

VOICE-C PTID

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Post-DSMB Supplemental Probing Guide for VOICE-C IDIs & EIs

Purpose: The purpose of this supplemental probing guide is to provide guidance on how to restructure and adjust probes for VOICE-C IDIs and EIs conducted after the unblinding of oral tenofovir participants, per the recommendations of the VOICE DSMB in September, 2011.

Instructions: This supplemental probing guide should be used for all Group 1 (IDI and EI) and Group 2 (IDI) interviews, effective immediately, irrespective of arm assignment. A copy of this guide should be brought to each interview and filed in the participant binder with the guides used for the interview.

Section A. IDI Guidance:

1. Start the interview by acknowledging that the VOICE DSMB results are unexpected and unusual circumstances, and explain that you want to talk about how s/he is experiencing these changes to the study and how s/he feels about these results.

Begin the interview with the last question in the guide, which is a general question about the VOICE study and study products. For example in the group 1 IDI it reads: Is there anything [else] you would like to tell me about the study products or your experience using the gel/tablets?

- a. Additional probes for those continuing in the trial (in the oral Truvada group/vaginal group) and their partners
 - i. How do you feel about the light blue tablets being discontinued? How does this change your use of your [other] study products?
- b. Additional probes for those in oral TDF group and their partners:
 - i. Experience in the study, experience of being discontinued from the study.

2. Then move to other questions depending on the flow of the conversation during the interview, for example (*note the question numbers refer to the group 1 IDI guide, apply these probes as appropriate to the group 2 IDI guide*):
 - a. Q1: Additional probes: How did you find out about the VOICE results? What did you hear other people in your community saying about the VOICE results? How did you feel about what they were saying?
 - b. Q4: Additional probes: How do you feel about the VOICE study now and how has this influenced your interest in participating in future trials?
 - c. Q5: Additional probes (**for TDF arm participants only**): How do you feel about being taken off the product early before the end of the study?
 - d. Q6: Additional probes: What did the staff at the VOICE clinic tell you about the VOICE results? What did you understand by what they told you? How satisfied are you with this information?

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- e. Q9 & 11: Additional probes: Did you tell anyone (partner, friends, household members, colleagues etc.) about the VOICE results, and **(for TDF arm participants only)**: that you are off the study product? What did you say? How did they react? What did they say? What concerns did they raise?
- f. Q14: Additional probes: What do you think brought about these results? Do you think the outcome is because of the tablet not being effective or the ways in which participants used the tablet or something else?
- g. Q17: Additional probes: **(for TDF arm participants only)**: What did you think about the tablets while you were using them? How have your feelings changed now that you have heard that the light blue tablets will be discontinued?
- h. Q18: Additional probes: **(for TDF arm participants only)**: How does stopping to use the tablet change... your sexual behavior; ... condom use; ... relationships; ...use of contraception? What are you going to do about this?

For TDF arm participants only: All other questions in the guide will be asked in the past tense since the participant is off the product. These questions should be linked to her current circumstances – being off the study product, and how this influences her preference for the trial product, her life, vaginal practices, health care seeking, including HIV testing, etc.

Section B. EI Guidance:

TDF arm participants randomly pre-selected for the EI group will receive an IDI or FGD instead. Interviews with all other newly enrolled or continuing EI participants (in oral Truvada or gel arms) should follow this guidance:

1. Start by acknowledging that the VOICE DSMB results are unexpected and unusual circumstances, and explain that you want to talk about how she is experiencing these changes to the study and how she feels about these results.
2. Additional probes:
 - a. Is there anything [else] you would like to tell me about the study products or your experience using the gel/tablets?
 - b. How do you feel about the light blue tablets being discontinued? How does this change your use of your [other] study products?
 - c. Q14: Additional probes: What do you think brought about these results? Do you think the outcome is because of the tablet not being effective or the ways in which participants used the tablet or something else?
3. Resume the flow of the interview, probing around the VOICE DSMB results, as appropriate (see item 2a – 2h above).