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## 

## Baseline Questionnaire (BAQ)

***Beginning a Questionnaire: Entering Participant Information***

At the beginning of each Baseline Questionnaire, a screen will appear asking for the participant’s ID number (PTID). Type the 9-digit PTID, including dashes, into the box on the screen and click the “Next” button.

The next screen will ask for the staff to re-enter the PTID, including dashes, to confirm the participant’s ID. Below the PTID, select the participant’s appropriate group number from the drop-down menu, and select the appropriate visit code from the next drop-down menu.

To enter today’s date, click on the box below “Select today’s date”. A calendar will appear with today’s date highlighted. Click on today’s date, and the date will be entered in the box. Repeat these steps to confirm today’s date in the box below “Select today’s date to confirm.”

When all the participant’s information is entered correctly, click on the “Next” button to begin the questionnaire.

***Practice Questions***

Note: while in the actual questionnaires participants are allowed to refuse to answer and skip a question, this option is NOT allowed during the practice questions. All participants will be required to give an answer to each of the practice questions. However these data will not be kept or analyzed, in case the participant has concerns. Also, as we want to keep the “refuse to answer” at a minimum, staff will explain this option to participants, but they will not be practicing it.

**Introduction** The first two screens of the Practice section introduce the participants to the practice and teach participants how to navigate between screens by pressing the “NEXT” and “PREVIOUS” buttons.

**PRAC1.** This question gives an example of a question where only one answer is allowed. The participant should answer the question by clicking on the button next to the answer he/she wishes to select. If the participant wants to change his/her answer after selecting a response, he/she should select another answer by clicking the button next to the new answer he/she wants to select.

**PRAC2**. This question gives an example of choosing answers in a table and teaches participants how to answer a question where only one answer is allowed per question. It also shows how to answer questions with buttons and shows the participant how to change an answer once a choice is selected. The tables in the questionnaire will include one question per row and answer choices in columns. Participants should select one answer per question by clicking on the button. If the participant wants to change his/her answer after selecting a response, he/she should select another answer by clicking the button next to the new answer he/she wants to select.

**PRAC3.** This question gives an example of choosing an answer in a drop-down menu. Participants will click on the down arrow to display the available options in the menu and select one answer. To change an answer, the participant may click on the down arrow again and select a different answer.

**PRAC4.**This question teaches participants how to answer a question where more than one answer is allowed, and shows the participant how to change an answer once it is selected by clicking again to de-select the response. This question also introduces the answer category of ‘Other.’ If a participant selects 'Other,' she/he should be instructed to fill in the box beside the response with a specific description of what ‘Other’ means. If the participant selects the last **bolded** option in a list, all other responses that have been selected will be removed because this option is incompatible with the other responses. Instruct the participant to make sure to only select the last bolded option when all of the other choices do not apply.

At the end of the practice questions, a screen will appear to let the participant know he/she has finished the practice. The Baseline questionnaire begins after this screen and the participant must click “Next” to proceed to the Baseline questionnaire.

***Baseline Questionnaire (BAQ)***

The first screen of the Baseline Questionnaire explains to the participants that all answers are confidential and will not affect their participation in the study. Participants should be encouraged to ask questions of the study staff if they do not understand any part of the questionnaire. When the participants clicks “Next” on this screen, they will be taken to the first question.

**Q1.** This question refers to any research studies the participant has volunteered for and participated in before this one.

**Q2.** This question asks the participant to identify all reasons for deciding to participate in this study. Participants should mark all choices they feel are applicable. If the “Other” option is selected, participants must fill in the box beside the response with a description of another reason for joining the study that is not already on the list.

**Q3.** This question will only be asked if participants marked more than one reason for participating in the study in the previous question. If participants marked more than one reason, this question will ask the participant to identify the main reason he/she decided to participate in the study. Participants will be offered a list of choices that corresponds to all the options they marked in the previous question. One answer may be selected. If the participant only marked one reason in the previous question, Q3 will not appear.

At the end of the Baseline Questionnaire, a message will appear letting participants know they have completed the questionnaire, and in order to save their answers, they must click the “Next” button. After clicking the “Next” button, a final screen will indicate to the participants that they have completed the questionnaire and they should communicate this to the staff.

## Behavioral Questionnaire (BEH)

This questionnaire will be completed by female participants only.

***Beginning a Questionnaire: Entering Participant Information***

At the beginning of each Behavioral Questionnaire, a screen will appear asking for the participant’s ID number (PTID). Type the 9-digit PTID, including dashes, into the box on the screen and click the “Next” button.

The next screen will ask for the staff to re-enter the PTID, including dashes, to confirm the participant’s ID. Below the PTID, select the participant’s appropriate group number from the drop-down menu, and select the appropriate visit code from the next drop-down menu.

To enter today’s date, click on the box below “Select today’s date”. A calendar will appear with today’s date highlighted. Click on today’s date, and the date will be entered in the box. Repeat these steps to confirm today’s date in the box below “Select today’s date to confirm.”

Under “Select date of participant’s last computer interview”, select the date from the calendar that appears when clicking on the date box that corresponds to the participant’s last clinic visit where she completed a questionnaire on the computer. When this is entered at the enrollment visit, this will refer to the date of her screening visit. Use the arrows on either side of the month to view a different month. Confirm the date of the last computer interview by selecting the correct date.

When all the participant’s information is entered correctly, click on the “Next” button to begin the questionnaire.

***Behavioral Questionnaire (BEH)***

The first screen of the Behavioral Questionnaire explains to the participants that all answers are confidential and will not affect their participation in the study. Participants should be encouraged to ask questions of the study staff if they do not understand any part of the questionnaire. When the participants click the “Next” button on this screen, they will be taken to the first question.

***Current Sexual Activity***

In these questions we ask about female participants’ current sex lives. The section begins with a list of sexual terms and definitions of sexual behavior. If at any time a participant has questions about a specific term, refer her to the list of sexual terms and help her to understand the meaning of what is being asked.

Note: “Finger sex” refers to masturbation with finger insertion, as well as a partner inserting finger(s) in the participant’s vagina.

**Q1.** This question asks about the different kinds of sexual activity the participant has engaged in **since her last study visit.** The date of her last study visit will appear in the question as it is entered on the log-in screen by the study staff. When the question is answered at the baseline visit, this will refer to time since her screening visit. If the participant has questions about the sexual terms used, please refer her back to the list of terms and definitions and clarify the meaning of the question. Be sure to tell the participant that none of her answers will affect her participation in the study. More than one answer may be selected. If there is another sexual activity she has engaged in that is not listed, the participant should choose “other” and describe that sexual activity in the space provided.

**Q2.** This sub-question refers to the last time the participant engaged in each type of sexual activity recorded in question 1. The question will be repeated for each type of sexual activity that the participant recorded in Q1. The participant should select one answer for each activity. If the participant selected “None of the above,” in Q1, this question will be skipped.

**Recent Intravaginal Practices**

The next questions ask about items that women sometimes insert into their vaginas for a variety of reasons (contraception, personal hygiene, menstrual control or other reasons). Please note that these questions are about putting items **inside** the vagina and not about using them outside the vagina, on the external genitalia. Some participants may not have inserted any of the items into their vaginas. The participant is reassured that none of her answers will affect her participation in the study.

**Q3.** This question asks about all the items that a participant has inserted into her vagina **since her last study visit.** The date of her last study visit will appear in the question as it is entered on the log-in screen by the study staff. When the question is answered at the baseline visit, this will refer to time since her screening visit. More than one answer may be selected. If there is an item she has used that is not listed, the participant should choose “Other product” and describe that item in the space provided.

**Q4.** This sub-question refers to the last day the participant inserted each item she recorded in Q3. The question will be repeated for each item that the participant recorded in Q3. The participant should select one answer for each item. If the participant selected “None of the above,” in Q3, this question will be skipped.

Examples of recording the day of product use:

* If today is Monday, and a participant last inserted a product at 11:57PM on Saturday night, the day will be recorded as: 2 days ago.
* If today is Monday, and a participant last inserted a product at 12:05AM, just after Midnight on Sunday morning, the day will be recorded as: Yesterday.

**Q5.** This sub-question refers to the last time the participant inserted each item she recorded in Q3 if she reported that she inserted it either “today” or “yesterday”. If the product was inserted 2 or more days ago, this question will be skipped. Times are listed in a drop-down menu by hour starting with morning hours through midnight: 1 AM, 2 AM, … 12 Noon, 1 PM,… 12 Midnight. The participant should select one answer from the drop-down menu that corresponds to the last time she used the product today or yesterday, rounding to the nearest hour. If she is unsure of the exact time she used the product, she should give her best estimate of the time.

Examples of rounding to the nearest hour:

* If a participant last inserted a product at 11:57PM, last night, the time should be recorded as: Yesterday at 12 Midnight.
* If today is Monday, and a participant last inserted a product at 12:05AM, just after Midnight on Sunday morning, the time will be recorded as: Yesterday at 1AM.

At the end of the Behavioral Questionnaire, a message will appear letting participants know they have completed the questionnaire, and in order to save their answers, they must click the “Next” button. After clicking the “Next” button, a final screen will indicate to the participants that they have completed the questionnaire and they should communicate this to the staff.

## Exit Acceptability Questionnaire – Men (EAM)

This questionnaire will be completed by male participants only.

***Beginning a Questionnaire: Entering Participant Information***

At the beginning of the Exit Acceptability Questionnaire, a screen will appear asking for the participant’s ID number (PTID). Type the 9-digit PTID, including dashes, into the box on the screen and click the “Next” button.

The next screen will ask for the staff to re-enter the PTID, including dashes, to confirm the participant’s ID. Below the PTID, select the participant’s appropriate group number from the drop-down menu, and select the appropriate visit code from the next drop-down menu.

To enter today’s date, click on the box below “Select today’s date”. A calendar will appear with today’s date highlighted. Click on today’s date, and the date will be entered in the box. Repeat these steps to confirm today’s date in the box below “Select today’s date to confirm.”

When all the participant’s information is entered correctly, click on the “Next” button to begin the questionnaire.

***Practice Questions***

Note: while in the actual questionnaires participants are allowed to refuse to answer and skip a question, this option is NOT allowed during the practice questions. All participants will be required to give an answer to each of the practice questions. However these data will not be kept or analyzed, in case the participant has concerns. Also, as we want to keep the “refuse to answer” at a minimum, staff will explain this option to participants, but they will not be practicing it.

Intro. The first two screens of the Practice section introduce the participants to the practice and teach participants how to navigate between screens by pressing the “NEXT” and “PREVIOUS” buttons.

**PRAC1.** This question gives an example of a question where only one answer is allowed. The participant should answer the question by clicking on the button next to the answer he wishes to select. If the participant wants to change his answer after selecting a response, he should select another answer by clicking the button next to the new answer they want to select.

**PRAC2.** This question gives an example of choosing answers in a table and teaches participants how to answer a question where only one answer is allowed per question. It also shows how to answer questions with buttons and shows the participant how to change an answer once a choice is selected. The tables in the questionnaire will include one question per row and answer choices in columns. Participants should select one answer per question by clicking on the button. If the participant wants to change his answer after selecting a response, he should select another answer by clicking the button next to the new answer they want to select.

**PRAC3.** This question teaches participants how to answer a question where more than one answer is allowed, and shows the participant how to change an answer once it is selected by clicking again to de-select the response. This question also introduces the answer category of ‘Other.’ If a participant selects 'Other,' she/he should be instructed to fill in the box beside the response with a specific description of what ‘Other’ means. If the participant selects the last **bolded** option in a list, all other responses that have been selected will be removed because this option is incompatible with the other responses. Instruct the participant to make sure to only select the last bolded option when all of the other choices do not apply.

***Part A: Product Acceptability***

After the practice questions, the next two screens introduce the male participants to the topic of questions in the survey about their experience with the gel and this study. The first set of questions is about their experience with the gel since starting the study, up through and including today.

**Q1.** This question asks about the participant’s level of comfort with his partner using the gel during the study, including today. One answer may be selected.

**Q2.** This question asks for the participant’s opinion of the study gel and whether he liked or disliked the gel during the study, up through and including today. One answer may be selected.

**Q2a.** This sub-question asks participants to explain why they liked or disliked the study gel. They may answer by typing in their response.

***Part B: Trial Acceptability***

The questions in this section ask the male participants about their experiences participating in the study.

**Q3.** This question asks the participant to rate his overall experience participating in the study. One answer may be selected.

**Q4.** This question asks the participant to rate several study procedures on how bothered or not bothered the participant felt by each procedure during the study. One answer per item in each row may be selected.

1. Sexually abstinent means not having penetrative sex or ejaculating during a specific time.
2. Computer-administered questionnaires refers to all the surveys like this one that the participant completed on the computer at study visits.
3. Physical examination means having vital signs, general appearance, and any symptoms checked by the clinic staff/physician.
4. Genital examination means having the penis, scrotum, and lymph nodes checked by the clinic staff/physician.
5. Semen collection means collecting semen in a cup at the screening visit.
6. Having blood drawn means having a needle inserted in a vein in the arm to collect blood in a tube for lab tests.
7. Being tested for HIV means having a blood sample taken at screening and final visit.
8. Being tested for other sexually transmitted infections means taking a urine sample to check for gonorrhea and chlamydia; and a blood sample for Hepatitis B and HIV.
9. Your partner’s gel use means having your partner use the study product.
10. Having sex at specified times and location means following the study schedule for sex.
11. Having your partner participant in the study means having your partner come to the clinic and study visits and follow the study procedures.

**Q5.** This question asks if the participant would be willing to participate in another study like this one sometime in the future. One answer may be selected.

**If the participant selects “Yes”, the questionnaire will continue with Q6-7. If the participant selects, “No”, the questionnaire will skip to Q8-9.**

**Q6.** This sub-question refers to Q5 and asks the participant for any reasons why he would be willing to participate in a study like this in the future. More than one answer may be selected. If the “Other” option is selected, the participant should type a response in the box next to “please specify”.

**Q7.** This question will be asked if the participant marked more than one reason he would be willing to participate in future studies in Q6. If only one reason was selected in Q6, this question will be skipped. The participant may select one answer from the drop-down menu that will display all the reasons selected in Q6.

**Q8.** This sub-question refers to Q5 and asks the participant for any reasons why he would not be willing to participate in a study like this in the future. More than one answer may be selected. If the “Other” option is selected, the participant should type a response in the box next to “please specify”.

**Q9.** This question will be asked if the participant marked more than one reason he would not be willing to participate in future studies in Q8. If only one reason was selected in Q8, this question will be skipped. The participant may select one answer from the drop-down menu that will display all the reasons selected in Q8.

At the end of the Exit Acceptability Questionnaire - Men, a message will appear letting participants know they have completed the questionnaire, and in order to save their answers, they must click the “Next” button. After clicking the “Next” button, a final screen will indicate to the participants that they have completed the questionnaire and they should communicate this to the staff.

## Exit Acceptability Questionnaire – Women (EAW)

This questionnaire will be completed by female participants only.

***Beginning a Questionnaire: Entering Participant Information***

At the beginning of the Behavioral Questionnaire, a screen will appear asking for the participant’s ID number (PTID). Type the 9-digit PTID, including dashes, into the box on the screen and click the “Next” button.

The next screen will ask for the staff to re-enter the PTID, including dashes, to confirm the participant’s ID. Below the PTID, select the participant’s appropriate group number from the drop-down menu, and select the appropriate visit code from the next drop-down menu.

To enter today’s date, click on the box below “Select today’s date”. A calendar will appear with today’s date highlighted. Click on today’s date, and the date will be entered in the box. Repeat these steps to confirm today’s date in the box below “Select today’s date to confirm.”

When all the participant’s information is entered correctly, click on the “Next” button to begin the questionnaire.

***Part A: Product Acceptability***

The first two screens introduce the female participants to the topic of the questions in the survey about their experience with the gel and this study. The first set of questions is about their experience with the gel since starting the study, including today.

**Q1.** This question asks about the participant’s level of comfort using the gel during the study, up through and including today. One answer may be selected.

**Q2.** This question asks for the participant’s opinion of the study gel and whether she liked or disliked the gel during the study, up through and including today. One answer may be selected.

**Q2a.** This sub-question asks the participant to explain why she liked or disliked the study gel. She may answer by typing in her response.

***Part B: Trial Acceptability***

The questions in this section ask the participant about her experience participating in the study.

**Q3.** This question asks the participant to rate her overall experience participating in the study. One answer may be selected.

**Q4** This question asks the participant to rate several study procedures on how bothered or not bothered the participant felt by each procedure during the study. One answer per item in each row may be selected.

1. Sexually abstinent means not having penetrative sex or ejaculating during a specific time.
2. Computer-administered questionnaires refers to all the surveys like this one that the participant completed on the computer at study visits.
3. Physical examination means having vital signs, general appearance, and any symptoms checked by the clinic staff/physician.
4. Pelvic examination means collecting samples for research purposes and also having clinic staff/physician check on health of vagina
5. Genital swab specimen collection is for research purposes and to check for STIs
6. Rinsing the vagina and cervix with fluids is part of the pelvic exam.
7. Genital tissue biopsy means taking a small tissue sample from the vagina and cervix
8. Rectal sponge means placing a small sponge in the rectum for about 5 minutes
9. Having blood drawn means having a needle inserted in a vein in the arm to collect blood in a tube for lab tests.
10. Being tested for HIV means having a blood sample taken at screening and final visit.
11. Being tested for other sexually transmitted infections means taking a urine sample to check for gonorrhea and chlamydia; a blood sample for Hepatitis B and HIV; and a vaginal swab for trichomonas.
12. Providing a urine sample means collecting urine in a cup
13. Using the study gel means using the study product.
14. Having sex at specified times and location means following the study schedule for sex.
15. Having your partner participate in the study means having your partner come to the clinic and study visits and follow the study procedures.

**Q5.** This question asks if the participant would be willing to participate in another study like this one sometime in the future. One answer may be selected.

**If the participant selects “Yes”, the questionnaire will continue with Q6-7. If the participant selects, “No”, the questionnaire will skip to Q8-9.**

**Q6.** This sub-question refers to Q5 and asks the participant for any reasons why she would be willing to participate in a study like this in the future. More than one answer may be selected. If the “Other” option is selected, the participant should type a response in the box next to “please specify”.

**Q7.** This question will be asked if the participant marked more than one reason she would be willing to participate in future studies in Q6. If only one reason was selected in Q6, this question will be skipped. The participant may select one answer from the drop-down menu that will display all the reasons selected in Q6.

**Q8.** This sub-question refers to Q5 and asks the participant for any reasons why she would not be willing to participate in a study like this in the future. More than one answer may be selected. If the “Other” option is selected, the participant should type a response in the box next to “please specify”.

**Q9.** This question will be asked if the participant marked more than one reason she would not be willing to participate in future studies in Q8. If only one reason was selected in Q8, this question will be skipped. The participant may select one answer from the drop-down menu that will display all the reasons selected in Q8.

At the end of the Exit Acceptability Questionnaire - Women, a message will appear letting participants know they have completed the questionnaire, and in order to save their answers, they must click the “Next” button. After clicking the “Next” button, a final screen will indicate to the participants that they have completed the questionnaire and they should communicate this to the staff.