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Follow-up behavioral and acceptability (FU4) CRF [Visit 5, 9]

Information in italics is for the interviewer and will not be read aloud to the participant.

IIVILIVI	FIMER READS	The follo	wing augst	ions ask you	shout your	oninions a	nd evnerie	nces with t	ho
vaginal			~ .	•	•	•	•		
vaginal ring you used <u>over the past month</u> . Your honest opinions are very important in making sure we									
	have the best information possible for developing dual purpose prevention products that will be liked and can be easily used by people like you.								
			te you.						
	Product Acce	•				-		_	
				lid you like or		-	_	•	
	where 1 mea	ans extrem	ely disliked	d and 10 mear	ns extremel	y well like	d? (Show Re	esponse Ca	ırd 16)
w	2	3	4	5	6		8	9	10
$\overline{}$									
	2	3	<u></u> 4	5	<u>6</u>	7	8	9	10
¹ Extremel	y disliked		I .	•			<u> </u>	9Ver	y well liked
² Very disli	ked							¹⁰ Extremel	ly well liked
2.	Please rate h	ow easy o	r difficult it	was for you t	to use the r	ing since y	our last visi	it, from 1-1	0, with 1
		•		eing extreme					,
					,, (
	2	(3)	4	5	6		8	9	(10)
		З	<u></u> 4	5	<u></u> 6		□ 8	<u></u> 9	
¹ Extremel	y difficult		•		•		•	•	⁹ Very easy
² Very diffi	cult							¹⁰ Extr	emely easy
3.	On a scale of	1 1 1 1 h							
_	On a scale of	1 to 10, n	ow worried	d were you wh	nen using th	ne vaginal	ring since y	our last vis	it, where
				d were you wh O means not a	_	_			it, where
				•	_	_			it, where
				•	_	_			it, where
				•	_	_			it, where
				•	_	_			it, where
0	1 means extr	remely wor	rried and 1	0 means not a	at all worrie	ed? (Show	Response C	9 🖂	10
	1 means extr	remely wor	rried and 1	0 means not a	at all worrie	ed? (Show	Response C	9 D9	10
1 1 Extremel 2Very wor	1 means extr	Temely wor	rried and 1	0 means not a	at all worrie	7	Response C	9 9 9N 10 Not at	10 Interpretation of the state
1 1-Extremel 2 Very wor 4.	1 means extr	Temely working and the state of	rried and 1	0 means not a	en using th	ed? (Show	Response C	9 10 Not at our last visi	10 Interpretation of the state
1 1-Extremel 2 Very wor 4.	1 means extr	Temely working and the state of	rried and 1	0 means not a	en using th	ed? (Show	Response C	9 10 Not at our last visi	10 Interpretation of the state
1 1-Extremel 2 Very wor 4.	1 means extr	Temely working and the state of	rried and 1	0 means not a	en using th	ed? (Show	Response C	9 10 Not at our last visi	10 Interpretation of the state
1 1-Extremel 2 Very wor 4.	1 means extr	Temely words	ow excited and 10	0 means not a	en using th	ed? (Show	Response C 8 In sering since your response Ca	9 10 Not at our last visi	10 Interpretation of the state
1 1-Extremel 2 Very wor 4.	1 means extr	Temely words	ow excited and 10	0 means not a	en using th	ed? (Show	Response C 8 In sering since your response Ca	9 10 Not at our last visi	10 Interpretation of the state
1 1Extremel 2Very wor 4.	1 means extraction and the second an	at all excit	ow excited and 10	0 means not a	en using the	ed? (Show	Response C 8 In since your seponse Ca 8	9 10 Not at our last visi rd 19) 90 90 91 90 90 90 90	Not worried all worried t, where
1 1Extremel ² Very wor 4.	1 means extraction and the second an	at all excit	ow excited and 10	0 means not a	en using the	ed? (Show	Response C 8 In since your seponse Ca 8	9 10 Not at our last visi rd 19) 90 90 91 90 90 90 90	Not worried all worried t, where
1 1Extremel 2Very wor 4. 1 1Not at all 2Not excit	1 means extraction and the second an	at all excit	ow excited and 10	0 means not a	en using the nely excited	ed? (Show	Response C 8 In since your seponse Ca 8	g g g g g g g g g g g g g g g g g g g	lo l
1 1Extremele 2Very wor 4. 1 1Not at all 2Not excit 5. How a	1 means extraction and the second an	f 1 to 10, he at all excit	ow excited and 10	0 means not a	en using the nely excited	ed? (Show	Response C 8 ing since your response Ca 8 Last All All All All All All All All All Al	gard 18) 9 10Not at our last visit rd 19) 9 10Extrematical acceptable	lo l
1 1Extremele 2Very wor 4. 1 1Not at all 2Not excit 5. How a	1 means extraction and the second an	f 1 to 10, he at all excit	ow excited and 10	0 means not a	en using the nely excited	ed? (Show	Response C 8 In since your sesponse Ca 8 In Not at all a	gard 18) 9 10Not at our last visi rd 19) 9 10Extremacceptable table	Not worried all worried t, where
1 1Extremele 2Very wor 4. 1 1Not at all 2Not excit 5. How a	1 means extraction and the second an	f 1 to 10, he at all excit	ow excited and 10	0 means not a	en using the nely excited	ed? (Show	Response C 8 ing since your sesponse Ca 8 2 Not at all a 2 Not accep 3 Somewhar	grad 18) 9 10 Not at our last visited 19) 9 10 Extrematication acceptable table tacceptable	Not worried all worried t, where
1 1Extremele 2Very wor 4. 1 1Not at all 2Not excit 5. How a	1 means extraction and the second an	f 1 to 10, he at all excit	ow excited and 10	0 means not a	en using the nely excited	ed? (Show	Response C 8 In since your sesponse Ca 8 In Not at all a 2 Not accep	gard 18) 9 10Not at our last visit rd 19) 9 10Extremacceptable table tacceptable tacceptable	Not worried all worried t, where

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	_		
6. How acceptable to you was the amount of time it took to remove the ring? (Show Response Card 20)	☐ ₂ Not ac ☐ ₃ Some\ ☐ ₄ Accep	what acceptal	
7 The payt statements are about things that you may have	387		
 The next statements are about things that you may have experienced when you were using this [v5: "first", v9: "second"] vaginal ring over the past month. For each of the following statements, please tell me if you agree or disagree. 	Yes (Agree)	No (Disagree)	N/A
a. I thought a lot about the ring over the past month		\square_2	
b. The vaginal ring felt uncomfortable during normal activities			
c. The vaginal ring felt painful during normal activities			
d. The vaginal ring felt too hard			
e. The vaginal ring felt too soft or not hard enough	1	2	
f. The vaginal ring caused side effects	1	2	
g. I felt like I could easily remove the vaginal ring as it was explained to me		<u></u>	
 I felt uncomfortable with the vaginal ring in place during menses 		\square_2	<u></u> 3
i. The vaginal ring made sex more enjoyable			
j. I did not feel the vaginal ring during sex			3
 It was exciting to use a new option that is being designed for dual purpose prevention 		\square_2	
I. I felt like I had control over the vaginal ring.			
8. [If 7g = Yes] Please describe the side effects you've experienced	Specify:	<u> </u>	
while using the vaginal ring.			
If one is needed, complete an AE form.			
Ease of Use			
9. Since the last visit, were you aware of the feeling of the vaginal ring during your normal daily activities?	=	nost of the tir ometimes	ne
10. Since the last visit, did you notice any of the following changes in your vagina?		wetness than dryness than	
(Mark all that apply)	₃ More	itchiness that	n normal
	=	, specify:	ii iioiiiiai
	6 No no	 ticeable char	nges
Burden			
11. Since your last visit, how often did your use of the vaginal ring interfere with any of your regular daily activities?	2 Some		

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Asked at Visit 9 only (Q12-21)						
12. How, if at all, would the following chan affect your use of vaginal rings in the fu Response Card 21) [Response option only included if selected in prior que	iture? (Show	More likely to use	N chang us	ge in	Less lik to us	•
a. More wetness than normal		1		2		3
b. More dryness than normal c. More itchiness than normal		1]2		3
c. More itchiness than normal d. More soreness than normal		1		2		3
		1]2		3
		1				3
Discreetness and Product Use - Asked at Visit 9 only INTERVIEWER READS: The next questions ask about discreetly (without others knowing) and whether you not.	t your views of whethe		~	_		
13. How involved was your main partner when you were deciding whether to join this study?	1 Not at all involve 2 A little involved 3 Very involved 4 I don't have a pa		skip to	Q17		
14. Was your main partner aware that you were using the vaginal ring this past month?	1 Yes, I chose to te 2 Yes, they found o 3 Yes, they discove 4No, they don't kn	out from ered the	somed	ne elso me oth	ner way	kip
15. How supportive was your main partner of your use of the ring when they first found out?	☐ 1 Very supportive ☐ 2 A little supportiv ☐ 3 Not very support ☐ 4 Not at all suppor	ive				
16. How supportive is your main partner now of your use of the ring?	☐ 1 Very supportive ☐ 2 A little supportive ☐ 3 Not very support ☐ 4Not at all support	ive				
17. In the future, if vaginal rings were avail purpose HIV and pregnancy prevention to you that the vaginal ring could be us following people knowing? (Show Response Card 22)	, how important is it	Very unimportant	Somewhat unimportant	Somewhat important	Very important	N/A
a. Spouse/main sexual partner (if not spo	use)	<u> </u>	<u></u>	<u></u> 3	 4	5
b. Casual (other) sexual partner(s)				З	 4	

c. Family, specify: __

e. Community members

d. Friends

____4

4

___2

___2

 \square_2

____3

___3

 \square_1

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	18. In the future, if the vaginal ring were available, how easy or	프	<u>+</u>		ksı	
	difficult would it be to use this product without the	Very difficult	Difficult	Easy	Very easy	N/A
	following people knowing?	7 등	ä		Ver	
a.	(Show Response Card 23) Spouse/main sexual partner (if not spouse)			Пз	4	
b.	Casual (other) sexual partner(s)		2	З	<u></u> 4	5
_	Family analysis			3	4	5
	Family, specify:					5
d.	Friends		2	3	4	5
e.	Community members		<u></u>	З	<u></u> 4	5
Q19-21	- Asked at Visit 9 only					
	19. Did you tell anyone- other than your main partner - about	□₁ No (one			
	your use of the vaginal ring while you were in the study?	2 Cas	ual (ot	ther) se	xual	
		partner	٠,			
		==		ecify:_		
		4 Oth	er, sp	ecify: _		
	20. Did any of these people find out because you felt forced to	1 Yes				
	tell them?	2 No	→ skij	o to Q2	1	
20a. If y	res, who?					
	21. Did anyone find out about your vaginal ring use without	1 Yes				
	you telling them?	₂ No				
21a. If y	res, who?					
Ring Use	e During Sex, Menstruation and Vaginal Practices					
INTERVI	EWER READS: I will now ask you some questions about sex, mens	truation,	and o	ther va	ginal	
practice	s in the last month. I know it can be awkward to talk about some	of these	things	s; I hop	e you fe	el
comfort	able to answer freely, and you can always skip questions if you w	ould pref	er.			
	22. What kinds of sex have you had since inserting the [v5:	1 Ora	l			
	"first", v9: "second"] vaginal ring one month ago?	2 Vag	inal			
	Select all that apply	₃ Ana	ıl			
		☐4 Digi	tal			
		₅ Nor	ne			
		_	er, sp			
		Only	y non-	recepti	ve sex	
	23. Did using the vaginal ring affect		Yes	S	No	
	a. How often you had any type of sex?					
	If yes, in what ways:		_ :	ı	2	
	b. Your overall desire to have sex?			1		
	<i>If yes,</i> in what ways:			ı		

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If Q22 = "5. None" or "7. Only non-receptive sex", skip 23c - 32			
c. Your feelings of intimacy or emotional closeness with	your partner		
during sex? If yes, in what ways:			2
d. The types of sex you engaged in?			
d. The types of sex you engaged in:			\square_2
If yes, in what ways:			
24. How acceptable was this [v5: "first", v9: "second"]	Acceptable	Somewhat	Not
vaginal ring's effect on: (Show Response Card 24)		acceptable	acceptable
Response options included only if selected "yes" in prior question	<u> </u>		
a. How often you had any type of sex		2	3
b. Your overall desire to have sex	1	2	3
 Your feelings of intimacy or emotional closeness with your partner during sex 	П	<u></u>	З
d. The types of sex you engaged in		2	
25. How did this [v5: "first", v9: "second"] vaginal ring		ot affected	
affect your sexual pleasure?	2 I had les	s sexual pleas	sure than
	usual		
		re sexual ple	asure than
	usual		
26. How do you think this [v5: "first", v9: "second"]		ot affected	
vaginal ring affected your partner's sexual pleasure?		d less sexual p	oleasure
	than usual	d mara savua	l plancura
	than usual	d more sexua	i pieasure
	4 I do not	know	
	 _		
27. Did your partner notice this [v5: "first", v9: "second"]		ow they notic	
vaginal ring?	l	talked about	
		ow they notic	ced it but we
	did not talk a		
	1 = 1	did not notic	o it
28. Did your partner notice any changes related to you	1 Change		Je it
using the [v5: " first ", v9: " second "] vaginal ring?		in taste in scent or sm	nell
asing the [vs. mst) vs. second] vaginaring.		in lubrication	
		felt the ring d	
		in the feeling	•
	\bigcap_{6} Other, s	•	
	No chan		
	\square_8 I do not	know	
29. (Skip unless Q22=2 (had vaginal sex)) How often did you			
use condoms when having vaginal sex, since inserting	2 Sometin	nes	
the [v5: "first", v9: "second"] vaginal ring?	₃ Rarely		
	4 Never		
30. (Skip unless 22=2 (had vaginal sex)) Did you remove the	1 Yes		
[v5: "first", v9: "second"] vaginal ring during sex?	□ ₂ No		

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31. (Skip unless 22=2 (had vaginal sex)) Overall, how did you feel about the [v5: "first", v9: "second"] vaginal ring being present during sex?32. The next two questions ask you about the last two	☐ 1 Liked it ☐ 2 Did not like it ☐ 3 No opinion ☐ 4 N/A, I always removed the ring during sex ☐ 1 Yes
weeks. Have you inserted anything other than the study product into your vagina in the last two weeks? This could include things like medications, tampons, lubricants, and cleansers.	$\square_2 \text{ No} \rightarrow \text{skip to Q34}$
33. What else did you insert into your vagina in the last two weeks? (Read list and select each that apply)	☐ 1 Condom (male or female) ☐ 2 Tampons ☐ 3 Lubricants ☐ 4 Douches ☐ 5 Sex toys ☐ 6 Water (alone or with soap) ☐ 7 Vaginal medications ☐ 8 Vaginal moisturizers ☐ 9 Vaginal products, to make the vagina dry or tight ☐ 10 Materials such as paper, cloth, sponges, or cotton wool ☐ 11 Other, specify:
Use During Menses or Bleeding	
Use During Menses or Bleeding 34. In the past month, have you had any vaginal bleeding o spotting?	
34. In the past month, have you had any vaginal bleeding o	r
34. In the past month, have you had any vaginal bleeding o spotting?35. Was the vaginal bleeding expected (usual menses) or	r $\square_1 \text{ Yes}$ $\square_2 \text{ No } \rightarrow \text{ skip to } \text{ Q37}$ $\square_1 \text{ Expected}$
34. In the past month, have you had any vaginal bleeding o spotting?35. Was the vaginal bleeding expected (usual menses) or unexpected?36. How did you feel about the vaginal ring being present	r
 34. In the past month, have you had any vaginal bleeding o spotting? 35. Was the vaginal bleeding expected (usual menses) or unexpected? 36. How did you feel about the vaginal ring being present during bleeding? 	r

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38. Has the vaginal ring been removed or come out in the past two weeks? Check all that apply	
39. [If Q38 = 1] How many times has the ring been removed intentionally in the past two weeks?	times intentionally
40. [If Q38= 1] Why was the vaginal ring removed? Check all that apply	☐ 1 It was uncomfortable ☐ 2 It felt like it was falling out ☐ 3 I wanted to show my partner/ my partner wanted to see it ☐ 4 My partner asked me not to wear it ☐ 5 I wanted to clean it ☐ 6 I was menstruating ☐ 7 I wanted to have sex without it ☐ 8 I was sick (e.g. diarrhea) and worried that it would be expelled ☐ 9 Other (specify):
41. [If Q38 = 2] How many times has the vaginal ring come out unintentionally or accidentally in the past two weeks?	times unintentionally
42. [If Q38 = 2] Do you know what caused the ring to come out? [Probes: when did this happen? What were you doing when this happened?]	Describe:

Product Attributes			
43. For each of the following, what is your opinion of (Show Response Card 25)	I liked it/ No problem	Neutral/ No opinion	I did not like it/ It was a problem
a. How the vaginal ring is inserted		\square_2	3
b. How the vaginal ring felt during insertion		2	3
c. How the vaginal ring felt while you were using it		\square_2	
d. The size of the vaginal ring		2	3
e. How long the protection would last (i.e. one month protection)		2	З
f. How the vaginal ring looks		2	3
g. How using the vaginal ring affected your body		2	3
h. Vaginal ring side effects		2	З

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 i. Any increases to vaginal wetness caused by the vaginal ring 		2	З
j. The color of the vaginal ring		2	З
k. The smell of the vaginal ring		2	3
I. The shape of the vaginal ring	1	2	3
m. The flexibility of the vaginal ring	1	2	3
n. The vaginal ring's ability to be kept discreet from others		2	З
Satisfaction The next question about satisfaction will be used to assess one of the primal extra care to ensure the participant is alert and engaged at this point in the this may be a good point at which to take a stretch break.	questionnaire. F	or V9, if appro	priate,
44. Please rate on a scale of 1-10 how satisfied you are, overa the past month, where 1 means extremely dissatisfied and			
(Show Response Card 26)	a 10 means exti	ciricly satisfic	-u.
1 2 3 4 5 6	7 8	9	10
□1 □2 □3 □4 □5	□6 □7	□ 8 □	9 10
¹ Extremely dissatisfied ² Very dissatisfied			ry satisfied ly satisfied
End of Visit 5			
Gains and Losses – Asked at Visit 9 only			
45. For each of the following statements, please tell me if you a lot. In the future, if the vaginal ring were available for HI' table]			_
tubiej	Disagree	Agree somewhat	Agree a lot
 Using a vaginal ring on a regular basis may interfere with my sexual relationships. 			Пз
 b. Using a vaginal ring on a regular basis may enhance/improve my sexual relationships. 			Пз
 Using a vaginal ring on a regular basis may give me greater control of my sexual health. 		2	З
d. Using a vaginal ring on a regular basis may make people think I am at high-risk/that I take sexual risks.			<u></u> з
e. People in my community who are similar to me may want to use a vaginal ring. "Similar" means women who may share the same life circumstances as you, be in a similar situation in terms of relationships, age, living situation, education.			Пз

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Future Recommendation and Interest in Product Use – Asked at Visit 9 only	
46. In the future, if available for HIV prevention, how likely is it that you would recommend the vaginal ring to a friend? (Show Response Card 27)	☐ 1 Very likely ☐ 2 Somewhat likely ☐ 3 Somewhat unlikely ☐ 4 Very unlikely
47. In the future, how likely are you to want to use a product that combines HIV and pregnancy prevention together into one product? (Show Response Card 27)	☐ 1 Very likely ☐ 2 Somewhat likely ☐ 3 Somewhat unlikely ☐ 4 Very unlikely
48. In the future, if a vaginal ring were available for dual purpose HIV and pregnancy prevention, how interested would you be in using it? (Show Response Card 28)	☐ 1 Very interested ☐ 2 Somewhat interested ☐ 3 Somewhat uninterested ☐ 4 Very uninterested
Preferred Ring Use – Asked at Visit 9 only	
INTERVIEWER READS: I will now ask you some questions about your preference between the two vaginal rings you've used during this study.	
49. Which ring was more comfortable for you to use over the course of the month?	☐ 1 The first ring ☐ 2 The second ring ☐ 3 Both rings were equally comfortable to use ☐ 4 Neither ring was comfortable to use/both were uncomfortable
50. Which vaginal ring was easier to insert?	☐ 1 The first ring ☐ 2 The second ring ☐ 3 Both rings were equally easy to insert ☐ 4 Neither ring was easy to insert
51. Which vaginal ring was easier to remove?	☐ 1 The first ring ☐ 2 The second ring ☐ 3 Both rings were equally easy to remove ☐ 4 Neither ring was easier to remove
52. Which ring was better to use during sex? 53. Overall, which ring would you prefer to use in the	☐ 1 The first ring ☐ 2 The second ring ☐ 3 Neither ring ☐ 4 I did not have sex with either ring inserted ☐ 5 I did not have sex with the 1st ring inserted ☐ 6 I did not have sex with the 2nd ring inserted ☐ 1 The first ring
future?	☐2 The second ring ☐3 I would use either ☐4 I would use neither

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$ \begin{array}{c} $
☐ 1 No, neither needs changes → END ☐ 2 Yes, the first ring needs to be changed ☐ 3 Yes, the second ring needs to be changed ☐ 4 Yes, they both need to be changed Changed
1