

MTN-024 CASI Questionnaire

Question by Question (QxQ) Guide

QxQ Table of Contents

Beginning a Questionnaire.....	1
Baseline Questionnaire	1
Follow-up Questionnaire (4-Week and 8-Week visits)	7
Exit Questionnaire	13

Beginning a Questionnaire

Entering Participant Information

At the beginning of each CASI 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 appropriate visit code from the 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.

Follow-up and Exit questionnaires will ask for the staff to enter the date of the participant’s last computer interview. To enter the date, click on the box below “Please select date of last computer interview”. When the calendar appears, select the date that corresponds to the participant’s last clinic visit where she completed a questionnaire on the computer. 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 in the second box.

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

Baseline 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 she wishes to select. If the participant wants to change her answer after selecting a response, she should select another answer by clicking the button next to the new answer she wants to select.

MTN-024 CASI Questionnaire

Question by Question (QxQ) Guide

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 one button per row. If the participant wants to change his/her answer after selecting a response, she should select another answer by clicking the button next to the new answer 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 should be instructed to fill in the box beside the response with a specific description of what 'Other' means.

At the end of the practice questions, a screen will appear to let the participant know 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

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 click "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. It may be any type of research.

Q2. This question asks the participant to identify the main reasons for deciding to participate in this study. Participants may mark only one answer. If the "Other" option is selected, participants must fill in the space beside the response with a description of another reason for joining the study that is not already on the list.

Q3. This question asks the participant about her current living situation. One answer may be selected. If the "Other" option is selected, participants must fill in the space beside the response with a description of another reason for joining the study that is not already on the list. The option "Rent a room in a group house" may be a house or apartment where the participant lives with housemates or roommates and rents a part of the house or apartment, such as a room. The option "Stay with partner/relatives/family" means a house or apartment where the participant lives that belongs to or is rented by the participant's partner, relative, or family member, and the participant does not own or rent the house or apartment. The option "Stay with friends" means a house or apartment where the participant lives that belongs to or is rented by the participant's friend, and the participant does not own or rent the house or apartment.

MTN-024 CASI Questionnaire Question by Question (QxQ) Guide

Q4. This question asks the participant about her sexual orientation. One answer may be selected.

Q5. This question asks about the total number of pregnancies the participant has ever had. All pregnancies should be included as specified in the question.

Q5a. This question is a follow up to question 5, and will only be asked if the participant's answer to question 5 was 1 pregnancy or more. The question asks the participant about the outcome of each pregnancy reported in question 5. More than one category may be selected, and the number of each pregnancy outcome should be indicated for each category. The total number indicated in question 5a should match the total number reported in question 5. If there are no pregnancies to report in a certain category, the participant should enter "0" for that category.

Q6. This question asks the participant the number of days she had an alcoholic **drink in the past 30 days**. This includes beer, wine, hard liquor, or any other type of alcohol, and any drinks containing any of these types of alcohol such as a cocktail. A number between 0 and 30 may be selected.

Q7. This question asks how often, in general, does the participant have four or more alcoholic drinks at one time. This would mean having four or more of any combination of: a glass or bottle of beer, a glass of wine, a shot of hard liquor, or a cocktail containing liquor or alcohol, in a single day. One response may be selected.

Q8. This question asks if the participant has used any recreational drugs **in the past 30 days** by smoking, swallowing or snorting. This means any drugs that are taken to "get high". It does not include medication taken by direction of a physician. One response may be selected.

Q9. This question asks if the participant has **ever in her life** injected any recreational drug using a needle. This means any drugs that are taken to "get high". It does not include medication taken by direction of a physician. One response may be selected.

Q9a. This question is a follow up question to question 9. It will only be asked if the participant answers "yes" to question 9. The question asks participants if they have injected any recreational drug by using a needle only **in the past 30 days**. One answer may be selected.

Q10. This question asks if the participant has **ever** engaged in sexual activity to get food, drugs, a place to stay, or money from another person. One answer may be selected.

Q11. This question asks if the participant has **ever in her life** been told that she had a sexually transmitted infection or been given medical treatment for a sexually transmitted infection. Some examples include: Chlamydia, Gonorrhea, HPV, genital warts, HIV, syphilis, Hepatitis B, Bacterial vaginosis (BV), genital herpes, pubic lice ("crabs"), or Trichomoniasis ("trich"). One answer may be selected.

Q12 a-f. This question is a multi-part question that asks about types of sexual activity the participant has **ever had in her life**. Each sub-question will ask about a different type of sexual activity. The participant should answer yes or no for each sub-question. A table of definitions (see below) of the sexual activities asked about will appear with each sub-question that the participant may refer to if there is a question about what the sexual activity term means.

MTN-024 CASI Questionnaire Question by Question (QxQ) Guide

When we say:	We mean:
Vaginal sex	When a man inserts his penis into your vagina
Anal sex	When a man puts his penis into your anus/butt
Receiving oral sex	When a partner puts his or her mouth or tongue on your vagina or anus/butt
Giving oral sex	When you put your mouth or tongue on your partner's penis, vagina or anus/butt
Finger sex	When you or a partner inserts finger(s) into your vagina or anus/butt
Non-penetrative sex	When you have any kind of sex with yourself or with a partner, without inserting something into your vagina or anus/butt (e.g. rubbing each other, mutual masturbation or self masturbation)

Q13. This question asks if a condom was used the last time the participant had vaginal sex. This includes any time in the past that was the last time the participant had vaginal sex. The participant should answer yes or no.

Q14. This question is a multi-part question that asks about sexual activity the participant has had **in the past 30 days**.

Q14a-f. Each sub-question will ask about a different type of sexual activity. The participant should answer yes or no to each question based on her activity **in the past 30 days**. A table of definitions of the sexual activities (see above) asked about will appear with each sub-question that the participant may refer to if there is a question about what the sexual activity term means.

Q14a.i. This question is a sub-question to question 14a about vaginal sex in the past 30 days. This question will only be asked if the participant answers “yes” to question 14a. The question asks how many times the participant had vaginal sex **only in the past 30 days**.

Q15. This question asks if the participant has a primary sex partner now. A primary sex partner may be a person they have any type of sexual activity with on a regular basis, or it may be a person the participant considers to be her main partner regardless of their current sexual activity. This might be a spouse, domestic partner, boyfriend, or girlfriend. One response may be chosen.

Q15a. This is a follow up question that will only be asked if the participant indicates she has a primary sex partner. The question asks if the participant’s partner knows she is participating in the study. This may be because she told her partner that she is participating, or the partner may have found out another way. One response may be chosen. If the participant does not know if her partner is aware of her study participation, she should select the answer “Don’t know”.

Q15b. This is a follow up question that will only be asked if the participant indicates she has a primary sex partner. This question asks when the participant first had any sexual activity with her primary partner. This may be any of the sexual activities listed in the sexual definitions table. If the participant does not know the exact date, she should make her best estimate of the month and year she began her relationship with her primary partner.

Q15c. This is a follow up question that will only be asked if the participant indicates she has a primary sex partner. The question asks if the primary partner she answered about in the previous question is a man or a woman. One response may be selected. If the answer “Other” is chosen, the

MTN-024 CASI Questionnaire Question by Question (QxQ) Guide

space next to “please specify” should be used to describe the gender of the participant’s primary partner.

Q15d. This is a follow up question that will only be asked if the participant indicates she has a primary sex partner. The age in years should be selected from the drop-down menu. The participant may estimate if she does not know her partner’s exact age.

Q15e. This is a follow up question that will only be asked if the participant indicates she has a primary sex partner. The question refers to any difficulty in sexual performance by the participant’s primary partner. This may include problems with getting or maintaining an erection, problems with ejaculation, low arousal or little interest in sexual activities, or any other problems the participant may consider sexual performance difficulty. One response may be selected.

Q15f. This is a follow up question that will only be asked if the participant indicates she has a primary sex partner. This question refers to any medication that the participant’s primary partner may have taken in the past 3 months to help with sexual problems or to otherwise improve sexual performance. This may include medications prescribed by a physician or other substances. One response may be selected.

Q16. This question asks about the participant’s use of any medication or other substance taken to improve their sexual experience. The question refers to any medication or substance taken in the past 3 months. One response may be selected.

Q17. This question asks for the total number of people the participant has had sexual activity with in **her whole life**. Sexual activity asked about is explained in the table of sexual definitions (see above for question 12 and 14). This number includes persons the participant only had sexual activity with once, and should include the participant’s current primary sex partner.

Q18. This question asks about the number of people the participant has had sexual activity with in **the past 3 months**. Sexual activity asked about is explained in the table of sexual definitions. This number includes persons the participant only had sexual activity with once, and should include the participant’s current primary sex partner.

Q19. This question asks if the participant has experienced pain while having vaginal sex, in **the past 3 months**. This may be any type of pain related to having vaginal sex. One response may be selected.

Q19a. This is a follow up question to question 19 and will only be asked if the participant reported that vaginal sex was ever painful in the past 3 months (some of the time, most of the time, or all of the time.) The participant should choose the response that best describes the amount of pain she experienced if she had pain during vaginal sex. One response may be selected.

Q20 a-j. These questions ask the participant about items that women sometimes insert into their vaginas for personal hygiene or other reasons. They are about putting the items **inside the vagina**, not using them outside the vagina. The question refers to whether the participant has **ever used these items in her life**.

Note: the question about male condom refers to the participant having sexual activity while a partner used a male condom.

MTN-024 CASI Questionnaire Question by Question (QxQ) Guide

Q21. This question asks about the use of douche for personal hygiene inserted inside the vagina anytime **in the past 3 months**. Douching is washing or cleaning out the vagina with water or other mixtures of fluids. Most douches are prepackaged mixes of water and vinegar, baking soda, or iodine, and may be purchased at drug and grocery stores. The mixtures usually come in a bottle and can be squirted into the vagina through a tube or nozzle.

Q22. This question asks the participant about her worry for future use of the study vaginal ring in general. The question refers to any worries she may have about the ring being inside her vagina all the time for 3 months. One response may be selected.

Q23 a-o. This is a multi-part question asking the participant about different types of things she might be worried about as she starts to use the study vaginal ring. All of the questions refer to worries for future use of the ring during the study. Each question should be answered “Yes” if she is worried, or “No” if she is not worried.

23o. If there is anything that the participant is worried about when using the ring that is not specifically listed in another question in this section, she can mark “Yes” to “anything else” and write in what she is worried about in the space next to “please specify.”

Q24. The questions in this table are part of the Menopause Rating Scale.

The questions in this table ask the participant to rate any menopausal symptoms that she may feel at the time of the questionnaire. Each symptom is explained in parentheses following the symptom in the question on the questionnaire. The participant may mark one rating for each symptom. If she does not experience the symptom in the question, she should mark the button that corresponds to “None.”

Questions 25-30 are part of the Urogenital Distress Inventory (UDI-6).

Q25. This question asks if the participant feels the need to urinate more frequently than feels usual, in a way that she feels disrupts her everyday activities or her sleep. This could mean needing to urinate more than approximately eight times a day or waking up in the night to go to the bathroom.

Q25a. This is a follow up question to Q25, and will only be asked if the participant reported that she experiences frequent urination. The question asks how much having to urinate frequently bothers her, and she should select one response.

Q26. This question asks if the participant experiences urine leaking out that she cannot control before she can get to the bathroom if she has a sudden, strong urge to urinate.

Q26a. This is a follow up question to Q26, and will only be asked if the participant reported that she experiences urine leakage with a feeling of urgency. The question asks how much urine leakage with a feeling of urgency bothers her, and she should select one response.

Q27. This question asks if the participant experiences urine leaking out that she cannot control before she can get to the bathroom when she coughs, sneezes, or laughs.

Q27a. This is a follow up question to Q27, and will only be asked if the participant reported that she experiences urine leakage when she coughs, sneezes or laughs. The question asks how much urine leakage from coughing, sneezing or laughing bothers her, and she should select one response.

MTN-024 CASI Questionnaire Question by Question (QxQ) Guide

Q28. This question asks if the participant experiences small amounts of urine drops leaking out that she cannot control. This could be at any time, not necessarily due to urgency or physical movement that puts pressure on the bladder (such as coughing, sneezing, or laughing).

Q28a. This is a follow up question to Q28, and will only be asked if the participant reported that she experiences small amounts (drops) of urine leakage. The question asks how much having drops of urine leakage bothers her, and she should select one response.

Q29. This question asks if the participant ever has trouble urinating because she feels that it is difficult to release urine from her bladder or completely empty her bladder.

Q29a. This is a follow up question to Q29, and will only be asked if the participant reported that she experiences difficulty emptying her bladder. The question asks how much the difficulty emptying her bladder bothers her, and she should select one response.

Q30. This question asks if the participant usually feels pain or discomfort in her pelvis (lower abdomen or genital area). This would mean feeling pain or discomfort most of the time.

Q30a. This is a follow up question to Q30, and will only be asked if the participant reported that she usually experiences pain or discomfort in the lower abdomen or genital region. The question asks how much this pain bothers her, and she should select one response.

Q30b. This is a follow up question to Q30, and will only be asked if the participant reported that she experiences pain or discomfort in the lower abdomen or genital region. The question asks if the abdominal or genital pain goes away after she empties her bladder, and she should select one response.

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.

Follow-up Questionnaire (4-Week and 8-Week visits)

The first screen of the Follow-up 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 in the table on the questionnaire (also below) 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.

MTN-024 CASI Questionnaire Question by Question (QxQ) Guide

<u>When we say:</u>	<u>We mean:</u>
Vaginal sex	When a man inserts his penis into your vagina
Anal Sex	When a man puts his penis into your anus/butt
Receiving oral sex	When a partner puts his or her mouth or tongue on your vagina or anus/butt
Giving oral sex	When you put your mouth or tongue on your partner's penis, vagina or anus/butt
Finger sex	When you or a partner inserts finger(s) into your vagina or anus/butt
Non-penetrative sex	When you have any kind of sex with yourself or with a partner, without inserting something into your vagina or anus/butt (e.g. rubbing each other, mutual masturbation or self masturbation)

Q1. This question asks if the participant ever used the study vaginal ring **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.

Q2. This question is a multi-part question that asks the participant about her current sex life and the types of sexual activity she has had **in the past 30 days before the day of this 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.

Q2a-f. Each line on the table asks about a different type of sexual activity. The participant should answer yes or no to each question based on her activity **in the past 30 days** by selecting the button for 'Yes' or 'No' on the line next to the sexual activity.

A table of definitions of the sexual activities asked about will appear below the question that the participant may refer to if there is a question about what a sexual activity term means (see table above).

Q3. This question is a follow-up to question 2a about vaginal sex in the past 30 days. This question will only be asked if the participant answered "yes" to having had vaginal sex in the past 30 days. The question asks how many times the participant had vaginal sex **only in the past 30 days**. The participant should enter a number in the answer box that corresponds to the number of times she had vaginal sex in the past 30 days.

Q4. This question is a follow-up question to Q1 and Q2. It will only be asked if the participant answered "Yes" to having used the study vaginal ring since the last computer interview and having had vaginal sex in the last 30 days. The participant should enter a number in the box that corresponds to the number of times she had vaginal sex while the study ring was in her vagina in the past 30 days. If she never had the vaginal ring in her vagina during vaginal sex, she should enter "0". The participant may receive an error message if she enters a number that is more than her answer for Q3 (i.e. if she answered in this question that she had vaginal sex with the ring in more times than she reported having vaginal sex in Q3.)

MTN-024 CASI Questionnaire

Question by Question (QxQ) Guide

Q5. This question is a follow-up question to Q4. It will only be asked if the participant entered a number greater than 0 for Q4 to indicate that she had vaginal sex with the ring in at least once. The participant may choose only one response.

Q6. This question is a follow-up to question 2b about anal sex in the past 30 days. This question will only be asked if the participant answered “yes” to having had anal sex in the past 30 days. The question asks how many times the participant had anal sex **only in the past 30 days**. The participant should enter a number in the answer box that corresponds to the number of times she had anal sex in the past 30 days.

Q7. This question is a follow-up to question 2a and will only be asked if the participant answered “Yes” to Q2a that she had vaginal sex in the past 30 days. The question refers to the **last time** the participant had vaginal sex. If the participant’s male partner used a condom the most recent time she had vaginal sex, she should answer “yes”. If her partner did not use a condom, she should answer “no”.

Q8. This question is a follow-up to question 2a and will only be asked if the participant answered “Yes” to Q2a that she had vaginal sex in the past 30 days. The question refers to the **last time** the participant had vaginal sex. If the participant used the study lubricant (preSeed) the most recent time she had vaginal sex, she should answer “Yes, the study lubricant (preSeed)”. If she used another type of lubricant that was not preSeed, she should answer “Yes, another commercial lubricant.” If she did not use any lubricant, she should answer “No”.

Q9. This question is a follow-up to Q1, Q2a and Q4, and will only be asked if the participant answered that she has used the study vaginal ring since the last computer questionnaire **and** that she had vaginal sex in the past 30 days **and** that she has had vaginal sex with the ring in her vagina at least once in the past 30 days. If the participant had the vaginal ring in her vagina during the most recent time she had vaginal sex, she should answer “Yes”. If she did not have the ring in, she should answer “No.”

Q9a. This question is a follow-up to Q9 and will only be asked if the participant answered “Yes” that she had the study ring in her vagina the last time she had vaginal sex in the last 30 days. This question refers to the most recent time the participant had vaginal sex in the past 30 days. If the participant had the vaginal ring in her vagina for any part of the day **before** she had vaginal sex with the ring in, she should answer “Yes.”

Q9b. This question is a follow-up to Q9 and will only be asked if the participant answered “Yes” that she had the study ring in her vagina the last time she had vaginal sex in the last 30 days. This question refers to the most recent time the participant had vaginal sex in the past 30 days. If the participant had the vaginal ring in her vagina for any part of the day **after** she had vaginal sex with the ring in, she should answer “Yes.”

Q10. This question refers to the participant’s ring use since her last computer questionnaire. If the ring ever came all the way out of the participant’s vagina on its own, the participant should enter the number of times the ring came out. This means that the ring slipped out all by itself without the participant or someone else removing it. This could be even for just a moment before it was put back in. If the ring never slipped out by itself, the participant should enter “0”.

Q11. This series of questions is follow-up to Q10, and will only be asked if the participant answered that the ring came out of her vagina on its own one or more times. The question refers to the

MTN-024 CASI Questionnaire

Question by Question (QxQ) Guide

activity the participant was doing at the time the ring came out of her vagina on its own. Each question should be answered Yes or No.

- a. This refers to the ring slipping out while the participant was urinating or peeing.
- b. This refers to the ring slipping out while the participant was having a bowel movement.
- c. This refers to the ring slipping out while the participant was lifting something very heavy or doing some other physical activity that put strain on her muscles and pushed the ring out.
- d. This refers to the ring slipping out while the participant was having sex. This could be any of the sexual activities listed in the table at the beginning of the questionnaire. The question also refers to the time just after having any of the sexual activities listed in the table. For example this could mean just as she stood up after sex, the ring slipped out on its own.
- e. This refers to the ring slipping out while the participant was doing any kind of exercise activity including walking, running, swimming, yoga, weight training, playing a sport, etc.
- f. This refers to the ring slipping out **by itself** if the participant put a finger in her vagina to make sure the ring was in place. This **does not include** times when the participant took the ring out on purpose to check on it and put it back in.
- g. This question allows the participant to enter any other reason not listed above when the ring may have slipped out by itself. If there was another activity the participant was doing when the ring slipped out on its own, she should select “Yes, please specify” and type the activity into the space. If there were no other reasons, the participant should select No.

Q12. This question refers only to the last time the ring slipped out by itself, and will only be asked if the participant answered that the ring came out one or more times on its own. The participant should select the position her body was in when the ring slipped out by itself. If the position is not listed, she should select, “Other, please specify” and type the position into the space.

Q13. This question refers only to the last time the ring slipped out by itself, and will only be asked if the participant answered that the ring came out one or more times on its own. The participant should select the answer that best describes what she did with the ring when the ring slipped out by itself. If no answer is listed that describes what she did with the ring, she should select, “Other, please specify” and type what she did with the ring into the space.

Q13a. This question is a follow-up question to Q13 and will only be asked if the participant answered that she reinserted the ring herself. This question refers to anything the participant may have done with the ring to clean it before she put it back in her vagina. This could be rinsing or wiping with water or cleaning with soap and water or another type of cleaner.

Q14. This question refers to the participant’s ring use since her last computer questionnaire. If the ring ever came part of the way out of the participant’s vagina on its own but did not slip fully out of her vagina, the participant should enter the number of times the ring came partially out. This means that the ring slipped part of the way out all by itself without the participant or someone else moving it. This could be even for just a moment before it was put back in place. If the ring never slipped part way out by itself, the participant should enter “0”.

Q15. This series of questions is follow-up to Q14, and will only be asked if the participant answered that the ring came part way out of her vagina on its own one or more times. The question refers to the activity the participant was doing at the time the ring slipped part way out of her vagina on its own. Each question should be answered Yes or No.

MTN-024 CASI Questionnaire Question by Question (QxQ) Guide

- a. This refers to the ring slipping part way out while the participant was urinating or peeing.
- b. This refers to the ring slipping part way out while the participant was having a bowel movement.
- c. This refers to the ring slipping part way out while the participant was lifting something very heavy or doing some other physical activity that put strain on her muscles and pushed the ring out.
- d. This refers to the ring slipping part way out while the participant was having sex. This could be any of the sexual activities listed in the table at the beginning of the questionnaire. The question also refers to the time just after having any of the sexual activities listed in the table. For example this could mean just as she stood up after sex, the ring slipped part way out on its own.
- e. This refers to the ring slipping part way out while the participant was doing any kind of exercise activity including walking, running, swimming, yoga, weight training, playing a sport, etc.
- f. This refers to the ring slipping part way out **by itself** if the participant put a finger in her vagina to make sure the ring was in place. This **does not include** times when the participant took the ring part way out on purpose to check on it and put it back in.
- g. This question allows the participant to enter any other reason not listed above when the ring may have slipped part way out by itself. If there was another activity the participant was doing when the ring slipped part way out on its own, she should select “Yes, please specify” and type the activity or situation into the space. If there were no other reasons, the participant should select No.

Q16. This question refers only to the last time the ring slipped partially out by itself, and will only be asked if the participant answered that the ring came part way out one or more times on its own. The participant should select the position she was in when the ring slipped part way out by itself. If the position is not listed, she should select, “Other, please specify” and type the position into the space.

Q17. This question refers only to the last time the ring slipped partially out by itself, and will only be asked if the participant answered that the ring came part way out one or more times on its own. The participant should select the answer that best describes what she did with the ring when the ring slipped part way out by itself. If no answer is listed that describes what she did with the ring, she should select, “Other, please specify” and type what she did with the ring into the space.

Q18. This question is a follow-up to Q17, and will only be asked if the participant answered that she took the ring completely out of her vagina. The participant should select the answer that best describes what she did after she removed the ring. If no answer is listed that describes what she did with the ring, she should select, “Other, please specify” and type what she did with the ring into the space.

Q18a. This question is a follow-up question to Q18 and will only be asked if the participant answered that she reinserted the ring herself. This question refers to anything the participant may have done with the ring to clean it before she put it back in her vagina. This could be rinsing or wiping with water or cleaning with soap and water or another type of cleaner.

Q19. This question refers to the participant’s ring use since her last computer questionnaire. If the ring was ever taken all the way out of the participant’s vagina on purpose, the participant should enter the number of times the ring was removed. This means that the ring was taken out of the participant’s vagina either by the participant herself or by someone else, including a study staff

MTN-024 CASI Questionnaire

Question by Question (QxQ) Guide

member, partner, doctor, etc. This could be even for just a moment before it was put back in place. If the ring was never taken out, the participant should enter “0”.

Q19a. This is a follow up question to Q19 and will only be asked if the participant answered that the ring was taken out or removed on purpose one or more times since her last computer questionnaire. The question refers to the person who took the ring out of the participant’s vagina. The participant should select one response. If someone other than the participant or a study staff member removed the ring, the participant should select “Someone else took it out, *please specify your relationship to that person, e.g. partner, friend, etc.*” and the participant should type the person who removed the ring into the space.

Q20. This series of questions is a follow up to Q19 and will only be asked if the participant answered that the ring was taken out or removed on purpose one or more times since her last computer questionnaire. The questions refer to all the reasons the participant removed the ring or had the ring taken out by someone else since her last computer questionnaire.

- a. “Causing discomfort or pain” means the participant or someone else took the ring out because she felt the ring hurting her.
- b. “you felt that it was out of place in your body” means the participant or someone else took the ring out because it felt like it was not staying in the right place. This includes times the participant took the ring out because it moved or slipped out of the right place while she was checking the ring placement with her finger.
- c. “you wanted to clean it” means the participant or someone else took the ring out because she wanted to wash or rinse the ring off with water, soap or another cleaner.
- d. “you wanted to show it to someone” means the participant took the ring out because she wanted to let another person see what the ring looked like.
- e. “you had some worries about it” means the participant or someone else took the ring out because she was concerned about the ring being inside her. This could be because she was worried about the safety of the ring, or worried about her partner’s safety, or any other worry about the ring itself.
- f. “you didn’t like it” means the participant or someone else took the ring out because she didn’t like the idea of the ring, the feel of the ring, or any other aspect of the ring that caused her not to like it.
- g. “you felt it was interfering with **your** sexual pleasure” means the participant or someone else took the ring out because it was getting in the way of her own enjoyment of sexual activity.
- h. “you felt it was interfering with **your partner’s** sexual pleasure” means the participant or someone else took the ring out because it was getting in the way of her partner’s enjoyment of sexual activity.
- i. “Was there another reason that the ring was taken out or removed” means any other reason not listed in the previous questions (a-h) that the participant or someone else took the ring out. If the participant answers “Yes” she should type in the reason in the space next to “please specify”.

MTN-024 CASI Questionnaire Question by Question (QxQ) Guide

Q21. This is a follow up question to Q19 and will only be asked if the participant answered that the ring was taken out or removed on purpose one or more times since her last computer questionnaire. The participant should select the answer that best describes what she did after the ring was taken out or removed. If no answer is listed that describes what she did with the ring, she should select, “Other, please specify” and type what she did with the ring into the space.

Q21a. This is a follow-up question to Q21 and will only be asked if the participant answered that the ring was put back in before her next appointment either by herself or by a study staff member. The question refers to anything the participant did to wash off or rinse the ring with water, soap, or any type of cleaner before the ring was put back into her vagina.

At the end of the Follow-up 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 Questionnaire

The first screen of the Follow-up 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 in the table on the questionnaire (also below) 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.

<u>When we say:</u>	<u>We mean:</u>
Vaginal sex	When a man inserts his penis into your vagina
Anal Sex	When a man puts his penis into your anus/butt
Receiving oral sex	When a partner puts his or her mouth or tongue on your vagina or anus/butt
Giving oral sex	When you put your mouth or tongue on your partner's penis, vagina or anus/butt
Finger sex	When you or a partner inserts finger(s) into your vagina or anus/butt
Non-penetrative sex	When you have any kind of sex with yourself or with a partner, without inserting something into your vagina or anus/butt (e.g. rubbing each other, mutual masturbation or self masturbation)

MTN-024 CASI Questionnaire

Question by Question (QxQ) Guide

Q1. This question asks if the participant ever used the study vaginal ring **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.

Q2. This question is a multi-part question that asks the participant about her current sex life and the types of sexual activity she has had **in the past 30 days before the day of this 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.

Q2a-f. Each line on the table asks about a different type of sexual activity. The participant should answer yes or no to each question based on her activity **in the past 30 days** by selecting the button for 'Yes' or 'No' on the line next to the sexual activity.

A table of definitions of the sexual activities asked about will appear below the question that the participant may refer to if there is a question about what a sexual activity term means (see table above).

Q3. This question is a follow-up to question 2a about vaginal sex in the past 30 days. This question will only be asked if the participant answered "yes" to having had vaginal sex in the past 30 days. The question asks how many times the participant had vaginal sex **only in the past 30 days**. The participant should enter a number in the answer box that corresponds to the number of times she had vaginal sex in the past 30 days.

Q4. This question is a follow-up question to Q1 and Q2. It will only be asked if the participant answered "Yes" to having used the study vaginal ring since the last computer interview and having had vaginal sex in the last 30 days. The participant should enter a number in the box that corresponds to the number of times she had vaginal sex while the study ring was in her vagina in the past 30 days. If she never had the vaginal ring in her vagina during vaginal sex, she should enter "0". The participant may receive an error message if she enters a number greater than her answer for Q3 (i.e. if she answers in this question that she had sex with the ring in more times than she answered that she had sex in Q3.)

Q5. This question is a follow-up question to Q4. It will only be asked if the participant entered a number greater than 0 for Q4 to indicate that she had vaginal sex with the ring in at least once. The participant may choose only one response.

Q6. This question is a follow-up to question 2b about anal sex in the past 30 days. This question will only be asked if the participant answered "yes" to having had anal sex in the past 30 days. The question asks how many times the participant had anal sex **only in the past 30 days**. The participant should enter a number in the answer box that corresponds to the number of times she had anal sex in the past 30 days.

Q7. This question is a follow-up to question 2a and will only be asked if the participant answered "Yes" to Q2a that she had vaginal sex in the past 30 days. The question refers to the **last time** the participant had vaginal sex. If the participant's male partner used a condom the most recent time she had vaginal sex, she should answer "yes". If her partner did not use a condom, she should answer "no".

Q8. The question refers to the **last time** the participant had vaginal sex. If the participant used the study lubricant (preSeed) the most recent time she had vaginal sex, she should answer "Yes, the

MTN-024 CASI Questionnaire Question by Question (QxQ) Guide

study lubricant (preSeed)". If she used another type of lubricant that was not preSeed, she should answer "Yes, another commercial lubricant." If she did not use any lubricant, she should answer "No".

Q9. This question is a follow-up to Q1, and will only be asked if the participant answered that she has used the study vaginal ring since the last computer questionnaire. If the participant had the vaginal ring in her vagina during the most recent time she had vaginal sex, she should answer "Yes". If she did not have the ring in, she should answer "No."

Q9a. This question is a follow-up to Q9 and will only be asked if the participant answered "Yes" that she had the study ring in her vagina the last time she had vaginal sex in the last 30 days. This question refers to the most recent time the participant had vaginal sex in the past 30 days. If the participant had the vaginal ring in her vagina for any part of the day **before** she had vaginal sex with the ring in, she should answer "Yes."

Q9b. This question is a follow-up to Q9 and will only be asked if the participant answered "Yes" that she had the study ring in her vagina the last time she had vaginal sex in the last 30 days. This question refers to the most recent time the participant had vaginal sex in the past 30 days. If the participant had the vaginal ring in her vagina for any part of the day **after** she had vaginal sex with the ring in, she should answer "Yes."

Q10. This question refers to the participant's ring use since her last computer questionnaire. If the ring ever came all the way out of the participant's vagina on its own, the participant should enter the number of times the ring came out. This means that the ring slipped out all by itself without the participant or someone else removing it. This could be even for just a moment before it was put back in. If the ring never slipped out by itself, the participant should enter "0".

Q11. This series of questions is follow-up to Q10, and will only be asked if the participant answered that the ring came out of her vagina on its own one or more times. The question refers to the activity the participant was doing at the time the ring came out of her vagina on its own. Each question should be answered Yes or No.

- a. This refers to the ring slipping out while the participant was urinating or peeing.
- b. This refers to the ring slipping out while the participant was having a bowel movement.
- c. This refers to the ring slipping out while the participant was lifting something very heavy or doing some other physical activity that put strain on her muscles and pushed the ring out.
- d. This refers to the ring slipping out while the participant was having sex. This could be any of the sexual activities listed in the table at the beginning of the questionnaire. The question also refers to the time just after having any of the sexual activities listed in the table. For example this could mean just as she stood up after sex, the ring slipped out on its own.
- e. This refers to the ring slipping out while the participant was doing any kind of exercise activity including walking, running, swimming, yoga, weight training, playing a sport, etc.
- f. This refers to the ring slipping out **by itself** if the participant put a finger in her vagina to make sure the ring was in place. This **does not include** times when the participant took the ring out on purpose to check on it and put it back in.
- g. This question allows the participant to enter any other reason not listed above when the ring may have slipped out by itself. If there was another activity the participant was doing when the ring slipped out on its own, she should select "Yes, please specify" and

MTN-024 CASI Questionnaire

Question by Question (QxQ) Guide

type the activity or situation into the space. If there were no other reasons, the participant should select No.

Q12. This question refers only to the last time the ring slipped out by itself, and will only be asked if the participant answered that the ring came out one or more times on its own. The participant should select the position her body was in when the ring slipped out by itself. If the position is not listed, she should select, "Other, please specify" and type the position into the space.

Q13. This question refers only to the last time the ring slipped out by itself, and will only be asked if the participant answered that the ring came out one or more times on its own. The participant should select the answer that best describes what she did with the ring when the ring slipped out by itself. If no answer is listed that describes what she did with the ring, she should select, "Other, please specify" and type what she did with the ring into the space.

Q13a. This question is a follow-up question to Q13 and will only be asked if the participant answered that she reinserted the ring herself. This question refers to anything the participant may have done with the ring to clean it before she put it back in her vagina. This could be rinsing or wiping with water or cleaning with soap and water or another type of cleaner.

Q14. This question refers to the participant's ring use since her last computer questionnaire. If the ring ever came part of the way out of the participant's vagina on its own but did not slip fully out of her vagina, the participant should enter the number of times the ring came partially out. This means that the ring slipped part of the way out all by itself without the participant or someone else moving it. This could be even for just a moment before it was put back in place. If the ring never slipped part way out by itself, the participant should enter "0".

Q15. This series of questions is follow-up to Q14, and will only be asked if the participant answered that the ring came part way out of her vagina on its own one or more times. The question refers to the activity the participant was doing at the time the ring slipped part way out of her vagina on its own. Each question should be answered Yes or No.

- a. This refers to the ring slipping part way out while the participant was urinating or peeing.
- b. This refers to the ring slipping part way out while the participant was having a bowel movement.
- c. This refers to the ring slipping part way out while the participant was lifting something very heavy or doing some other physical activity that put strain on her muscles and pushed the ring out.
- d. This refers to the ring slipping part way out while the participant was having sex. This could be any of the sexual activities listed in the table at the beginning of the questionnaire. The question also refers to the time just after having any of the sexual activities listed in the table. For example this could mean just as she stood up after sex, the ring slipped part way out on its own.
- e. This refers to the ring slipping part way out while the participant was doing any kind of exercise activity including walking, running, swimming, yoga, weight training, playing a sport, etc.
- f. This refers to the ring slipping part way out **by itself** if the participant put a finger in her vagina to make sure the ring was in place. This **does not include** times when the participant took the ring part way out on purpose to check on it and put it back in.
- g. This question allows the participant to enter any other reason not listed above when the ring may have slipped part way out by itself. If there was another activity the participant was doing when the ring slipped part way out on its own, she should select "Yes, please

MTN-024 CASI Questionnaire

Question by Question (QxQ) Guide

specify” and type the activity or situation into the space. If there were no other reasons, the participant should select No.

Q16. This question refers only to the last time the ring slipped partially out by itself, and will only be asked if the participant answered that the ring came part way out one or more times on its own. The participant should select the position she was in when the ring slipped part way out by itself. If the position is not listed, she should select, “Other, please specify” and type the position into the space.

Q17. This question refers only to the last time the ring slipped partially out by itself, and will only be asked if the participant answered that the ring came part way out one or more times on its own. The participant should select the answer that best describes what she did with the ring when the ring slipped part way out by itself. If no answer is listed that describes what she did with the ring, she should select, “Other, please specify” and type what she did with the ring into the space.

Q18. This question is a follow-up to Q17, and will only be asked if the participant answered that she took the ring completely out of her vagina. The participant should select the answer that best describes what she did after she removed the ring. If no answer is listed that describes what she did with the ring, she should select, “Other, please specify” and type what she did with the ring into the space.

Q18a. This question is a follow-up question to Q18 and will only be asked if the participant answered that she reinserted the ring herself. This question refers to anything the participant may have done with the ring to clean it before she put it back in her vagina. This could be rinsing or wiping with water or cleaning with soap and water or another type of cleaner.

Q19. This question refers to the participant’s ring use since her last computer questionnaire. If the ring was ever taken all the way out of the participant’s vagina on purpose, the participant should enter the number of times the ring was removed. This means that the ring was taken out of the participant’s vagina either by the participant herself or by someone else, including a study staff member, partner, doctor, etc. This could be even for just a moment before it was put back in place. If the ring was never taken out, the participant should enter “0”.

Q19a. This is a follow up question to Q19 and will only be asked if the participant answered that the ring was taken out or removed on purpose one or more times since her last computer questionnaire. The question refers to the person who took the ring out of the participant’s vagina. The participant should select one response. If someone other than the participant or a study staff member removed the ring, the participant should select “Someone else took it out, *please specify your relationship to that person, e.g. partner, friend, etc.*” and the participant should type the person who removed the ring into the space.

Q20. This series of questions is a follow up to Q19 and will only be asked if the participant answered that the ring was taken out or removed on purpose one or more times since her last computer questionnaire. The questions refer to all the reasons the participant removed the ring or had the ring taken out by someone else since her last computer questionnaire.

- a. “Causing discomfort or pain” means the participant or someone else took the ring out because she felt the ring hurting her.
- b. “you felt that it was out of place in your body” means the participant or someone else took the ring out because it felt like it was not staying in the right place. This includes times

MTN-024 CASI Questionnaire Question by Question (QxQ) Guide

the participant took the ring out because it moved or slipped out of the right place while she was checking the ring placement with her finger.

c. “you wanted to clean it” means the participant or someone else took the ring out because she wanted to wash or rinse the ring off with water, soap or another cleaner.

d. “you wanted to show it to someone” means the participant took the ring out because she wanted to let another person see what the ring looked like.

e. “you had some worries about it” means the participant or someone else took the ring out because she was concerned about the ring being inside her. This could be because she was worried about the safety of the ring, or worried about her partner’s safety, or any other worry about the ring itself.

f. “you didn’t like it” means the participant or someone else took the ring out because she didn’t like the idea of the ring, the feel of the ring, or any other aspect of the ring that caused her not to like it.

g. “you felt it was interfering with **your** sexual pleasure” means the participant or someone else took the ring out because it was getting in the way of her own enjoyment of sexual activity.

h. “you felt it was interfering with **your partner’s** sexual pleasure” means the participant or someone else took the ring out because it was getting in the way of her partner’s enjoyment of sexual activity.

i. “Was there another reason that the ring was taken out or removed” means any other reason not listed in the previous questions (a-h) that the participant or someone else took the ring out. If the participant answers “Yes” she should type in the reason in the space next to “please specify”.

Q21. This is a follow up question to Q19 and will only be asked if the participant answered that the ring was taken out or removed on purpose one or more times since her last computer questionnaire. The participant should select the answer that best describes what she did after the ring was taken out or removed. If no answer is listed that describes what she did with the ring, she should select, “Other, please specify” and type what she did with the ring into the space.

Q21a. This is a follow-up question to Q21 and will only be asked if the participant answered that the ring was put back in before her next appointment either by herself or by a study staff member. The question refers to anything the participant did to wash off or rinse the ring with water, soap, or any type of cleaner before the ring was put back into her vagina.

Q22. This question refers to the last 30 days before this questionnaire. It asks the participant if she felt that she used the study ring and followed the study procedures the way she was told to by the study. The question asks the participant to rate how she feels about how well she used the study ring and followed the study directions. For example, if the participant feels she used the study ring all the time and followed study directions all the time, she could answer “Excellent.” If she feels that she did not use the study ring very much or didn’t follow the study directions, she could answer “Very poor”.

Q23. This question asks if the participant ever had the study ring in her vagina while she was in the study. For participants who have been in the study for 3 months, this would refer to having the ring in her vagina anytime since she was first enrolled in the study. For a participant ending the study

MTN-024 CASI Questionnaire Question by Question (QxQ) Guide

early before completing 3 months on-study, this would refer to having the ring in her vagina anytime that she has been in the study since enrollment.

Sexual Behavior Questions

<u>When we say:</u>	<u>We mean:</u>
Vaginal sex	When a man inserts his penis into your vagina
Anal Sex	When a man puts his penis into your anus/butt
Receiving oral sex	When a partner puts his or her mouth or tongue on your vagina or anus/butt
Giving oral sex	When you put your mouth or tongue on your partner's penis, vagina or anus/butt
Finger sex	When you or a partner inserts finger(s) into your vagina or anus/butt
Non-penetrative sex	When you have any kind of sex with yourself or with a partner, without inserting something into your vagina or anus/butt (e.g. rubbing each other, mutual masturbation or self masturbation)

Q24. This question asks about types of sex the participant has had while in the study **in the past 3 months**. It refers **only to vaginal, anal and finger sex**. The types of sexual activity are defined in the table of definitions (see above) and the participant can refer to this table if she has any questions on the activities asked about. If she has been less than 3 months since the participant started the study, she should answer only for the time while she was in the study.

Q25. This question is a follow-up question to Q24 and will only be asked if a participant answers that she has had vaginal, anal or finger sex while she was in the study in the past 3 months. The question asks how many sex partners the participant has had since starting the study, and should include any person she has had vaginal, anal, or finger sex with, including her primary partner and persons the participant only had sexual activity with once. The types of sexual activity are defined in the table of definitions (see above) and the participant can refer to this table if she has any questions on the activities asked about. If she has been less than 3 months since the participant started the study, she should answer only for the time while she was in the study.

Q26. This question asks if the participant has a primary sex partner now. A primary sex partner may be a person they have any type of sexual activity with on a regular basis, or it may be a person the participant considers to be her main partner regardless of their current sexual activity. This might be a spouse, domestic partner, boyfriend, or girlfriend. One response may be chosen.

Q27. This question is a follow-up question to Q26 and will only be asked if the participant answered that she currently has a primary partner. The question refers to whether the participant's current primary partner is the same person that was her primary partner at the beginning of the study. If her primary partner is a new partner since the beginning of the study, she should answer "Yes." If it is the same person as the beginning of the study, she should answer "No."

Q27a. This is a follow up question that will only be asked if the participant indicates she has a primary sex partner. The question asks if the participant's partner knows she is participating in the study. This may be because she told her partner that she is participating, or the partner may have

MTN-024 CASI Questionnaire

Question by Question (QxQ) Guide

found out another way. One response may be chosen. If the participant does not know if her partner is aware of her study participation, she should select the answer “Don’t know”.

Q27b. This is a follow up question to Q27 that will only be asked if the participant indicates she has a new primary sex partner since the start of the study. This question asks when the participant first had any sexual activity with her new primary partner. This may be any of the sexual activities listed in the sexual definitions table. If the participant does not know the exact date, she should make her best estimate of the month and year she began her relationship with her primary partner.

Q27c. This is a follow up question to Q27 that will only be asked if the participant indicates she has a new primary sex partner since the start of the study. The question asks if the primary partner she answered about in the Q27 is a man or a woman. One response may be selected. If the answer “Other” is chosen, the space next to “please specify” should be used to describe the gender of the participant’s new primary partner.

Q27d. This is a follow up question to Q27 that will only be asked if the participant indicates she has a new primary sex partner since the start of the study. The age in years should be selected from the drop-down menu. The participant may estimate if she does not know her partner’s exact age.

Q27e. This is a follow up question that will only be asked if the participant indicates she has a primary sex partner. The question refers to any difficulty in sexual performance by the participant’s primary partner. This may include problems with getting or maintaining an erection, problems with ejaculation, low arousal or little interest in sexual activities, or any other problems the participant may consider sexual performance difficulty. One response may be selected.

Q27f. This is a follow up question that will only be asked if the participant indicates she has a primary sex partner. This question refers to any medication that the participant’s primary partner may have taken in the past 3 months to help with sexual problems or to otherwise improve sexual performance. This may include medications prescribed by a physician or other substances. One response may be selected.

Q28. This question asks about the participant’s use of any medication or other substance taken to improve their sexual experience. The question refers to any medication or substance taken in the past 3 months. One response may be selected.

Q29. This question refers to anytime while the participant has been in the study. This may be less than 3 months for participants who are taking this questionnaire before completing 3 months on the study.

Q29a. This question is a follow-up to Q29 and will only be asked if a participant answered that she experienced pain at least some of the time during vaginal sex in the past 3 months.

Product Preference and Acceptability Questions

Q30. This question asks the participant about her worries about using the study vaginal ring in general. The question refers to any worries she may have right now about the ring being inside her vagina all the time for 3 months. One response may be selected.

Q31 a-o. This is a multi-part question asking the participant about different types of things she might be worried about using the study vaginal ring. All of the questions refer to worries she has

MTN-024 CASI Questionnaire Question by Question (QxQ) Guide

right now, today. Each question should be answered “Yes” if she is worried, or “No” if she is not worried.

31o. If there is anything that the participant is worried about when using the ring that is not specifically listed in another question in this section, she can mark “Yes” and type in what she is worried about in the space next to “please specify.”

Q32. This question asks the participant to rate her experience with the ring over the whole study. It refers to how hard or easy the participant thought it was to use the ring. This could be following the study directions or using the study ring itself. One answer may be selected.

Q33. This question asks the participant to rate her experience with the ring over the whole study. It asks the participant to estimate how often she **thought** about the ring inside her vagina **on average** during the study. This could mean wondering about the ring. One answer may be selected.

Q34. This question asks the participant to rate her experience with the ring over the whole study. It asks the participant to estimate how often she was **aware** of the ring while doing her regular activities. This could mean feeling the ring in her vagina while exercising, working, having sex, or just sitting or any other daily activity. One answer may be selected.

Q35. This question asks the participant to rate her experience with the ring over the whole study. It asks the participant to estimate how comfortable the ring felt in her vagina on average. One answer may be selected.

Q36. This question asks the participant about her experience with the ring over the whole study. It asks if the participant ever checked the placement of the ring in her vagina. This could be by inserting a finger to feel that the ring was in place.

Q36a. This is a follow-up question to Q36. It will be asked if the participant answered that she checked to see if the ring was inside her vagina at any time during the study. The question asks how often **on average** over the whole study the participant checked the ring

Q36b. This is a follow-up question to Q36. It will be asked if the participant answered that she checked to see if the ring was inside her vagina at any time during the study. It asks how the participant checked to make sure the ring was still in her vagina. If she used another way besides inserting finger(s), then she should select “Other” and type in the space next to “please specify” to explain how she checked the ring.

Q37. This multi-part question asks the participant about her experience with the ring over the whole study. It asks if the participant noticed differences in her vagina while using the ring. This would mean that her vagina felt different than it did before the study or while she was not using the ring.

Q37a. This question asks if the participant noticed more secretion or natural lubrication of her vagina when she started using the ring than before the study or while she was not using the ring.

Q37b. This question asks if the participant noticed less secretion or natural lubrication of her vagina when she started using the ring than before the study or while she was not using the ring.

Q79c. This question asks if the participant noticed any other changes besides her vagina being wetter or drier when she started using the ring than before the study or while she was not using the ring. If

MTN-024 CASI Questionnaire

Question by Question (QxQ) Guide

there are other changes the participant noticed, she should select “Yes” and type a description of the changes in the space next to “please specify.” If she felt no changes or no other changes besides the vaginal secretions, then she should answer “No.”

Q37d. This is a follow up question to each part of Q37. It will be asked for each question that the participant answered “Yes” to noticing a change in her vagina during the study. The question asks if the change or difference the participant felt in her vagina while using the study ring bothered her. She should select one answer to rate how much the change bothered her.

Q38. This question will only be asked if the participant answered that she used the study ring at some time in the study and that she had sex while the ring was in her vagina at some time during the study. It asks the participant to rate **on average over the whole study** how often she could feel the ring in her vagina when she had sex. This could mean any of the sexual activities listed in the table of activities above. It refers to the participant noticing that the ring was inside her vagina because it was moving or rubbing the surface of her vagina in a way that she could feel it.

Q38a. This is a follow-up question to Q38 and will only be asked if the participant answered that she could feel the ring in her vagina at some time while having sex during the study with the ring in her vagina. It asks the participant to rate **on average over the whole study**, how much being able to feel the ring inside her vagina when she had sex bothered her.

Q39. This question will only be asked if the participant answered that she used the study ring at some time in the study and that she had sex while the ring was in her vagina at some time during the study. It asks the participant to rate **on average over the whole study** how often her main sex partner could feel the ring in her vagina when she had sex. This could mean any of the sexual activities listed in the table of activities above. It refers to the participant’s partner noticing that the ring was inside her vagina because they could feel it when they had sex. If she did not talk about this with her partner, then she may select “Don’t know.”

Q39a. This is a follow-up question to Q39 and will only be asked if the participant answered that her partner could feel the ring in her vagina at some time while having sex during the study with the ring in her vagina. It asks the participant to rate **on average over the whole study**, how much being able to feel the ring inside her vagina when she had sex bothered her partner.

Q40. This question will only be asked if the participant answered that she used the study ring at some time in the study and that she had sex while the ring was in her vagina at some time during the study. It asks if, over the whole study, the participant minded using the ring during sex. This could mean that having the ring in during sex bothered her or her partner, or that it was inconvenient in some way.

Q41. This question will only be asked if the participant answered that she used the study ring at some time in the study and that she had sex while the ring was in her vagina at some time during the study. It asks how the ring affected her enjoyment during sexual activities on average over the whole study. One answer may be selected.

Q42. This question will only be asked if the participant answered that she has a primary sex partner. It asks how the ring affected the partner’s enjoyment during sexual activities on average over the whole study. If the participant did not talk about this with her partner, she may select “Don’t know.” One answer may be selected.

MTN-024 CASI Questionnaire

Question by Question (QxQ) Guide

Q43. This question will only be asked if the participant answered that she has a primary sex partner. It asks if the participant's use of the ring during the study changed the performance of the participant's main sex partner. This could be something the participant talked about with her main partner, or something that the participant noticed without talking to her partner.

Q44. This question will only be asked if the participant answered that she has a primary sex partner. It asks if the participant doesn't want her partner to be able to feel the ring is in her vagina when they have sex. This could be any of the sexual activities listed in the table of definitions above. The participant should answer even if her primary sex partner doesn't know she is in the study and using the study vaginal ring.

Q45. This question will only be asked if the participant answered that she has a primary sex partner. It asks if the participant's main sex partner ever asked her to remove the ring from her vagina during the study or to stop using the ring altogether. This could have been at any time in the study and could have been during sex or not. This could be because the partner didn't like the way the ring felt, or because the partner had concerns about the ring, or any other reason. The participant should answer "yes" if her partner asked her to remove the ring or stop using it and she did not.

Q46. This question refers to the participant's experience using the ring over the whole study. It asks if the participant ever felt uncomfortable in a part of her body while using it in the study and how much.

Q46a. This is a follow up to Q46, and will only be asked if the participant answered that she had physical discomfort because of the ring during the study. It asks the participant to rate how much the physical discomfort was a problem over the whole study.

Q47. This question refers to the participant's experience using the ring over the whole study. It asks if the participant ever felt that the ring hurt her physically while using it in the study and how much.

Q47a. This is a follow up to Q47, and will only be asked if the participant answered that she felt pain because of the ring during the study. It asks the participant to rate how much the pain was a problem over the whole study.

Q48. This question refers to the participant's experience using the ring over the whole study. It asks if the participant ever experienced the ring moving or slipping in her vagina and not staying in place the way it was supposed to, and how much.

Q48a. This is a follow up to Q48, and will only be asked if the participant answered that she felt the ring moving or not staying in place in her vagina during the study. It asks the participant to rate how much the ring moving or slipping out of place was a problem over the whole study.

Q49. This question refers to the participant's experience using the ring over the whole study. It asks if the participant ever felt any negative emotional feelings because of the use of the ring during the study, and how often. This could mean feeling worried about or afraid of using the ring. It could be a negative feeling related to her partner's reaction to the ring or the study.

Q49a. This is a follow up to Q49, and will only be asked if the participant answered that she felt the ring caused emotional discomfort or unpleasant feelings during the study. It asks the participant to rate how much the emotional discomfort was a problem over the whole study.

MTN-024 CASI Questionnaire

Question by Question (QxQ) Guide

Q50. This question refers to the participant's experience using the ring over the whole study. It asks if the ring ever interfered with the participant's normal daily activities, and how often. This could mean that using the ring made the participant change the way she performed normal activities, or that it prevented her from doing things as she normally would.

Q50a. This is a follow up to Q50, and will only be asked if the participant answered that she felt the ring interfered with her normal daily activities during the study. It asks the participant to rate how much the interference was a problem over the whole study.

Q51. This question refers to the participant's experience using the ring over the whole study. It asks if the participant ever felt constipation, or unable to have a bowel movement, because of the ring at any time during the study.

Q51a. This is a follow up to Q51, and will only be asked if the participant answered that she felt the ring cause her to feel constipated, or unable to have a bowel movement, during the study. It asks the participant to rate how much the constipation was a problem over the whole study.

Q52. This question refers to the participant's experience using the ring over the whole study. It asks if the participant ever felt a change in the amount or occurrence of urine leaking out that she could not control because of the ring at any time during the study.

Q53. This question asks if the ring was ever stuck in the participant's vagina when she wanted to take it out. This could be at any time during the study that she wanted to remove the ring from her vagina, for any reason, and she was unable to get the ring out on her own.

Q54. This question refers to any other problem that the participant may have had with the ring at any time in the study that is not listed in the previous questions. If the participant had a problem that is not asked about on this questionnaire, she should select "Yes" and type in the problem she had in the space next to "Please specify".

Q55. This question asks about the participant's preferences about the ring based on her experience over the whole study. It refers to whether she likes wearing it every day or not. If she does not have a feeling one way or the other about wearing it every day or not, she can select "I don't have a preference."

Q56. This question asks about the participant's opinion of the ring over the whole study and about all aspects of the ring. This includes how it feels to wear it all the time, or what she thinks of the ring itself.

Q57. This question asks the participant to compare her opinion of the ring after the whole study with her opinion of the ring at the beginning of the study. This means weighing how much she likes or dislikes the ring after using it for up to 3 months against how much she liked or disliked the ring when she hadn't yet used it or had used it for only a short time at the beginning of the study.

Q58. This question refers to a participant's feelings and opinions about her male sex partner using condoms when they have sex. This refers to the use of condoms for any reason or at any time, and may refer to the male condoms used during the study or previous experience with condoms in the participant's life.

MTN-024 CASI Questionnaire Question by Question (QxQ) Guide

Q59. This question asks the participant to choose which study product – the vaginal ring or male condoms - she likes better or would rather use to prevent HIV. She may choose one answer.

Q60. This question asks the participant to choose which study product – the vaginal ring or male condoms – her partner likes better or would rather use to prevent HIV. She may choose one answer. If she does not know which product her partner likes better, she may select “Don’t know.”

Q61. Condom Scale – this is a series of questions about how the participant feels about condoms. For each statement about condoms the participant should choose a rating that best matches her opinion. Remind the participant that there are no right or wrong answers to these questions – we are only asking for her opinion. Even if she does not have any experience with a situation described in a statement, she should choose an answer that represents how she might feel if she was in that situation. Scale responses for all questions include: Strongly disagree, Disagree, Slightly disagree, No opinion, Slightly agree, Agree, Strongly agree

Q62. Ring Scale – this is a series of questions about how the participant feels about the vaginal ring. For each statement about the ring, the participant should choose a rating that best matches her opinion. Remind the participant that there are no right or wrong answers to these questions – we are only asking for her opinion. Even if she does not have any experience with a situation described in a statement, for example if she is not currently sexually active, she should choose an answer that represents how she might feel if she was in that situation. Scale responses for all questions include: Strongly disagree, Disagree, Slightly disagree, No opinion, Slightly agree, Agree, Strongly agree

Q63. This question asks about the number of times the participant used douche for personal hygiene inserted inside the vagina anytime **in the past 3 months**. Douching is washing or cleaning out the vagina with water or other mixtures of fluids. Most douches are prepackaged mixes of water and vinegar, baking soda, or iodine, and may be purchased at drug and grocery stores. The mixtures usually come in a bottle and can be squirted into the vagina through a tube or nozzle. If the participant did not use any douche in the past 3 months, she should answer “0” times.

Q64. The questions in this table are part of the Menopause Rating Scale.

The questions in this table ask the participant to rate any menopause symptoms that she may feel at the time of the questionnaire. Each symptom is explained in parentheses following the symptom in the question on the questionnaire. The participant may mark one rating for each symptom. If she does not experience the symptom in the question, she should mark the button that corresponds to “None.”

Questions 65-70b are part of the Urogenital Distress Inventory (UDI-6).

Q65. This question asks if the participant feels the need to urinate more frequently than feels usual, in a way that she feels disrupts her everyday activities or her sleep. This could mean needing to urinate more than approximately eight times a day or waking up in the night to go to the bathroom.

Q65a. This is a follow up question to Q65, and will only be asked if the participant reported that she experiences frequent urination. The question asks how much having to urinate frequently bothers her, and she should select one response.

Q66. This question asks if the participant experiences urine leaking out that she cannot control before she can get to the bathroom if she has a sudden, strong urge to urinate.

MTN-024 CASI Questionnaire

Question by Question (QxQ) Guide

66a. This is a follow up question to Q66a, and will only be asked if the participant reported that she experiences urine leakage with a feeling of urgency. The question asks how much urine leakage with a feeling of urgency bothers her, and she should select one response.

Q67. This question asks if the participant experiences urine leaking out that she cannot control before she can get to the bathroom when she coughs, sneezes, or laughs.

Q67a. This is a follow up question to Q67, and will only be asked if the participant reported that she experiences urine leakage when she coughs, sneezes or laughs. The question asks how much urine leakage from coughing, sneezing or laughing bothers her, and she should select one response.

Q68. This question asks if the participant experiences small amounts of urine drops leaking out that she cannot control. This could be at any time, not necessarily due to urgency or physical movement that puts pressure on the bladder (such as coughing, sneezing, or laughing).

Q68a. This is a follow up question to Q68, and will only be asked if the participant reported that she experiences small amounts (drops) of urine leakage. The question asks how much having drops of urine leakage bothers her, and she should select one response.

Q69. This question asks if the participant ever has trouble urinating because she feels that it is difficult to release urine from her bladder or completely empty her bladder.

Q69a. This is a follow up question to Q69, and will only be asked if the participant reported that she experiences difficulty emptying her bladder. The question asks how much the difficulty emptying her bladder bothers her, and she should select one response.

Q70. This question asks if the participant usually feels pain or discomfort in her pelvis (lower abdomen or genital area). This would mean feeling pain or discomfort most of the time.

Q70a. This is a follow up question to Q70, and will only be asked if the participant reported that she usually experiences pain or discomfort in the lower abdomen or genital region. The question asks how much this pain bothers her, and she should select one response.

Q70b. This is a follow up question to Q70, and will only be asked if the participant reported that she experiences pain or discomfort in the lower abdomen or genital region. The question asks if the abdominal or genital pain goes away after she empties her bladder, and she should select one response.

At the end of the Exit 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.