

MATRIX-001 Question by Question (QxQ) Guide

DEM CRF		
Q #	Field	Instructions
1	How old are you?	Participant should provide their age in years, to their best knowledge.
2	What sex were you assigned at birth?	Allow participant to respond in their own words. If their response matches any response other than “female”, flag this for study staff to verify eligibility as appropriate.
3	What is your gender identity?	This question refers to an individual’s gender. Allow the participant to respond in their own words. If their response matches “A gender not listed here”, prompt them to specify. If necessary to prompt response, you may read response options aloud.
4a, 4b	What is your race? What is your ethnicity?	Read off all response options, including “other”. Select all that apply. If asking about race may be seen as insensitive, this question can be prefaced with a reminder that we are asking questions about race/ethnicity because we have participants from South Africa, Kenya, and the U.S. and it is important to be able to have some way to categorize, across all countries, how our participants identify. The interviewer can encourage the participants to choose whichever option they most closely align with.
5	What is the language most spoken in your home	If unclear, specify that this is with regards to where the participant is living now. If outside of the languages listed at the end of the form, have participant specify.
7	What is your relationship status?	If the participant provides a response that is different from those listed, this may be recorded as “Other” – as an example, if the participant responded that they had one night stands, you may use the “Other, specify” option to write in this response.
10	Are you dependent on someone else for financial support?	Participant should specify if the answer is other than those listed. “Partners” here can include a boyfriend, husband, or sex partners.
11	Do you currently earn an income of your own, including any government grants?	Income can include any stable, regular income, including social/government grants or government assistance (such as social security or educational loans that are being used to fund month-to-month expenses).
14	How many people in total reside in your household, including you?	Inform the participant that they should include themselves and any other adults or children who live in the house at least half of the year. Please write “ND” if the participant does not want to respond.
16	Is there a place in your home that you can go where you know you will have privacy to use the vaginal insert?	If additional explanation is needed, the interviewer may want to explain this as a “safe space” for privacy.

BEH CRF		
Q #	Field	Instructions
2	How old is your main partner?	Have the participant provide their main partner's age in years. If they do not know the answer, have them estimate their main partner's age in years to their best knowledge.
3	How long have you and your main partner been in a relationship? [If you have been in a relationship for less than one year, how many months have you been together?]	Participant should respond with how long she has been in a relationship with her main partner . Please provide answer either years OR months, do not complete both. Use months if the response is less than one year. If the participant responds with years and months, round to the nearest number. For example, if the participant says "2 years and 8 months," enter "3 years"
5	Are you or your main partner currently using a method for HIV prevention?	This is a yes or no question. If no, skip to Q9.
6	What method(s) are you and your main partner using?	Male circumcision is an answer choice here, which should be selected if the participant considers male circumcision as an HIV prevention method. If a participant's partner is circumcised, but they did not consider it an HIV prevention strategy, it should not be selected. If the participant considers HIV testing as a prevention method and reports it, record it as "Other" and specify.
11	Which of the following methods for family planning have you ever used? Please answer based on your experiences with ALL your partners, both past and present. Have you ever used... <i>(insert response option, mark all that apply)</i>	If "Other", prompt: "Is there any other method you have used for family planning?" Note that the Nuva Ring may be a common answer that falls under "Other", especially for participants in the United States. If common local names of the methods are not listed here, you can use them to clarify these methods to the participant. e.g., IUD = Coil, Injectable = depo, EC = P2. If the participant reports withdrawal, please record it as "Other" and specify. The response "10) None" should only be selected if no other methods of family planning are reported.
12	In the last three months, how often have you inserted anything into your vagina to... <i>(Show response card)</i>	This question is focused on anything the participant may have inserted into their vagina themselves. It is not focused on partners, and therefore does not include a partner's fingers or penis. If a participant reports insertion of their own fingers for pleasure this may be recorded. Other, specify should be used to designate another <i>reason</i> why something was inserted.
14	Have you ever inserted a vaginal suppository?	This includes vaginal suppositories to treat infections, dryness, birth control or other uses.
15	In your lifetime, did you ever enter into a sexual relationship with a partner mainly in order to get things that you need, money, gifts, or other things that are important to you?	This is a yes or no question. Be sure the participant understands that it applies to their entire lifetime and can go beyond money to include other needed or important things.

BL CRF		
Q #	Field	Instructions
1	On a scale of 1 to 10, how comfortable do you think the insertion process will be for the vaginal insert, where 1 means extremely uncomfortable and 10 means extremely comfortable?	If participant is struggling to choose a response, encourage them to select the number that seems based on what they currently know about the insert.
4b	I think that the vaginal insert may feel uncomfortable or painful during normal activities	Normal activities might include walking, working, sitting, standing.
4c	I am concerned that the vaginal insert will cause side effects	Do not offer examples of side effects. If explanation is needed, indicate that side effects means unwanted or undesirable effects.
4j	I prefer to use an HIV product that I can control and use myself	HIV products that the participant can control herself could include vaginal films, vaginal rings, female condoms, daily pills, and any other products that don't require a sexual partner's participation (such as a male condom).
5	For each of the following statements, please tell me if you agree with it (yes) or not (no). In the future, if the vaginal insert were available for HIV prevention...	This is a question asking participants to think beyond this study, to a time when the insert might be available for use. For each statement, reread the last sentence of the question and offer the choices "Yes" or "No" if needed. For the example of 5a, you would read "In the future, if the vaginal film were available for HIV prevention, using a vaginal film on a monthly basis may interfere with my sexual relationships."
7	Who did you tell about your use of the vaginal insert while you are in the study?	Include anyone that the participant has already told about their insert use in the study. Allow participant to provide answer before prompting with response options. If the participant responds with "family" or "other", prompt them to specify
8	In the future, if vaginal inserts were available for HIV prevention, how important is it to you that vaginal inserts could be used without the following people knowing?	This question is about discreet product use. If the participant is confused about how to answer this question, try rephrasing their response back to them. For example, "It is [very important] that your [partner] not know about you using the insert?"
10	In the future, how likely are you to want to use an HIV prevention product?	This can include products that are developed in the future or already available products, including HIV prevention vaginal rings, etc.

FU1 CRF		
Q #	Field	Instructions
3	Do you think the instructions to place the insert inside the vagina were clear?	If the participant needs further clarification, ask them to think about their overall experience with instructions for insertion, and whether they were clear (this may include the written instruction document, explanation by the clinician, etc.).
4	Did the shape of the vaginal insert help you understand how to put it in your vagina?	The insert is shaped with a pointed end that is meant to be inserted first. This question is asking whether that shape made it intuitive for the participant to think about how to insert the product.

CO CRF		
Q #	Field	Instructions
3	Was the vaginal insert insertion observed by a clinician?	Observation in this case would mean that a clinician or research nurse is behind a curtain or not watching but is available for questions.
5	How many attempts did the participant need to successfully insert the vaginal insert?	Indicate the number of attempts needed for self-insertion.
6	Based on your observation, how difficult or easy was it for the participant to insert the vaginal insert?	If "easy" or "very easy", end the form here. If any other response, explain why it was difficult for the participant to insert the vaginal insert in the open-ended response space that follows this question.

FU2 CRF		
Q #	Field	Instructions
2	Did you insert doses on both days?	Wait for the participant to respond before prompting with the answer choices “yes”, “no, I inserted yesterday only” or “no, I inserted the day before only”.

FU3 CRF		
Q #	Field	Instructions
5	The next statements are about things that you may have experienced when you were using the vaginal insert. [...]	For 5b: Normal activities might include walking, working, sitting, standing. For 5c and 5d, the participant may interpret “side effects” and “felt sick” differently. It is possible to choose one and not the other and still be consistent.
6	The first time you used the vaginal insert, at the start of the study, was it easy or difficult to insert?	Ask participant to think about the very first time she used the insert. If she cannot recall, ask her to try to remember her experience with using the insert early in the study.
12	Since the last visit, did you notice any of the following changes in your vagina?	“I had no changes in my vagina” should only be selected if no other options are selected. If participant reports abnormal discharge and does not specifically identify study product, an AE for vaginal discharge should be captured.
13	How, if at all, would the following changes in your vagina affect your use of vaginal inserts in the future? <i>[Response option only included if selected in prior question]</i>	This question is only included for items that were selected was selected in the prior question. When administering the form in paper, the interviewer will need to look at the prior question, and only use rows that matched something ticked in item 12.
14	Since your last visit, how often did your use of the vaginal insert interfere with any of your regular daily activities?	Regular activities might include walking, working, sitting, or standing.
20	Who did you tell about your use of the vaginal insert while you were in the study? <i>Mark all that apply</i>	Main partner is not listed as a response here, as this has already been asked and answered in Q17.
21	In the future, if vaginal inserts were available for HIV prevention, how important is it to you that vaginal insert could be used without the following people knowing?	This question is about discreet product use. If the participant is confused about how to answer this question, try rephrasing their response back to them. For example, “It is [very important] that your [partner] not know about you using the insert?”
23	Since your last visit, how many times were you able to use the vaginal insert every other day?	The participant should have inserted the study product at Visit 6, and then 5 times at home every other day between Visits 6 and 7.
27	Have you inserted anything other than the study product into your vagina since your enrollment visit?	This may include items that were partner-inserted, as well as self-inserted.
28	What else did you insert into your vagina since enrollment? (select all that apply)	Read each item from the list aloud to the participant and select each that applies. If the participant’s response is “Other”, prompt them to specify. Penile-vaginal sex should be recorded in question 29, however “fingers” should be recorded in “Other, specify”.

29	Have you had any sex since the first insert was put in, including oral, vaginal, or anal sex?	If the participant interprets this as a yes/no question: "no" = "none"; "yes" = prompt through each option (oral, vaginal, anal, other). If the participant reports finger sex, this may be recorded under "Other, specify" Response option "None" is mutually exclusive of other options and is not intended to be selected along with other options. This question impacts administration of questions 30, 32, and 33
31	What did you think about this effect of product use? [a-d]	Response options included only if selected "yes" in prior question. When administering the form in paper, the interviewer will need to look at the prior question, and only use rows that matched something ticked in item 30.
34	For each of the following statements, please tell me if you agree with it not at all, somewhat, or a lot. In the future, if the vaginal insert were available for HIV prevention... (Show response card)	For 34e "People in my community who are similar to me" should be interpreted as people the respondent would consider to be in a similar stage of life, perhaps a similar relationship status or living situation, someone they would consider a peer.
35	For each of the following, what is your opinion of...	Having the participant and interviewer use their thumbs to indicate responses may make for a fun exercise as you near the end of the form!
39, 40, 41	In the future [...]	This is a question asking participants to think beyond this study, to a time when the vaginal insert might be available for use, i.e. it has already been proven to be an efficacious product. Would they prefer to use the product before or after sex?
44	Please rate on a scale of 1-10 how satisfied you are, overall, with using the vaginal insert, where 1 means extremely dissatisfied and 10 means extremely satisfied.	This question is critically important for answering the secondary objective of the study. Please ensure the participant is alert and attentive when answering.