MATRIX-002 Final behavioral and acceptability (FU4) CRF [Visit 9] PTID: Visit #:	eptability (FU4) CRF (Visit 91 PTID: Visit #:
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Final behavioral and acceptability (FU4) CRF [Visit 9]

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

The * next to some questions indicates a question (same or similar) also asked at baseline/midpoint.

INTERVIEWER READS: The following questions ask you about your opinions and experiences with the second vaginal film you used over the past month. Your honest opinions are very important in making sure we have the best information possible for developing HIV prevention products that will be liked and can be easily used by people like you. If the film came out after you inserted it, please do your best to respond with your opinions about the film while it was still in place in your vagina. **Overall Product Acceptability** *On a scale of 1 to 10, how much did you like or dislike using the second vaginal film, where 1 means extremely disliked and 10 means extremely well liked? (Show Response Card 21) 10 \prod_{1} \prod_{2} \square_3 \prod_{4} \prod_{5} \Box 6 \prod_{7} \square_8 \prod_{9} \prod_{10} ¹Extremely disliked ⁹Very well liked ²Very disliked ¹⁰Extremely well liked Worries and excitement 2. Please rate how easy or difficult it was for you to use the film (have it inserted in your vagina) in the last month, from 1-10, where 1 means extremely difficult and 10 means extremely easy. (Show Response Card 22) 2 3 10 **8** \prod_{1} □ 6 \square_7 \square_{10} ¹Extremely difficult ⁹Very easy ¹⁰Extremely easy ²Very difficult *On a scale of 1 to 10, how worried were you when using the vaginal film during the past month, where 1 means extremely worried and 10 means not at all worried? (Show Response Card 23) 2 10 \square_5 \square_8 \square_1 \square_3 \square_4 \Box_6 \square_7 \square_{10} ¹Extremely worried ⁹Not worried ¹⁰Not at all worried ²Very worried *On a scale of 1 to 10, how excited were you when using the vaginal film during the past month, where 1 means not at all excited and 10 means extremely excited? (Show Response Card 24) 10 \square_1 \prod_{2} \square_7 \square_8 \square_3 \prod_4 \square_6 \prod_{9} 10 ¹Not at all excited ⁹Very excited 2Not excited ¹⁰Extremely excited

5. How acceptable to you was the overall process of inserting the	□₁ Not at	all acceptable			
film? (Show Response Card 25)	☐₂ Not acceptable				
	☐₃ Somewhat acceptable				
	 □₄Acceptable				
	□₅ Highly	acceptable			
6. How confident were you that the film was inserted correctly?	□₁ Not at all confident				
(Show Response Card 26)	□₂ Somew	hat confident			
	□₃ Fairly c	onfident			
	□₄ Very co	onfident			
7. How acceptable to you was the time it took to insert the film?	☐₁ Not at all acceptable				
(Show Response Card 25)	□₂ Not acc	☐ ₂ Not acceptable			
	☐ ₃ Somewhat acceptable				
	Accept	•			
		acceptable			
8. The next statements are about things that you may have					
experienced when you were using the vaginal film this	Yes	No			
month.	Agree	Disagree	N/A		
a. *The vaginal film came out, or did not stay correctly in					
place		_			
8.a.i. <i>If response=Yes, ask:</i> What do you think caused	1	2			
that?					
b. *The vaginal film felt uncomfortable during normal					
activities		2	□ 3		
c. *The vaginal film felt painful during normal activities			\square_3		
d. I thought a lot about the film over the last month					
e. *The vaginal film caused side effects					
f. *I felt like I could easily use the vaginal film as it was					
explained to me	1	2			
g. *I did not notice the film during menses			\square_3		
h. *The vaginal film made sex more enjoyable					
i. *The vaginal film caused pain during sex					
· · · · · · · · · · · · · · · · · · ·		<u>2</u>	<u></u> □3		
j. *It was exciting to use a new option that is being		\square_2			
designed for HIV prevention					
k. *I felt like I had control over the vaginal film	<u> </u>	2			
[If 8e = Yes] Please describe the side effects you've experienced	Specify:				
while using the vaginal film.					
Ease of use					
9. How long do you think it took for the <u>second</u> film (the one	days				
you used this last month) to dissolve in your vagina after		t think it dissol	ved at all		
insertion?	2 Not su	ire			
10. How often were you aware of the feeling of the vaginal film		of the time			
during your normal daily activities?	₂ Somet	imes			
	₃ Never				

		\square_4 N/A, film came out		
11. Over the last month, did you check to see	if the vaginal film	1 Yes		
was still present in the vagina?		2 No		
12. Since the last visit, did you notice any of th	_		e wetness tha	
changes in your vagina? (Mark all that app	ly)	2 More	e dryness thar	n normal
		☐ ₃ More	e itchiness tha	ın normal
		4 More	e soreness tha	ın normal
		₅ Othe	r:	
		☐ ₆ No n	oticeable cha	nges → <i>skip</i>
		to Q14		
13. How, if at all, would the following changes	in your vagina			
affect your use of vaginal films in the futur		More	No change	Less likely
Response Card 27)	•	likely to	in use	to use
[Response option only included if selected i	n prior question]	use		
a. More wetness than normal	, , ,		2	3
b. More dryness than normal			2	3
c. I had more itchiness than normal			2	
d. I had more soreness than normal			2	3
e. Other:			2	3
Burden				
14. *Since your last visit, how often did your u	se of the vaginal	□ 1 Most	of the time	
film interfere with any of your regular daily	_	=	etimes	
	,		er → skip to Q	16
		=	skip to Q16	
15. Which daily activities were disrupted by fil	m use?		•	
Discreetness and product use				
INTERVIEWER READS: The next questions ask about	t your views of whe	ther the v	aginal film car	n be used
discreetly (without others knowing) and whether y	ou have let others	know abou	t your produc	t use or not.
16. How involved was your main partner	☐ ₁ Not at all involved			
when you were deciding whether to join				
this study?	☐₃ Very involved			
	₄I don't have a	partner ->	skip to Q20	
17. Is your main partner aware that you used				
the vaginal film?	2 Yes, they four	nd out fror	n someone els	se
	3 Yes, they discovered the film some other way			her way
	\square_4 No, they don't know I'm using the film \rightarrow <i>skip to</i>			\rightarrow skip to
	Q20			
18. How supportive was your main partner of	1 Very support	ve		
your use of the film when they first found	2 A little suppo	rtive		
out?	₃ Not very supp	ortive		
	4Not at all supp	oortive		
19. How supportive was your main partner of	1 Very supporti	ve		
your use of the film during this study?	· = · · ·			
	3 Not very supp			
	☐4Not at all supp	oortive		

20. Did anyone find out about your vaginal film use without you telling them?	1 Yes	022				
·	$2 \text{ No } \rightarrow \text{ skip to}$ 1 Yes	ŲZZ				
21. Did any of these people find out because you felt forced to tell them?	No					
22. *In the future, if vaginal films were available					4	
prevention, how important is it to you that		ant	ant	nt nt	Very important	
could be used without the following people	-	Very	ewh	ewh	lodu	N/A
(Show Response Card 28)	, Kilowing.	Very	Somewhat	Somewhat important	y in	Z
(Show Response cura 20)		j j	ے	ν :-	Ver	
a. Spouse/main sexual partner (if not spouse)			2	<u></u> 3	<u></u> 4	5
b. Casual (other) sexual partner(s)			2	3	<u>4</u>	5
c. Family, specify:				3	□ 4	5
d. Friends				3	 4	5
e. Community members				3	 4	5
23. In the future, if the vaginal film were availa	ble, how easy or				>	
difficult would it be to use this product with	nout the	r√ cult	cult	Easy	eas	₹ Y
following people knowing?		Very difficult	Difficult	Еа	Very easy	Z
(Show Response Card 29)					>	
a. Spouse/main sexual partner (if not spouse)				3	□ 4	5
b. Casual (other) sexual partner(s)				3	□ 4	5
c. Family, specify:				3	<u>4</u>	5
d. Friends				3	<u>4</u>	5
e. Community members			2	3	□ 4	5
24. *Who else did you tell about your use of th	e vaginal film	□₁ No o	ne			
while you were in the study?		2 Casu	al (othe	er) sexu	ıal partr	er(s)
		☐₃ Fami	ly, spec	ify:		
		₄Othe	r, <i>speci</i> j	fy:		
Adherence		11.1.1.1.1				
INTERVIEWER READS: I'm going to ask some question			past m	nonth.	Your	
answers to these questions will not change your inv	olvement in this st	tuay.				
25. Have you had any sex since the second vag	inal film was	□₁Oral				
inserted, including oral, vaginal, or anal sex	?	2 Vagir	nal			
Select all that apply		₃ Anal				
		4 None	<u> </u>			
		=	r <i>, speci</i> j			
		☐ ₆ Only	non-re	ceptive	esex	
Impact on Sex						
INTERVIEWER READS: I will now ask you some ques	tions about sex. m	enstruation	n, and c	other va	aginal	
practices in the last month. I know it can be awkwa					_	el
comfortable to answer freely, and you can always s			_			
26. Did using the film affect	,	•	Yes		No	

a. How often you had any type of sex? If yes: In what ways: ———————————————————————————————————		. 🗀 1	2	
b. Your overall desire to have sex? If yes: In what ways:				
If 25 = "4. None", skip to 35				
c. Your feelings of intimacy or emotional closeness with y during sex? If yes: In what ways:	your partner	. 1	2	
d. The types of sex you engaged in? If 25=4, skip If yes) In what ways: ———————————————————————————————————		П	2	
27. How acceptable was the vaginal film's effect on: (Show Response Card 30) Response options included only if selected "yes" in prior question	Acceptable	Somewhat acceptable	Not acceptable	
a. How often you had any type of sex		\square_2	3	
b. Your overall desire to have sex		2	З	
 c. Your feelings of intimacy or emotional closeness with your partner during sex 		2	З	
d. The types of sex you engaged in	1	\square_2	3	
28. How did the film affect your sexual pleasure?	☐ 1 It was not affected ☐ 2 I had less sexual pleasure than usual ☐ 3 I had more sexual pleasure than usual ☐ 4 N/A, film not present during sex → skip to Q32			
29. How did the film affect your partner(s)' sexual pleasure (main or other)?	☐ 1 It was not affected ☐ 2 They had less sexual pleasure than usual ☐ 3 They had more sexual pleasure than usual ☐ 4 I do not know ☐ 5 N/A, film not present during sex → skip to Q32			
30. Did your partner(s) notice the vaginal film at all, (main or other)?				

31. Did your partner(s) notice any changes to your vagina related to you using the vaginal film (main or other)?	☐ 1 Change in taste ☐ 2 Change in scent or smell ☐ 3 Change in lubrication ☐ 4 Other, specify: ☐ 5 No changes ☐ 6 I don't know
32. (Skip unless 25=2 (had vaginal sex)) How often did you use condoms when having vaginal sex, since inserting the second vaginal film?	☐ 1 Always ☐ 2 Sometimes ☐ 3 Rarely ☐ 4 Never ☐ 5 N/A, film not present during sex → skip to Q35
33. Did any film come out when you had sex? If 25=4, skip	☐ 1 Yes ☐ 2 No ☐ 3 Not sure ☐ 4 N/A, film not present during sex → skip to Q35
34. Overall, how did you feel about the film being present during sex?	1 Liked it 2 Did not like it 3 No opinion 4 N/A, film not present during sex
35. Have you inserted anything into your vagina since your last visit? 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 desiccants, to make the vagina dry or tight ☐ 10 Materials such as paper, cloth, or cotton wool ☐ 11 Other, specify:
Use during menses	
36. In the past month, have you had any vaginal bleeding or spotting?	$\square_1 \text{Yes}$ $\square_2 \text{No} \rightarrow \textbf{skip to 40}$
37. Was the vaginal bleeding expected (usual menses) or unexpected?	☐₁ Expected ☐₂ Unexpected
38. How did you feel about the film being present during bleeding?	☐ 1 liked using it during bleeding ☐ 2 l did not like using it during bleeding ☐ 3 No opinion ☐ 4 N/A, film not present during bleeding → skip to Q40
39. Was the film disrupted during bleeding?	☐ ₁ Yes, specify:

Dis	rupted could mean displaced/moved/shifted a little in	☐ ₃ Not sure						
the	vagina or completely came out.							
Gains and losses								
	each of the following statements, please tell me if you disa	agree ag	ree sc	mewhat	or a	ogree a		
	In the future, if the vaginal film were available for HIV prev	_				_		
100.	The factore, if the vaginarium were available for this pres	verition	[III3C	i icein ji c	,,,,	abicj		
		Disagre	isagree Agree		Disagree Agree		Agree	
			_		somewhat			
a.	*Using it on a regular basis may interfere with my					Пз		
	sexual relationships.	L1	2			3		
b.	*Using a vaginal film on a regular basis may					Пз		
	enhance/improve my sexual relationships.			2		3		
C.	*Using a vaginal film on a regular basis may give me			2		Пз		
	greater control of my sexual health.	<u> </u>						
d.	6 6 ,					Пз		
	with my vaginal health.							
e.								
	people think I am at high-risk for HIV/that I take sexual			2		<u></u> 3		
r	risks.							
f.	*People in my community who are similar to me may							
	want to use a vaginal film. "Similar" means women who may share the same life			\square_2		\square_3		
	circumstances as you, be in a similar situation in terms			2		<u></u> 3		
	of relationships, age, living situation, education.							
Product attributes								
	each of the following, what is your opinion of (show	_4_						
	sponse Card 31)					7"		
		I liked it/ No		eutral/		lid not like it/		
		problem	No	opinion	It v	vas a problem		
a.	How the vaginal film is inserted?			<u>2</u>		<u>3</u>		
b.	How the vaginal film felt during insertion?			<u>2</u>		<u>3</u>		
C.	How the vaginal film felt after it was inserted?			<u></u> 2		3		
d.	The size of the vaginal film?	1		2		3		
e.	How long the protection would last? (i.e. one month of			2		□ ₃		
f.	protection) How the vaginal film looks?							
	How using the vaginal film affected your body?			<u></u>		3		
g. h.	Vaginal film side effects?			2 		3 3		
i.	How quickly the vaginal film dissolved?					3		
	Any remaining film (This could mean amount, color, or							
J.	texture)			_2		3		
k.	Any increases to vaginal wetness caused by the film							
<u>K.</u> I.	The color of the vaginal film					3		
	The smell of the vaginal film					3		
n.	The shape of the vaginal film					3		
-	<u> </u>							

o. The vaginal film's ability to be kept discreet from others?	<u></u>
Satisfaction	
42. Please rate on a scale of 1-10 how satisfied you are, overall, w means extremely dissatisfied and 10 means extremely satisfie	
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	⁹ Very satisfied ¹⁰ Extremely satisfied
Future recommendation and interest in product use	
43. In the future if available for HIV prevention, how likely is it that you would recommend vaginal film to a friend? (Show Response Card 33)	☐ 1 Very likely ☐ 2 Somewhat likely ☐ 3 Somewhat unlikely ☐ 4 Very unlikely
44. *In the future, how likely are you to want to use any HIV prevention product? (Show Response Card 33)	☐ 1 Very likely ☐ 2 Somewhat likely ☐ 3 Somewhat unlikely ☐ 4 Very unlikely
45. *In the future, if a vaginal film were available for HIV prevention, how interested would you be in using it? If "3. Somewhat uninterested" or "4. Very uninterested" selected, please describe: ———————————————————————————————————	☐ ₁ Very interested ☐ ₂ Somewhat interested ☐ ₃ Somewhat uninterested ☐ ₄ Very uninterested
46. Which of the following options for HIV prevention best suits your needs right now? If "None of these" selected, please describe: ———————————————————————————————————	☐ Vaginal film, if, in the future it offered HIV protection ☐ Oral PrEP (pills taken daily by mouth) ☐ Male condoms ☐ An injectable, given every 2 months (CAB-LA) ☐ None of these
Film as a dual-purpose product	
INTERVIEWER READS: We're now going to talk about a film being developregnancy at the same time. The film would deliver two different type and one to prevent pregnancy and be a "2-in-1" product.	
47. *In the future, if a dual-purpose film were available for HIV prevention AND pregnancy, how interested would you be in using it?	☐ 1 Very interested ☐ 2 Somewhat interested ☐ 3 Not sure ☐ 4 Somewhat uninterested ☐ 5 Very uninterested

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48. Thinking about your current circumstances, what type of	∏₁ HIV p	revention film
film would you prefer?	2 Pregr	nancy prevention film
	₃ "2 in	1" film that protects
	against bo	th HIV and pregnancy
	☐₄ Not s	ure
	☐ ₅ None	, I don't like the film
END OF CRF		
CRF Completed By: (initials) CRF Completion Date:	_//_	(dd/mm/yyyy)