

MTN 024 Follow-Up 4-Week / 8-Week CASI Questionnaire

Version 1.0 (30 July 2013)

Thank you for returning to the clinic today for the MTN 024 study. Just as a reminder, there are no right or wrong answers to the questions we ask, and every answer is important. Please be as honest as you can. Some of the questions may seem very personal. We are using the computer to give you the most privacy possible. The study staff will not have access to your answers and none of your answers will prevent you from participating in the study. All of your answers will be kept confidential. If at any time you have a question or a problem, please ask the study staff to help you. Let's begin.

There are different types of sexual activities we will ask you about. As a reminder, we have listed below all the different types of sexual activities that we may ask you about.

<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)

1. Since your last computer interview on [DATE], did you ever use the vaginal ring?

- Yes
- No

[If No: repeat question and confirm answer]

We would like to ask you some questions about your current sex life.

2. In the past 30 days, what type(s) of sexual activity have you had?

a. Vaginal sex

- Yes
- No

b. Anal sex

- Yes
- No

c. Receiving oral sex

- Yes
- No

d. Giving oral sex

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- Yes
- No

e. Finger sex

- Yes
- No

f. Non-penetrative sex

- Yes
- No

The next questions are all about your sexual activity in **the past 30 days**:

Pre-skip: Ask if Q2A=1

3. In the past 30 days, how many times did you have vaginal sex?
_____ times (range check: 1+)

Pre-skip: Ask if Q1=1 and Q2A=1

4. In the past 30 days, how many times did you have vaginal sex with the ring in?
—

Pre-skip: Ask if Q1=1 and Q2A=1 and Q4 > 0

5. The last time you had vaginal sex with the ring in, did you use a lubricant product (ie lube)?

- Yes, the study lubricant (preSeed)
- Yes, another commercial lubricant
- No

Pre-skip: Ask if Q2B=1

6. In the past 30 days, how many times did you have anal sex? ____

Now we will ask about **the last time you had vaginal sex**:

Pre-skip: Ask if Q2A=1

7. **The last time you had vaginal sex**, was a condom used?

- Yes
- No

Pre-skip: Ask if Q2A=1

8. The last time you had vaginal sex— did you use a lubricant product (ie lube)?

- Yes, the study lubricant (preSeed)
- Yes, another commercial lubricant

- No

Pre-skip: Ask if Q1=1 and Q2A=1 and Q4 > 0

9. The last time you had vaginal sex, **was the ring in?**

- Yes
- No

Post-skip: Ask if Q9 = 1, else go to Q10

9a. Did you have the ring in your vagina BEFORE you had sex that same day?

- Yes
- No

9b. Did you have the ring in your vagina AFTER you had sex that same day?

- Yes
- No

Pre-skip: Ask if Q1=1, else go to FUCOMPLETE

Product Adherence Assessment

Ring Adherence Questionnaire

RARINGUSEINTRO

Now, we would like to ask you about your experience with the ring **since your last computer interview**, on [DATE], and including today.

10. **Since your last computer interview** on [DATE], how many times did the ring come **completely out of your vagina on its own**, even for just a minute?

__ times

Post-skip: If Q10 = 0, go to Q14

Please think of all the times the ring **came out on its own**. What were you doing during those times? You can answer “yes” to more than one of the following questions.

11. Did the ring ever come out ...
- a. while you were urinating?
 - Yes
 - No
 - b. while you were having a bowel movement?
 - Yes
 - No
 - c. while you were lifting heavy objects or straining?
 - Yes
 - No
 - d. while you were having sex or just after sex?

- Yes
- No
- e. while you were exercising?
 - Yes
 - No
- f. while you were checking the ring with your finger?
 - Yes
 - No
- g. for any other reason
 - Yes, *please specify:* _____
 - No

12. The **last time** the ring **came out on its own**, what position were you in?

- In a standing position
- In a sitting position
- In a squatting position
- Lying down
- I can't remember
- Other, *please specify:* _____

13. The **last time** the ring **came out on its own**, what did you do?

- I reinserted it immediately
- I left it out for a while and put it back in before my next appointment
- I contacted the clinic and someone at the clinic reinserted it
- I waited for my next appointment
- The ring was not reinserted
- Other, *please specify:* _____

14. **Since your last computer interview** on [DATE], how many times did the ring **partially slip out of position on its own, but was not completely out of your vagina?**

__ times

Post-skip: If Q14 = 0, go to Q19

15. Please think of all the times that the ring **partially slipped out on its own without coming out completely**. **What were you doing** during those *times*? You can answer "yes" to more than one of the following questions

Did the ring ever partially slip out...

- a. while you were urinating?

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- Yes
- No
- b. while you were having a bowel movement?
 - Yes
 - No
- c. while you were lifting heavy objects or straining?
 - Yes
 - No
- d. while you were having sex or just after sex?
 - Yes
 - No
- e. while you were exercising?
 - Yes
 - No
- f. while you were checking the ring with your finger?
 - Yes
 - No
- g. for any other reason
 - Yes, *please specify:* _____
 - No

16. The **last time** the ring **partially** slipped out on its own, what position were you in?
- In a standing position
 - In a sitting position
 - In a squatting position
 - Lying down
 - I can't remember
 - Other, *please specify:* _____

17. The **last time** the ring partially slipped out on its own, what did you do?
- Put the ring back in place
 - Took the ring out completely ---
 - Nothing
 - Other, *please specify:* _____)

Post-skip: If Q17 in(1,3,4), go to Q19

18. What did you do when you took the ring out?
- I reinserted it immediately
 - I left it out for a while and put it back in before my next appointment

- I contacted the clinic and someone at the clinic reinserted it
- I waited for my next appointment
- The ring was not reinserted
- Other, *please specify*: _____

19. **Since your last computer interview**, how many times did you or someone else **take out or remove the ring** from your vagina, even for just a minute? Please only count times when the ring was entirely taken out.

_____ times

Post-skip: If Q19 = 0, go to FUCOMPLETE

19a. The **last time** the ring was taken out or removed, who took out or removed the ring?

- I took it out
- A staff member took it out
- Someone else took it out, *please specify your relationship to that person, e.g. partner, friend, etc.*: _____

RAVOLREMOVREASON

Now, please think of all the times the ring **was taken out or removed**, either by yourself or someone else **since your last computer interview on [Date]**. Why was it taken out or removed? You can answer “yes” to more than one of the following questions.

20. Was the ring taken out or removed because...

- a. it was causing discomfort or pain?
 - Yes
 - No

- b. you felt that it was out of place in your body? Please include times when the ring felt like it moved out of place while you were checking on it.
 - Yes
 - No

- c. you wanted to clean it?
 - Yes
 - No

- d. you wanted to show it to someone?
 - Yes
 - No

- e. you had some worries about it?
 - Yes
 - No

- f. you didn't like it?
 - Yes
 - No

- g. you felt it was interfering with **your** sexual pleasure?
 - Yes
 - No

- h. you felt it was interfering with **your partner's** sexual pleasure?
 - Yes
 - No

- i. Was there another reason that the ring was taken out or removed?
 - Yes, *please specify:* _____
 - No

21. **The last time** the ring was taken out or removed, what did you do?

- I reinserted it immediately
- I left it out for a while and put it back in before my next appointment
- I contacted the clinic and someone at the clinic reinserted it
- I waited for my next appointment
- The ring was not reinserted
- Other, *please specify:* _____

Post-skip: Ask if Q21 in(1,2,3), else go to FUCOMPLETE

- 21a. Did you wash or rinse the ring before reinserting it?
- Yes
 - No

FUCOMPLETE

Thank you for completing this questionnaire! Please click on 'Next' when you are ready to save your responses. After you do so, you will not be able to change your answers