

**MTN-039 Follow-Up Visit 8**  
**(Brief Visit-Specific CASI)**

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## SECTION A. Overview of Experiences with Trial Participation

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We would like to understand your satisfaction with the clinical procedures that are part of this study. Please answer the following statements as honestly as possible.

Use the following scale for all questions in Section A.

1	2	3	4
Completely Disagree	Disagree	Agree	Completely Agree

### A1. Experiences of Participation

1. My experience participating in the trial has corresponded well with the information I have received about the trial.
2. The clinic staff took their time in explaining the content of the trial.
3. Based on my experience, I would recommend to others that they participate in HIV prevention trials.
4. The clinic staff was interested in my experiences with the study product in the trial.
5. The clinic staff have been interested in my experiences during treatment in the trial.
6. I am taken better care of because I am participating in a trial.
7. If a pharmaceutical company finances a trial, my desire to participate is lower compared with if it is healthcare/society conducting a trial.
8. I sensed expectation from the clinic staff that I would consent to participate in the trial.

### A2. Clinic Procedures

1. I was fully informed through the course of the trial about what was going to happen.
2. I felt free to ask the staff questions I wanted to ask.
3. People here seem to really care about me.
4. People here really know what they are doing.
5. The clinic staff seemed to hurry me through too quickly.
6. The clinic staff used words that were hard to understand.
7. The physician was too rough when performing the rectal exam.
8. I had a lot of pain during the rectal exam.
9. The rectal exam was more comfortable than I expected.
10. The rectal exam caused me great discomfort.
11. I was very anxious about having the rectal exam.
12. I was embarrassed by the rectal exam.
13. I look forward to the sessions I have with people here.
14. I was very satisfied with the care I received.

Please answer the following questions.

A3. Insert Application – use the following scale:

1	2	3	4
Completely Disagree	Disagree	Agree	Completely Agree

1. I felt comfortable using the two inserts at this study visit.
2. I had a lot of pain having the study product inserted into my rectum.
3. Having the insert applied was more comfortable than I expected.
4. Having the insert applied caused me great discomfort.
5. I was very anxious about having the insert applied.

## SECTION B. RECTAL INSERT ACCEPTABILITY

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The following questions are about your **overall experience with the two inserts used at this study visit.**

B1. Overall, how easy or difficult was it to use the **two inserts** when applied by clinic staff?

- Very difficult
- Difficult
- Easy
- Very easy

B2. How did it feel to have the **two inserts** inside you?

- Very comfortable
- Comfortable
- Uncomfortable
- Very uncomfortable

The following questions are about changes in your rectum that you may have experienced while using the **two inserts**.

B3. Did you have any problems using the **two study inserts** after they were administered?

- No
- Yes (please specify: \_\_\_\_\_)

B4. Did you experience any leakage after you used the **two study inserts**?

- No **[IF NO, SKIP TO B5]**
- Yes

B4a. How soon did leakage occur after insertion of the **two study inserts**?

- Less than 15 minutes after insertion
- 15-29 minutes after insertion
- 30-44 minutes after insertion
- 45 minutes to an hour after insertion
- More than an hour after insertion

B4b. How much were you bothered by leakage?

1—2—3—4—5—6—7—8—9—10

Not

Very

at all

much

B5. Since your last study visit, have you experienced any soiling of your underwear or linens?

- No **[IF NO, SKIP TO B6]**
- Yes

B5a. What type of soiling did you experience? (check all that apply)

- Stool
- Blood
- Other (Specify)

B5b. How soon did soiling occur after insertion of the **two study inserts**?

- Less than 15 minutes after insertion
- 15-29 minutes after insertion
- 30-44 minutes after insertion
- 45 minutes to an hour after insertion
- More than an hour after insertion

B5c. How much were you bothered by soiling of underwear or linens from the **two study inserts**?

1—2—3—4—5—6—7—8—9—10

Not at all Very much

B6. Since your last study visit, have you experienced any diarrhea?

- No **[IF NO, SKIP to B7]**
- Yes

B6a. How soon did you experience diarrhea after using the **two study inserts**?

- Less than 15 minutes after insertion
- 15-29 minutes after insertion
- 30-44 minutes after insertion
- 45 minutes to an hour after insertion
- More than an hour after insertion
- It was not when I used the study insert(s)

B7. Since your last study visit, have you experienced any other stomach or abdominal problems (such as cramps, bloating, gassiness or passing wind or urge to have a bowel movement)?

- No **[IF NO, SKIP TO C1]**
- Yes

B7a. How soon did you experience any stomach or abdominal problems after using the **two study inserts**?

- Less than 15 minutes after insertion
- 15-29 minutes after insertion
- 30-44 minutes after insertion
- 45 minutes to an hour after insertion
- More than an hour after insertion
- It was not when I used the study insert(s)

**SECTION C: EXPERIENCES USING THE TWO INSERTS**

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We would like to know your experiences applying the **two study inserts** into your rectum.

C1. How much did you like the process of clinic staff inserting the study **two study inserts** into your rectum?

0	1	2	3	4
Disliked very much	Disliked a little	Neither	Liked a little	Liked very much

C2. How easy was it to have the staff insert the **two study inserts**?

0	1	2	3	4
Very Difficult	Difficult	Neither	Easy	Very Easy

C3. How pleasurable did the **two study inserts** feel inside your rectum?

0	1	2	3	4
Very Pleasant	Pleasant	Neutral	Unpleasant	Very unpleasant

C4. Did you have any problems with the clinic staff inserting the **two study inserts** into your rectum?

- Yes
- No **[IF NO, Skip to C5]**

C4a. What problems did you have? \_\_\_\_\_

C5. How likely would you be to use the **two study inserts** if it were double the amount?

0	1	2	3	4
Extremely Unlikely	Unlikely	Neither	Likely	Extremely Likely

C6. How likely would you be to use the **two study inserts** if it were half the amount?

0	1	2	3	4
Extremely Unlikely	Unlikely	Neither	Likely	Extremely Likely

## SECTION D: RECTAL MICROBICIDE INTENTIONS

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Researchers are trying to develop alternatives to condoms and PrEP for the prevention of HIV transmission during intercourse. Microbicides could be one such alternative.

D1. If a rectal microbicide were available that provided some protection against HIV, how likely would you be to use it every time you have anal intercourse?

0	1	2	3	4
Extremely Unlikely	Unlikely	Neither	Likely	Extremely Likely

D2. If a rectal insert were available that provided some protection against HIV, how likely would you be to use it every time you have **receptive anal intercourse** with a **steady sex partner**?

0	1	2	3	4
Extremely Unlikely	Unlikely	Neither	Likely	Extremely Likely

D3. How likely would you be to use a microbicide insert every time you have **receptive anal intercourse** with a **one-night stand**?

0	1	2	3	4
Extremely Unlikely	Unlikely	Neither	Likely	Extremely Likely

D4. How likely would you be to use a microbicide insert every time you have **receptive anal intercourse** with other partners, men who were neither your **steady sex partner** nor **one-night stands**?

0	1	2	3	4
Extremely Unlikely	Unlikely	Neither	Likely	Extremely Likely

D5. How likely would you be to use a microbicide insert for receptive anal intercourse if you were using alcohol or drugs?

0	1	2	3	4
Extremely Unlikely	Unlikely	Neither	Likely	Extremely Likely

D6. If a rectal microbicide were available that provided some protection against HIV, and it came in the form of a suppository, how likely would you be to use it every time you have receptive anal intercourse?

0	1	2	3	4
Extremely Unlikely	Unlikely	Neither	Likely	Extremely Likely

D7. If a rectal microbicide were available that provided some protection against HIV, and it came in the form of a gel, like commercial sexual lubricant, how likely would you be to use it every time you have receptive anal intercourse?

0	1	2	3	4
Extremely Unlikely	Unlikely	Neither	Likely	Extremely Likely



D8. If a rectal microbicide were available that provided some protection against HIV, and it came in the form of an enema, how likely would you be to use it every time you have receptive anal intercourse?

0	1	2	3	4
Extremely Unlikely	Unlikely	Neither	Likely	Extremely Likely

D9. If a rectal microbicide were available that provided some protection against HIV, and it came in the form of a douche, how likely would you be to use it every time you have receptive anal intercourse?

0	1	2	3	4
Extremely Unlikely	Unlikely	Neither	Likely	Extremely Likely

D10. How likely would you be to use a microbicide insert on the occasions when you don't use condoms?

0	1	2	3	4
Extremely Unlikely	Unlikely	Neither	Likely	Extremely Likely

D11. How likely would you be to use a microbicide insert if you had to wait 30 minutes after application before having intercourse?

0	1	2	3	4
Extremely Unlikely	Unlikely	Neither	Likely	Extremely Likely

D12. How much would you be willing to spend on a microbicide product per sexual occasion?

- About as much as I spend on lube and condoms
- Twice as much as I spend on lube and condoms
- Three times as much as I spend on lube and condoms
- Other, please specify:

D13. If you have a steady sexual partner, would you want to use a microbicide without their knowledge?

1. No **[IF NO, SKIP TO D14]**
2. Yes

D13a. Under what circumstances would you use a microbicide without your steady partner's knowledge? \_\_\_\_\_ (text range 0-500) (fill-in)

D14. Would you want to use a microbicide without a casual sexual partner's knowledge?

1. No
2. Yes

## SECTION F: RECOMMENDATIONS

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F1. Would you change anything about your participation in the study?

- Yes
- No [**IF NO, SKIP TO F2**]

F1a. What would you change? \_\_\_\_\_

23. Do you have any other recommendations?

1. Yes (please explain: \_\_\_\_\_)
2. No

This is the end of the interview. 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.