MTN 039 Follow-up Visit 4

(Brief Visit-Specific WSI)

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SECTION A. Overview of experiences with trial participation

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.

A1. Insert Application – use the following scale:

 1	2	3	4
Completely	Disagree	Agree	Completely Agree
Disagree			

- 1. I felt comfortable using the insert at this study visit.
- 2. I had a lot of pain when the insert was administered.
- 3. Using the rectal insert was more comfortable than I expected.
- 4. Using the rectal insert caused me great discomfort.
- 5. I was very anxious about using the rectal insert.
- 6. I was very satisfied with the care I received.

SECTION B. RECTAL INSERT ACCEPTABILITY

- B1. Overall, how easy or difficult was it to use the study product when inserted by clinic staff?
 - Very difficult
 - Difficult
 - Easy
 - Very easy
- B2. How did it feel to have the insert inside you?
 - Very comfortable
 - Comfortable
 - Uncomfortable
 - Very uncomfortable

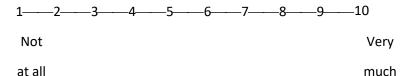
The following questions are about changes in your rectum that you may have experienced while using the insert.

- B3. Did you have any problems using the study insert after it was inserted?
 - No
 - Yes (please specify:_____)
- B4. Did you experience any leakage after you used the insert?
 - No [IF NO, SKIP TO B5]
 - Yes

B4a. How soon did leakage occur after insertion?

- 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?



- B5. Since your last study visit, have you experienced any soiling of your underwear or linens?
 - No [IF NO, SKIP TO B6]
 - Yes

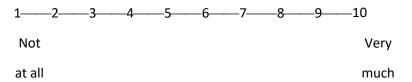
B5a. What type of soiling did you experience? (check all that apply)

- Stool
- Blood
- Other (Specify)

B5b. How soon did soiling occur after insertion of the insert?

- 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 insert?



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 insert?

- 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

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 Section C]
- Yes

B7a. How soon did you experience any stomach or abdominal problems after using the insert?

- 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

SECTION C: EXPERIENCES USING THE INSERT

We would like to know	v your experiences ap	plying the insert in	to your rectum.	
C1. How much did you	ı like the process of cli	nic staff applying tl	he study insert into y	our rectum?
0	1	2	3	4
Disliked very much	Disliked a little	Neither	Liked a little	Liked very much
C2. How easy was it t	to have the staff insert	t the study product	?	
0	1	2	3	4
Very Difficult	Difficult	Neither	Easy	Very Easy
C3. How comfortable	did the insert feel insid	de your rectum?		
0	1	2	3	4
Very Pleasant	1 Pleasant	Neutral	Unpleasant	Very unpleasant
Researchers are trying transmission during in C5. How likely would y	tercourse.			
	otection against HIV?	·	, ,,,	•
0	1	2	3	4
Extremely Unlikely	Unlikely	Neither	Likely	Extremely Likely
C6. How likely would	you be to use the inse	rt if it were double	the size?	
0	1	2	3	4
Extremely Unlikely	Unlikely	Neither	Likely	Extremely Likely
C7. How likely would y	ou be to use the inser	rt if it were half the	size?	
0	1	2	3	4
Extremely Unlikely	Unlikely	Neither	Likely	Extremely Likely

SECTION D: RECOMMENDATIONS

D1. Would you change anything about your study visit?					
		•	Yes		
		•	No [IF NO, SKIP TO D2]		
	D1a.	Wh	at would you change?		
D2. Do you have any other recommendations?					
		•	Yes (please explain:)		
		•	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.