partner]?	<input type="text"/> <input type="text"/> <input type="checkbox"/> ₉₉ Don't Know
25.	Are you currently living with your [husband/primary sex partner]?	<input type="checkbox"/> ₁ Yes <input type="checkbox"/> ₂ No
26.	Does he provide you with financial and/or material support?	<input type="checkbox"/> ₁ Yes <input type="checkbox"/> ₂ No
27.	Does he have any sex partners other than you?	<input type="checkbox"/> ₁ Yes <input type="checkbox"/> ₂ No <input type="checkbox"/> ₃ Don't Know
28.	In the past 3 months , have you had vaginal sex with your primary sex partner? By vaginal sex we mean when a man puts his penis inside of your vagina.	<input type="checkbox"/> ₁ Yes <input type="checkbox"/> ₂ No
29.	In the past 3 months , with how many other male partners have you had vaginal sex? By other male partners, we mean any man who is not your primary sex partner.	<input type="text"/> <input type="text"/>
30.	In total, how many different people have you had vaginal sex with in your lifetime ?	<input type="text"/> <input type="text"/>

IDI Procedures: the Middle

- Interview 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 PTID, date and staff initials

IDI 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

Conduct Sections A-B

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*

Section B. Use the following talking points for IDI participants and during the individual consent period for FGD participants.

2. **Participant's own PK results**

Capture Reaction to PK Results

- Record on PSF or make a note of the participant's reaction
- If noted elsewhere during IDI, be familiar with response options on PSF

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 Fear <input type="checkbox"/> ₁ Sadness <input type="checkbox"/> ₁ Disbelief	<input type="checkbox"/> ₁ Distress/ Unhappiness <input type="checkbox"/> ₁ Happiness <input type="checkbox"/> ₁ Surprise <input type="checkbox"/> ₁ Other, specify: _____
----	---	---	---

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)?

Conduct Section D [*HIV+ Women*]

Section D. Use the following talking points for IDI participants who have seroconverted:

8. Experience of product use and seroconversion

English: If it's okay with you, I'd like to talk more about your HIV sero-status...What in your view may have contributed to you getting HIV?

Translation:

Additional Probes:

- Was there any particular time or event where you think you may have gotten HIV?
- Have you had any recent changes in personal life, behaviors or circumstances that may have contributed to your getting HIV?
- What was your experience with taking the study product, both good and bad?
- What do you think about your participation in VOICE now, with all that happened to you?

CLOSING: Thank the participant for her invaluable contribution to the research and ask her if she has any questions or comments.



IDI Procedures: the End

- [*If participant is HIV negative, had “low drug detection” levels, and has been open about non-adherence*] ask if she would be willing to join an FGD of her peers.
- Thank and reimburse participant



Social Harms Form

- Social harms related or unrelated to VOICE and/or MTN-003D may be mentioned during interview
- No changes to form or procedures from Stage 1
- Slides from Protocol Training on SHs available at:
<http://www.mtnstopshiv.org/node/4639>



Post-Interview Procedures

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



PSFs for Enrolled IDI 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. 1: IDI Ppt Only

MTN-003D PTID

3 2 1 4

Date Form Initiated

20 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	3 2 1 - 7 8 9 1 0 - 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 GO TO 12
4.	Date of enrollment in MTN-003D Stage 2:	20 SEP 13 dd MMM yy	
5.	Date MTN-003D Stage 2 IDI conducted (record date or check N/A):	20 SEP 13 or <input type="checkbox"/> dd MMM yy N/A	
6.	Date MTN-003D Stage 2 FGD conducted (record date or check N/A):	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> or <input checked="" type="checkbox"/> dd MMM yy N/A → GO TO 8	
7.	FGD Participant Pseudonym:	_____	
8.	What is the participant's drug detection level classification (mark one)?	<input type="checkbox"/> ₁ Low drug <input type="checkbox"/> ₂ Inconsistent drug <input checked="" 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 type="checkbox"/> ₁ Distress/ Unhappiness <input type="checkbox"/> ₁ Fear <input checked="" type="checkbox"/> 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:	<div style="display: flex; justify-content: space-around; align-items: center;"> 2 0 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/> <hr/>		

Ex. 2: IDI Ppt [*Potential FGD Spark*]

MTN-003D PTID

1 2 3 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	1 2 3 - 4 5 6 7 8 - 9				
2.	Was the participant enrolled in MTN-003D Stage 1? (If yes, PTID will remain the same as Stage 1)	<table border="1"> <tr> <th>Yes</th> <th>No</th> </tr> <tr> <td><input checked="" type="checkbox"/>₁</td> <td><input type="checkbox"/>₂</td> </tr> </table>	Yes	No	<input checked="" type="checkbox"/> ₁	<input type="checkbox"/> ₂
Yes	No					
<input checked="" type="checkbox"/> ₁	<input type="checkbox"/> ₂					
3.	Was the participant enrolled in MTN-003D Stage 2?	<table border="1"> <tr> <th>Yes</th> <th>No</th> </tr> <tr> <td><input checked="" type="checkbox"/>₁</td> <td><input type="checkbox"/>₂</td> </tr> </table> <p style="text-align: right;">GO TO 12</p>	Yes	No	<input checked="" type="checkbox"/> ₁	<input type="checkbox"/> ₂
Yes	No					
<input checked="" type="checkbox"/> ₁	<input type="checkbox"/> ₂					
4.	Date of enrollment in MTN-003D Stage 2:	1 8 S E P 1 3 dd MMM yy				
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"/> dd MMM yy N/A				
6.	Date MTN-003D Stage 2 FGD conducted (record date or check N/A):	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> or <input type="checkbox"/> dd MMM yy N/A → GO TO 8				
7.	FGD Participant Pseudonym:	_____				
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 type="checkbox"/> ₁ Distress/ Unhappiness <input type="checkbox"/> ₁ Fear <input type="checkbox"/> ₁ Happiness <input type="checkbox"/> ₁ Sadness <input checked="" type="checkbox"/> ₁ Surprise <input type="checkbox"/> ₁ Disbelief <input type="checkbox"/> ₁ Other, specify: _____
10.	Date of termination from MTN-003D Stage 2:	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> dd MMM yy
11.	Reason for termination from MTN-003D Stage 2 <i>(mark one)</i> :	<input 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: _____ _____		



PSFs for Those Not Enrolled

- A PSF should be completed for all those randomly preselected to be part of MTN-003D who are considered for enrollment

Ex. 1: Did Not Give PTC

MTN-003D PTID

9 9 9 9

Date Form Initiated

1 9 S E P 1 3
 dd MMM yy

MTN-003D Stage 2 Participant Status Form (PSF)

Instructions: This form is to be completed for any MTN-003D participant who is considered for Stage 2 participation.

1. Complete VOICE PTID 2 0 2 - 3 5 6 2 1 - 7

		Yes	No
2.	Was the participant enrolled in MTN-003D Stage 1? <i>(If yes, PTID will remain the same as Stage 1)</i>	<input type="checkbox"/> ₁	<input checked="" type="checkbox"/> ₂
3.	Was the participant enrolled in MTN-003D Stage 2?	<input type="checkbox"/> ₁	<input checked="" type="checkbox"/> ₂ GO TO 12
4.	Date of enrollment in MTN-003D Stage 2:	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> dd MMM yy	
5.	Date MTN-003D Stage 2 IDI conducted <i>(record date or check N/A)</i> :	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> or <input type="checkbox"/> dd MMM yy N/A	
6.	Date MTN-003D Stage 2 FGD conducted <i>(record date or check N/A)</i> :	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> or <input type="checkbox"/> dd MMM yy N/A → GO TO 8	
7.	FGD Participant Pseudonym:	_____	

8.	What is the participant's drug detection level classification (<i>mark one</i>)?	<input 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 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:	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> dd MMM yy
11.	Reason for termination from MTN-003D Stage 2 (<i>mark one</i>):	<input 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 checked="" 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: _____ _____		

Ex. 2: “No Show”

MTN-003D PTID

4	3	0	0
--------------	--------------	--------------	--------------

9999
 MAT 30/OCT/13

Date Form Initiated

2	3	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	414-62310-5																
		<table border="1"> <tr> <th>Yes</th> <th>No</th> </tr> <tr> <td><input type="checkbox"/></td> <td><input checked="" type="checkbox"/></td> </tr> </table>	Yes	No	<input type="checkbox"/>	<input checked="" type="checkbox"/>												
Yes	No																	
<input type="checkbox"/>	<input checked="" type="checkbox"/>																	
2.	Was the participant enrolled in MTN-003D Stage 1? (If yes, PTID will remain the same as Stage 1)	<table border="1"> <tr> <td><input type="checkbox"/></td> <td><input checked="" type="checkbox"/></td> </tr> </table>	<input type="checkbox"/>	<input checked="" type="checkbox"/>														
<input type="checkbox"/>	<input checked="" type="checkbox"/>																	
3.	Was the participant enrolled in MTN-003D Stage 2?	<table border="1"> <tr> <td><input type="checkbox"/></td> <td><input checked="" type="checkbox"/></td> </tr> </table> GO TO 12	<input type="checkbox"/>	<input checked="" type="checkbox"/>														
<input type="checkbox"/>	<input checked="" type="checkbox"/>																	
4.	Date of enrollment in MTN-003D Stage 2:	<table border="1"> <tr> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> </tr> <tr> <td colspan="2">dd</td> <td colspan="3">MMM</td> <td>yy</td> </tr> </table>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	dd		MMM			yy				
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>													
dd		MMM			yy													
5.	Date MTN-003D Stage 2 IDI conducted (record date or check N/A):	<table border="1"> <tr> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td>or</td> <td><input type="checkbox"/></td> </tr> <tr> <td colspan="2">dd</td> <td colspan="3">MMM</td> <td>yy</td> <td></td> <td>N/A</td> </tr> </table>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	or	<input type="checkbox"/>	dd		MMM			yy		N/A
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	or	<input type="checkbox"/>											
dd		MMM			yy		N/A											
6.	Date MTN-003D Stage 2 FGD conducted (record date or check N/A):	<table border="1"> <tr> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td>or</td> <td><input type="checkbox"/></td> </tr> <tr> <td colspan="2">dd</td> <td colspan="3">MMM</td> <td>yy</td> <td></td> <td>N/A → GO TO 8</td> </tr> </table>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	or	<input type="checkbox"/>	dd		MMM			yy		N/A → GO TO 8
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	or	<input type="checkbox"/>											
dd		MMM			yy		N/A → GO TO 8											
7.	FGD Participant Pseudonym:																	

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 type="checkbox"/> ₁ Other, specify: _____
10.	Date of termination from MTN-003D Stage 2:	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> dd MMM yy
11.	Reason for termination from MTN-003D Stage 2 <i>(mark one)</i> :	<input 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 checked="" 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:

Participant scheduled on 23/SEP/13 did not show. Rescheduled for 25/SEP/13, did not show. Rescheduled again for 30/OCT/13 and did not show. No response when called.



IDI Debrief Report

- Purpose: To provide a summary of the participant's attitudes towards the key themes, participant mood, 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 IDI Debriefing Report

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

Basic IDI Information:

PTID: [REDACTED]	IDI Date: [REDACTED]
Study Arm: [REDACTED]	Interviewer #1: [REDACTED]
Drug Level Classification: [REDACTED]	Interviewer #2: [REDACTED]
Participated in Stage 1 [Y/N]: [REDACTED]	Note-taker: [REDACTED]
CRS/CTU: [REDACTED]	Person Completing Form: [REDACTED]
IDI Venue: [REDACTED]	

Debriefing Summary:

1. How did the IDI go today? (Describe in detail your subjective impressions of how the participant behaved, their emotional reactions [excited, sad, laughed, bored, confused, disappointed etc.], and any other important information about the context and experience)
[REDACTED]
2. How did the participant respond to the PK results discussion? (Record which visual representation was used to describe results to the participant, if any, as well as details about the participant's emotional/physical reaction that expand upon their reaction recorded on the PSF)
[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; include issues discussed during the theme card exercise, however record card codes in item 3, below):
[REDACTED]
 - c. Motivation to Join/Stay in the Trial:
[REDACTED]

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

e. [For HIV+ participants] HIV Sero-conversion Experience:
[REDACTED]

4. Record the numeric card codes selected during the theme identification exercise:

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 participant):
[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 IDI)
[REDACTED]



QUESTIONS?
