PTID:	Visit #:
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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.

vaginal ı	EWER READS								
_		: The follo	wing quest	ions ask you a	about your	opinions an	d experier	nces with t	he
have the	ring you used	l <u>over the p</u>	oast month	. Your honest	opinions a	re very impo	ortant in n	naking sur	e we
mare em	e best inform	ation poss	ible for dev	eloping dual	purpose pr	evention pro	oducts tha	it will be li	ked and
can be e	asily used by	people lik	e you.						
Overall I	Product Acce	ptability							
1.	On a scale of	1 to 10, h	ow much d	id you like or	dislike usin	g the vagina	I ring sinc	e your last	visit,
	where 1 mea	ns extrem	ely disliked	and 10 mear	s extremel	y well liked?	Show Re	esponse Ca	ırd 16)
U	2	3	4	5	6		8	9	10
-									
	2	3	<u></u> 4	5	<u></u> 6	7	8	9	10
¹ Extremel									y well liked
² Very disli									ly well liked
		•		was for you t					LO, with 1
	being extrem	nely difficu	It and 10 b	eing extremel	y easy. (Sho	ow Response	e Card 17)		
	2	3		5	6		8		10
			4						
	2	3	4	<u></u> 5	<u>6</u>		□ 8	9	10
¹ Extremel	y difficult			I				l	⁹ Very easy
² Very diffi	cult							¹⁰ Extr	remely easy
				l were you wh	_	_			it, where
	1 means extr	remely wo	ried and 1	0 means not a	t all worrie	d? (Show Re	esponse C	ard 18)	
U	2	3	4	5	6		8	9	10
		3	4	5	6	7	8	9	10
		3	4	5	6	7	8	9	10
¹ Extremel	y worried	3	4	s	6	7	8	91	Not worried
¹ Extremel ² Very wor	y worried ried							9 10 10Not at	Not worried
¹ Extremel ² Very wor 4.	y worried ried On a scale of	1 to 10, h	ow excited	were you wh	en using th	e vaginal rin	g since yo	¹⁰ Not at our last visi	Not worried
¹ Extremel ² Very wor 4.	y worried ried On a scale of	1 to 10, h	ow excited		en using th	e vaginal rin	g since yo	¹⁰ Not at our last visi	Not worried
¹ Extremel ² Very wor 4.	y worried ried On a scale of	1 to 10, h	ow excited	were you wh	en using th	e vaginal rin	g since yo	¹⁰ Not at our last visi	Not worried all worried
¹ Extremel ² Very wor 4.	y worried ried On a scale of	1 to 10, he at all excit	ow excited	were you wh means extren	en using th	e vaginal rin	g since yo	¹⁰ Not at our last visi	Not worried all worried
¹Extremel ²Very wor 4. 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	y worried ried On a scale of 1 means not	1 to 10, he at all excit	ow excited ed and 10	were you wh means extren	en using the nely excited	e vaginal rin I? (Show Res	g since yo	10Not at pur last visi rd 19)	Not worried all worried it, where
¹ Extremel ² Very wor 4. 4. 1 1 1 1 1 Not at all ² Not excit	y worried ried On a scale of 1 means not 2 excited ed	1 to 10, he at all excit	ow excited ed and 10	were you wh means extren 5	en using the nely excited	e vaginal rin I? (Show Res	since your sponse Care	10Not at visi rd 19) 9 9 10 Not at visi rd 19) 9 10 Extrem	Not worried all worried it, where
¹Extremel ²Very wor 4. 1 ¹Not at all ²Not excit	y worried ried On a scale of 1 means not 2 excited ed acceptable to	1 to 10, he at all excit	ow excited ed and 10	were you wh means extren	en using the nely excited	e vaginal rin l? (Show Res	g since you sponse Can 8	10Not at our last visi rd 19) 9 9 10Extrematics	Not worried all worried it, where
¹Extremel ²Very wor 4. 1 ¹Not at all ²Not excit	y worried ried On a scale of 1 means not 2 excited ed	1 to 10, he at all excit	ow excited ed and 10	were you wh means extren 5	en using the nely excited	e vaginal rin !? (Show Res	g since you sponse Can 8	10Not at pur last visi rd 19) 9 10 Not at pur last visi rd 19) 9 10 Extremacceptable table	Not worried all worried it, where
¹Extremel ²Very wor 4. 1 ¹Not at all ²Not excit	y worried ried On a scale of 1 means not 2 excited ed acceptable to	1 to 10, he at all excit	ow excited ed and 10	were you wh means extren 5	en using the nely excited	e vaginal rin 1? (Show Res 7 7 ring?	g since your sponse Can a spons	10Not at visi rd 19) 9 10Not at visi rd 19) 9 10Extremacceptable table tacceptab	Not worried all worried it, where
¹Extremel ²Very wor 4. 1 ¹Not at all ²Not excit	y worried ried On a scale of 1 means not 2 excited ed acceptable to	1 to 10, he at all excit	ow excited ed and 10	were you wh means extren 5	en using the nely excited	e vaginal rin I? (Show Res	g since you sponse Can 8	10Not at pur last visi rd 19) 9 10Extrem acceptable table tacceptable	Not worried all worried it, 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)	☐ ₁ Not at all acceptable ☐ ₂ Not acceptable ☐ ₃ Somewhat acceptable ☐ ₄ Acceptable ☐ ₅ Highly acceptable			
7. 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		<u></u>		
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		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		2		
h. I felt uncomfortable with the vaginal ring in place during menses		\square_2	<u></u> 3	
i. The vaginal ring made sex more enjoyable			<u></u>	
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 		2		
I. I felt like I had control over the vaginal ring.	\square_1			
8. [If 7f = Yes] Please describe the side effects you've experienced while using the vaginal ring.	Specify:			
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		wetness than		
in your vagina?		dryness than		
(Mark all that apply)		itchiness tha		
	=	soreness tha	n normal	
	₅ Other	, specify:		
	No no	 oticeable char	ogos.	
Burden	6 INO IIC	riceable chai	iges	
11. Since your last visit, how often did your use of the vaginal	Most	of the time		
ring interfere with any of your regular daily activities?	Some			
ring interfere with any or your regular daily activities:				
		not used		

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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	More likely	No		Less lik	kelv	
Response Card 21)	to	change	e in	to us	•	
[Response option only included if selected in prior qu	use	use	;			
a. More wetness than normal				2		3
b. More dryness than normal				2	3	3
c. More itchiness than normal				2	3	3
d. More soreness than normal				2		}
e. Other, specify:				2		3
Discreetness and Product Use - Asked at Visit 9 onl	у					
INTERVIEWER READS: The next questions ask about	t your views of whethe	er the va	ginal rin	g can	be used	
discreetly (without others knowing) and whether y not.	ou have to let others k	now abo	ut your	prod	uct use c	r
13. How involved was your main partner	\square_1 Not at all involve	ed				
when you were deciding whether to	2 A little involved					
join this study?	☐3 Very involved					
	₄I don't have a pa	rtner →	skip to	Q17		
14. Was your main partner aware that	\square_1 Yes, I chose to te					
you were using the vaginal ring this	\bigsqcup_{2} Yes, they found o					
past month?	☐3 Yes, they discove		_			
	☐4No, they don't kr	iow I was	s using t	he rin	$g \rightarrow sk$	rip
	to Q17					
15. How supportive was your main	☐ ₁ Very supportive					
partner of your use of the ring when	A little supportiv					
they first found out?	Not very support					
46 11.	Not at all suppor	tive				
16. How supportive is your main partner	Very supportive 2 A little supportive					
now of your use of the ring?	Not very support					
	4Not at all support					
17. In the future, if vaginal rings were avail						
purpose HIV and pregnancy preventior		tant	t nt		ant	
to you that the vaginal ring could be us	•	ıpor	wha	wha tant	oort	⋖
following people knowing?		Very unimporta	Somewhat unimportant	Somewhat important	Very important	N/A
(Show Response Card 22)		ı hə	So uni	Sori	/ery	
		^				
a. Spouse/main sexual partner (if not spo	use)	1	2	3	□ 4	5
b. Casual (other) sexual partner(s)		1	2	3	□ 4	5
c. Family, specify:		_1	2	3	<u></u> 4	5
d. Friends			2	3	<u></u> 4	5
e. Community members			2	З	<u></u> 4	

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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	<u></u> 1	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?	\square_2 No \rightarrow skip to Q21					
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				
		Digital					
		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:		_ :	l	2		
	b. Your overall desire to have sex?			1			
If yes, in what ways:							

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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 during sex? If yes, in what ways:	your partner		
d. The types of sex you engaged in? If yes, in what ways:			
24. How acceptable was this [v5: "first", v9: "second"] vaginal ring's effect on: (Show Response Card 24) Response options included only if selected "yes" in prior question	Acceptable	Somewhat acceptable	Not acceptable
a. How often you had any type of sex		2	□ ₃
b. Your overall desire to have sex		2	□ ₃
c. Your feelings of intimacy or emotional closeness with your partner during sex		_2	З
d. The types of sex you engaged in		2	З
25. How did this [v5: "first", v9: "second"] vaginal ring affect your sexual pleasure?	2 I had les usual	ot affected s sexual pleas ore sexual ple	
26. How do you think this [v5: "first", v9: "second"] vaginal ring affected your partner's sexual pleasure?	They had than usual	ot affected d less sexual p d more sexua know	
27. Did your partner notice this [v5: "first", v9: "second"] vaginal ring?	because we solve the because the because we solve the because we solve the because the		it ced it but we
28. Did your partner notice any changes related to you using the [v5: "first", v9: "second"] vaginal ring?	1 Change 2 Change 3 Change	in taste in scent or sm in lubrication felt the ring d in the feeling pecify: ges	nell
29. (Skip unless Q22=2 (had vaginal sex.)) How often did you use condoms when having vaginal sex, since inserting the [v5: "first", v9: "second"] vaginal ring?	1 Always 2 Sometin 3 Rarely 4 Never	nes	
30. (Skip unless 22=2 (had vaginal sex)) Did you remove the [v5: "first", v9: "second"] vaginal ring during sex?	☐ ₁ Yes ☐ 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 apply39. [If Q38 = 1] How many times has the ring been removed intentionally in the past two weeks?	☐ 1 Yes, the ring was removed intentionally ☐ 2 Yes, the ring came out unintentionally or accidentally ☐ 3 No, the ring has not come out, either accidentally or intentionally → skip to Q43 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 you (Show Response Card 25)	ır opinion of	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 inser	tion		\square_2	3
c. How the vaginal ring felt while you w	ere using it	_1	\square_2	3
d. The size of the vaginal ring			\square_2	3
e. How long the protection would last (a protection)	.e. one month		2	З
f. How the vaginal ring looks				3
g. How using the vaginal ring affected y	our body	1	2	3
h. Vaginal ring side effects		1		3

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								1	<u> </u>	
 i. Any increases to vaginal wetness caused by the vaginal ring 							1	2		<u></u> 3
j. The color of the vaginal ring							\Box_1	2		3
k. The smell of the vaginal ring							\square_1	2		<u></u> 3
I. The shape of the vaginal ring							1	2		3
		oility of the					<u></u> 1	2		<u>3</u>
n. T	he vagir	nal ring's ab	ility to be l	kept discre	et from others		<u>1</u>	2		3
extra care to e this may be a	ensure th good poi	e participan int at which	t is alert an to take a st	d engaged retch break		he questio	nnaire. F	or V9, if ap	prop	oriate,
					ed you are, ove		_	_		
	-			ns extreme	ly dissatisfied a	and 10 me	eans ext	remely sat	isfie	d.
(-	Show Re	esponse Car	d 26)	100000						100,000
0	2	3	4	5	6	7	8	9)	10
		\square_2	Пз	<u></u> 4	5	<u>6</u>	7	□ 8		9 10
¹ Extremely dissa ² Very dissatisfie										y satisfied y satisfied
End of Visi	it 5									
Gains and Lo	sses – A	sked at Visi	it 9 only							
а			_	-	ase tell me if yo e available for	_	_			_
						Disag	ree	Agree somewh	at	Agree a lot
		vaginal ring sexual rela		lar basis m	ay interfere					<u></u> 3
	_	vaginal ring e/improve r	_		•					3
	_	vaginal ring control of r	_		ay give me					3
	_	vaginal ring m at high-r	_		ay make peoplo risks.	e □₁		2		З
"Similar" mea	want to ans won a simila	use a vagin nen who ma	al ring. ay share th	e same life	r to me may e circumstances ips, age, living	5 🗀		□ 2		З

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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 prings you've used during this study.	eference between the two vaginal
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 changed ☐ 3 Yes, the second ring needs be changed ☐ 4 Yes, they both need to be changed
-

CRF Completed By: _____ (initials) CRF Completion Date: ___ / __ / __ _ (dd/mm/yyyy)