**MTN-003D**

In-depth Interview Topic Guide

**INSTRUCTIONS for the Interviewer: How to use the IDI Guide**

1. There are two levels of questions:

* Primary interview questions: are the numbered questions. They are the questions that you as the interviewer must ask participants.
* Probes: are indicated with a bullet. The interviewer should ensure that key topics listed in the probes have been addressed/discussed during the interview. So, depending on what has already been discussed, and the IDI context, you may ask these probes or not.
1. *Instructions/suggestions to interviewer are in italics.*
2. The IDI guide is divided into two columns.
* **The left-hand column** contains the research questions, IDI questions and probes. The IDI questions are suggestions for getting the discussion going. It is not required to read them verbatim, but they are written to ensure some consistency across IDIs. You may adapt the question, depending on how the interview develops, and the interviewer will have to ensure that at the end all the questions have been answered.
* **The right-hand column** is for summarising the themes brought up by the counselors in the IDI. These should be summaries of the general issues raised in connection with the question. They do not need to be detailed, as we have the details on the tape. **Note: the summaries should be filled by the IDI interviewer immediately after the IDI.**

**Before starting the IDI, ensure the participant has provided informed consent.**

**[*Read Introduction*]**: My name is \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. Thank you again for your willingness to be a part of this discussion. I am looking forward to hearing your thoughts on the questions I will ask you. Please know there are no right or wrong answers and we welcome every opinion about the topics we will discuss, so feel free to share your thoughts openly. If during our discussion, there are issues or concerns that you would like to talk about, feel free to bring them up, even if I didn’t ask about them.

As I mentioned before, the main goal of this study is to better understand VOICE participant’s use of study product and sexual behavior during VOICE participation. I want to remind you that what we discuss here will be kept confidential, and that we will not share your personal information or responses with the staff at the VOICE clinic.

|  |
| --- |
| **Adherence:** |
| **Motivations to Join the Trial:**  |
| First I would like to discuss your experience in VOICE… |
| 1. Can you tell me all the reasons that you joined VOICE?
* How did the benefits you received for participating in VOICE influence your decision? (e.g. reimbursements, getting health checked regularly, etc.)
* How did your personal life influence your decision? (e.g. partners/husband, family members, employment status, etc.)
* How did your community/the place where you live influence your decision? (e.g. community opinions/feelings about research in general and the study in particular)
 |  |
| **Risk Perception:**  |
| 1. Before you joined VOICE, how worried were you about getting HIV or having HIV?
* What made you feel that way?
* How did these feelings influence your joining VOICE?
1. During VOICE, how worried were you about getting or having HIV?
* How did these feelings influence whether you used or didn’t use the VOICE [tablets/gel]?
* How did these feelings or worries about getting HIV change over time during your VOICE participation? What made them change? (e.g. regular HIV tests, use of the product, change in risk behaviors, etc.)
 |  |
| **Life Events:** |
| Before we talk about the [tablets/gel], I’d like to get a better idea of the things that were going on in your life during your VOICE participation. 1. Thinking about the time between when you first joined VOICE and when you ended the study, did anything big change in your life? (e.g. changed partners, school/studies/jobs, got married, got pregnant, moved households, death of a significant other, etc.) Tell me about what changed.
* When did it change? *[****Note to interviewer:*** *use the timeline tool to help the participant estimate when the change occurred. We’re mainly interested in whether the participant was still using the product for any period of time after the change.]*
* How did this affect your product use?
 |  |
| **Factors Affecting Adherence:** |
| Now I’d like to talk more about factors that may have influenced women’s ability and willingness to use the [tablets/gel] in the VOICE trial. We know [taking a tablet/using a gel] every day is hard to do and a lot of people in VOICE weren't able to use the [tablets/gel] every single day. That's okay. What we'd like to understand better is what made it hard for some people to use the [tablets/gel]. 1. What were the reasons it was difficult for VOICE women in general to use the [tablets/gel] every day for the whole duration of VOICE?
2. Think about what life is like for women here in [Harare/Kampala/Durban]. Please describe the aspects about this place or this society that might have made it difficult for women to use [tablets/gel] every day during VOICE? (e.g. local leaders, church groups, societal attitudes towards research, etc.)
* How did those aspects make it harder for you?
1. Now, think about the time you were participating in the VOICE study, are there aspects about VOICE or the study clinic that made it difficult for you to use the [tablets/gel] every day for the whole duration of VOICE? (e.g. clinic environment/location, visit schedule and length, relationship with staff in general, adherence counseling approach, interaction with counselors, etc.)
* During the study, did you experience any change in how the staff counseled you on product adherence? How did this [change/lack of change] affect you and your product use?
* What was helpful or not helpful about the product adherence counseling you received?
1. What were the [other] reasons it was difficult for you to use the [tablets/gel] every day for the whole duration of VOICE? (*Probe on major life changes mentioned above*)
* Were there issues with your sexual partner(s) – main or others?
* In your household or family? (e.g. crowding and privacy issues, family and marital responsibilities, etc.)
* In your community? (e.g. neighbors, gossip, etc.)
 |  |
| **Adherence Rating Scale:**  |
| During your participation in VOICE you were asked many questions about product use. One question asked you to “rate in the past 4 weeks your ability to [take the tablets/use the gel] exactly as you were instructed.” “Taking or using the product as you were instructed” is understood differently by different people.1. What does that statement “[take the tablets/use the gel] exactly as you were instructed” mean to you?
* How did you understand the question in terms of how often you were supposed to [take the tablets/use the gel]?
* How did you understand the question in terms of the time of day you were supposed to use the product?
* How did you understand the question in terms of how easy or difficult it was to use?

Now let’s talk about the different response options to this question – very poor, poor, fair, good, very good, and excellent.1. What do each of these different response options mean to you?
* If a woman answered “excellent”, what do you think that meant? *[****Note to******Interviewer****: use the show cards to have women discuss other response options that they view as different.]*
* Is it possible that a woman could skip doses but still answer excellent or very good? Why/ why not?
* If a woman used the gel/both tablets each and every day, would she have answered “excellent”? Why/ why not?
1. What did you think about when you decided on your own response?
* How much did you think about the response you selected before choosing it?
* How much did you try to remember what you had actually done before responding?
* What was your typical answer? Why did you choose that answer?
* How did your response vary over time? Why did it vary?
 |  |
| **Other Adherence Measures:**  |
| Now, let’s talk about other ways that product use was measured. In a different study, where women were asked to report on their everyday use of a gel or tablet, almost all women said that they used the product every day. But, when their blood was tested, only about half of the women who said that they used the product every day actually had the drug in their blood.1. Why do you think there was a difference between what women said about their use of the product and what their blood tests showed?
* If the women didn’t actually use the products every day, what might have made them report that they did use it?
* Do you think there might have been anything about the study staff or the clinic that influenced their responses?
* What other reasons would make women reluctant to report what was really going on with their use of the products?
1. How do you think those study results compare to what may have happened with women in VOICE?
* Was there anything about the VOICE clinics, the procedures or the staff that influenced women’s ability to report times when the [tablets/gel] were/was not used?
* How about for you?
1. What could the VOICE study have done differently to get more honest or accurate responses?
* What could be changed about the clinics, procedures, or staff to make women feel comfortable reporting when they were not able to use the [tablets/gel]?
* How could the counseling be changed to make women more comfortable in discussing their challenges with product use?

In VOICE, you were asked about your use of the [tablets/gel] in a number of different ways (e.g. in interviewer administered questionnaires, ACASI, etc.).1. How could questions about use of [tablets/gel] be asked to make women more comfortable reporting not using [tablets/gel]?
* Does how the question is worded make a difference? How so?
1. What do you think is the best way staff should ask about use of [tablets/gel] to make participants most comfortable and get the most truthful answer?
* Does it matter who asks the question? How so?
 |  |
| **DSMB Results:** |
| 1. Can you tell me what you heard about VOICE stopping the tenofovir tablets and gels early?
* From whom did you hear about these results first?
* Can you explain in your own words what you understand happened?
* [*Probe about product not mentioned above:*]What about the [tablet/gel]?
1. [*For those who did not mention it above, explain that the tenofovir tablet and gel showed no protective effect against HIV in VOICE*] For what reasons do you think the tenofovir tablet and gel arms didn’t show protection against HIV in VOICE?
* What makes you think that?
* What changed for you after you heard the results? (e.g. change in product use for those in Truvada arm; feelings related to being discontinued from the trial for those on the stopped arms, etc.)
 |  |
| **Anal sex:** |
| **Understanding Anal Sex:** |
| We’ve now reached the second part of our interview. During this part of our discussion, I’d like to talk about different sexual behaviors women may engage in. I’d like to start by using pictures to help us understand how you think about the female body. *[****Note to******Interviewer****: Show the participant the visual template and probe around the following topics:** *Identify different part of the ano-genital area such as vulva, urethra, vaginal opening and anus and discuss some of their functions(if appropriate)*
* *Discuss ways one may feel pleasure or pain*
* *Explore participant’s words/terms for sexual behaviors, specifically vaginal sex from behind and anal sex*
* *Ask how participant understood the VOICE ACASI question on anal sex: “In the past 3 months how many times have you had anal sex? By anal sex we mean when a man puts his penis inside your anus.”*

*After the exercise is finished, explain what is meant by anal sex in the context of the 003D study before moving on to the next section of the interview.]* |  |
| **Anal Sex Decisions:** |
| Now let’s talk a little more about anal sex. In the VOICE ACASI, women were asked how many times they had anal sex in the past 3 months. At the beginning of the VOICE study, almost 900 women said they had anal sex at least one time in the past 3 months. 1. How common do you think anal sex among women is in this area or community?
* Is anal sex talked about openly?
* Which types of people do you think have anal sex?
1. What are all the reasons you think a woman might have anal sex?
2. How do you think anal sex is generally introduced into a sexual relationship?
* What types of relationships does it happen in?
* Who suggests or initiates anal sex (the man, the woman, both)? Do women have a choice to say yes or no?
* Does anal sex usually happen before or after a round of vaginal sex or does it happen when vaginal sex does not occur?
1. In what types of circumstances or situations do you think a woman might have anal sex?
* Have you ever found yourself in a similar circumstance/situation? Can you tell me about it?
 |  |
| **Lubricant/Gel Use During Anal Sex:** |
| 1. If a woman did have anal sex, what types of products would she use before or during sex?
* Are there any cleansing practices that are common before people have anal sex? What are they? (e.g. enemas, douching)
* Would she use any type of lubricant during anal sex? Why or why not?
* Would condoms be used? Why or why not?
* What other type(s) of product would she use?

Now let’s think specifically about the women in VOICE who were using the gel.1. Would a woman use the gel during anal sex?
* Why or why not?
1. If she did use the gel, how would she use it?
* Where would she use it? [*Use body mapping diagram if necessary*]
* If she used the gel rectally, for what reasons would she put the gel in her anus?
* [*If gel participant*] Have you ever found yourself in a situation when you used the gel rectally? Can you tell me about it?
 |  |
| 1. We have talked about a lot of different things today. Before we finish, I wonder if you have any questions for me or if you have any additional comments about your experience in VOICE or about the interview today?
2. Is there anything else that you think might have been important to the gel and tablet “failing” in VOICE, that we should think about or aspects of the VOICE study to improve upon for future trials?
 |  |

We’ve now reached the end of our discussion. Thank you for taking the time to talk to [me/us] today and share your opinions. We truly appreciate your willingness to participate and discuss these issues with us.