

CRF COMPLETION GUIDELINES

LIST OF CRFs

BEH

BL

CO

DEM

FU1

FU2

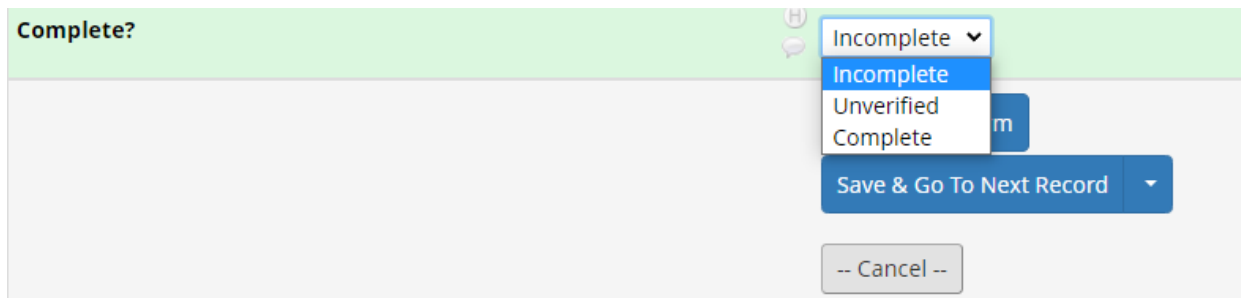
FU3

FU4

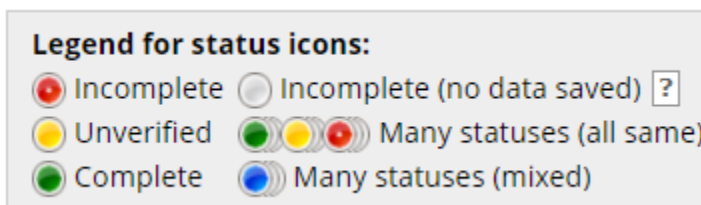
SPDEM

General Guidelines for MATRIX-002 Data Entry into REDCap

Data Entry/Corrections: After an eCRF has been completed, the user has the ability to save it with a status of “complete”, a status of “incomplete” or a status of “unverified”. Ultimately, the expectation is that eCRFs submitted will be in their “Complete” state, but at the time of data entry some data may be missing or questionable, requiring verification. The RedCap eCRFs may be saved with a status that signals study staff that an eCRF requires additional attention before being finalized.



When in the **Record Home Page**, users are able to view the status of all required eCRF by simply noting the color of the eCRF icon. See legend for status icons:



Once missing data are entered into empty fields, or unverified data are confirmed, the eCRF will need to be saved with a “Complete” status.

Any field within an eCRF may be updated/corrected by overwriting the incorrect data, then saving the eCRF again. An audit log is automatically maintained that notes which user made the correction. No other user action is necessary to make a correction.

To back out of a correction (i.e. maintain the eCRF as it was prior to unsaved correction(s)), the user can select “Cancel”. This will close the eCRF to editing and restore the eCRF to the state it was in prior to the editing session that was unsaved. Once saved, it will be impossible to restore eCRF to former versions.

Date and Time fields: Date fields follow the format: MM-DD-YYYY, with the month depicted in its numeric form. For example, Christmas of 2021 would be recorded as “25-12-2021”. Date fields can be entered in either of two ways. They can be typed into the date field in the above described format, or a date can be selected from a calendar. To enter a date in this way, select the calendar icon that is situated next to date fields, and using arrows in the top portion of the calendar, advance to the desired month and year. Once a day is selected, the calendar will disappear and the selected full date will populate the date field. Verify that date entered is the intended date.

Date of participant's randomization
* must provide value

Today D-M-Y

Jun 2023

Su	Mo	Tu	We	Th	Fr	Sa
				1	2	3
4	5	6	7	8	9	10
11	12	13	14	15	16	17
18	19	20	21	22	23	24

A few eCRFs contain time fields. The time field is entered through selection of hour and minutes from a what resembles a Likert scale. To enter a time, click on the time icon When time is properly selected by dragging Selection Cursors with your mouse, click on “Done” to populate field and cause the calendar to disappear.

Time of participant's randomization
* must provide value

Now H:M

Choose Time

Time 12:47

Hour

Minute

If entering data in real time, use of the “today” (date) and “now” (time) button will automatically fill in the current date and time. Users should be careful to double check that the date that they mean to enter is truly “today” or the time is “now” when using these buttons to autofill.

Date of participant's randomization
* must provide value

Today D-M-Y

Time of participant's randomization
* must provide value

Now H:M

MATRIX-002 REDCap Dashboard – Getting Started

A unique PTID (participant ID) is assigned to participants who have completed an informed consent session. A study clinician will assign these PTIDs in REDCap.

The Record Status Dashboard will show all existing records and their status for every data collection instrument. Select a PTID from the far-left column to navigate to the Participant Dashboard.

A Participant Dashboard will display on your screen:

Data Collection Instrument	V1 Screen SCR start 05-06-2023	V2 Enroll (1st film) Rand date	V3 (24-72 hr phone contact)	V4 (wk 1 phone contact)	V5 (wk 2 phone contact)	V6 (wk 4 clinic f/u, 2nd film) V6 date	V7 (24-72 hr phone contact)	V8 (wk 6 phone contact)	V9 (wk 8 clinic f/u) V9 date	V10 (wk 9 final phone contact)	+ Add new Interim visit Use "Add new" button above to add another interim visit	Ongoing Logs Complete as needed	Product Hold/Discontinuation	In Depth Interview
Establish PTID	●													
ICF Summary	●													
Demographic (DEM) Form	●													
Matrix-002 Randomization		●												
Baseline Medical and Menstrual History	●													
Screening Physical Exam and vital signs	●													
Pelvic Exam	●	●				●			●		●			
Hematology and Chemistry Results	●								●					
HIV, STI and Urine Test Results	●	●				●			●		●			
Updated Medical and Menstrual History		●		●	●	●		●	●	●	●			
Specimen Storage		●				●			●					
Visit Summary		●				●			●		●			
Baseline Behavioral (BEH) Form		●												
Baseline Acceptability (BL) Form		●												
Clinical Observations (CO) Form		●				●								
Post-Insertion Acceptability (FU1) Form		●				●								
Brief Acceptability (FU2) Form (surveys)		●		●	●	●	●	●						
Follow-up behavioral and acceptability (FU3) Form			●			●								
Final Behavioral and Acceptability (FU4)									●					
Concomitant Medications Log												●		
Preexisting Conditions Log												●		
Protocol Deviation Log												●		
Adverse Events Log												●		
Social Harms And Benefits Assessment Log												●		
Participant Disposition													●	
Study Product Hold/Discontinuation Log													●	
Discontinuation of Study Product													●	
HIV Confirmatory													●	
Pregnancy Report and Outcome													●	
PRN Hematology And Chemistry Results		●				●					●			
PRN Targeted Physical Exam		●				●			●		●			
PRN Missed Visit			●	●	●	●	●	●	●	●				
IDI Selection Tool														●
IDI Debriefing Report														●

Click the bubble for the CRF in the desired CRF to open the form and begin entering data.

SCREENING VISIT CRF (V1)

Demographic (DEM) Form

Document the date of the assessment. Note that information in italics is for the interviewer and will not be read aloud to the participant. Read the text in the yellow box labeled “Interviewer Reads” aloud. Record the participant’s responses to the questions following the response format indicated in the form. For example, document the participant’s age in the blank response box, and select their sex assigned at birth from the answer choices provided.



PTID	d2d-test-8002
Date of assessment: <i>* must provide value</i>	<input type="text"/> Today D-M-Y
<i>Note: Information in italics is for the interviewer and will not be read aloud to the participant. All response options should be read aloud to the participant unless shown in italics.</i>	
INTERVIEWER READS: The following are some questions regarding your background to help us describe the people who participated in this study. All the information you provide will be kept confidential and will not be shared with anyone else besides the research study staff.	
How old are you? <i>* must provide value</i>	<input type="text"/> years
What sex were you assigned at birth? <i>* must provide value</i>	<input type="radio"/> Female <input type="radio"/> Male <input type="radio"/> Intersex <input type="radio"/> Prefer not to answer reset
What is your gender identity? <i>* must provide value</i>	<input type="radio"/> Woman <input type="radio"/> Man <input type="radio"/> Transgender woman <input type="radio"/> Transgender man <input type="radio"/> Nonbinary, Gender Non-Conforming, or Genderqueer <input type="radio"/> A gender not listed here, please specify: <input type="radio"/> Prefer not to answer reset
<i>[For sites in South Africa, Zimbabwe, and Kenya]</i> What is your race or ethnicity? <i>* must provide value</i>	<input type="radio"/> Black African <input type="radio"/> Colored <input type="radio"/> Indian/Asian <input type="radio"/> White <input type="radio"/> Other, please specify: reset

Code the participant’s response for the language most spoken in their home using the Language Code text box as reference. If the participant’s most spoken language is not one of the sixteen options in the text box, specify in the blank response space that follows.

What is the language most spoken in your home?


Language Codes

1	Kikuyu
2	Kiswahili
3	English
4	Kamba
5	Luhya
6	Kisii
7	Afrikaans
8	Setswana
9	Sesotho
10	isiZulu
11	Xhosa
12	Ndebele
13	Tsonga
14	Venda
15	Sepedi
16	Shona

 
Language code

* must provide value

Other language, specify:

Where specified, read answer choices to the participant before recording their response. Note that answer choices in italics should not be read aloud. For some questions with blank response spaces, the unit of measurement is specified in blue text below the response space. Where instructed, write “ND” if the participant does not want to respond to a question. For questions with the italicized instructions “Mark all that apply”, you may select more than one answer choice if the participant’s response indicates it. See the image below for an example of each of these three cases.

In the past 30 days, how often did you worry that you would not have enough food?
[Read options and mark one]
 * must provide value

Never
 Rarely (once or twice)
 Sometimes (3-10 times)
 Often (more than 10 times)

reset

How many rooms are in the household you are currently living in? Rooms include kitchens, bedrooms, common or living rooms. Do not include bathrooms or halls.

total rooms

Please write 'ND' if the participant does not want to respond.
 * must provide value

How many people in total reside in your household, including you?

of household residents

Please write 'ND' if the participant does not want to respond.
 * must provide value

Who are the people you live with now?
 Mark all that apply
 * must provide value

Partner
 Sibling(s)
 Mother and/or father
 Other relative(s)
 Your child(ren)
 Friend(s)/Roommate(s)
 I live alone
 Other, please specify:

At the end of each CRF you must select a Form Status from the drop-down choices: Incomplete, Unverified, or Complete. Then, choose to save and exit the form, save and stay on the form, save and go to the next form, save and exit the record, or save and go to the next record.

Form Status

Complete? Complete

Save & Exit Form Save & ...

- Cancel -

- Save & Stay
- Save & Go To Next Form
- Save & Exit Record
- Save & Go To Next Record

ENROLLMENT VISIT CRFs (V2)

Baseline Behavioral (BEH) Form

Document the date of assessment. Note that information in italics is for the interviewer and will not be read aloud to the participant. Read the text in the yellow box labeled “Interviewer Reads” aloud. Record the participant’s responses to the questions following the response format indicated in the form.

PTID	d2d-test-8002
Date of assessment: <i>* must provide value</i>	<input type="text"/> Today D-M-Y
<i>Note: Information in italics is for the interviewer and will not be read aloud to the participant. All response options should be read aloud to the participant unless shown in italics.</i>	
INTERVIEWER READS: The following are some questions related to your sexual and reproductive health, and your relationship with any sexual partners.	
How many partners have you had in the last 6 months? <i>* must provide value</i>	<input type="text"/> # partners
Do you currently have a main partner? By main partner, I mean someone you have sex with on a regular basis who you consider to be your primary partner. <i>* must provide value</i>	<input type="radio"/> Yes <input type="radio"/> No reset
In the past 30 days, have you used vaginal lubricant (for any reason)? <i>* must provide value</i>	<input type="radio"/> Yes <input type="radio"/> No reset
In the past 30 days, have you had vaginal sex? <i>* must provide value</i>	<input type="radio"/> Yes <input type="radio"/> No reset
When making choices about HIV prevention, who do you speak with to help you make the decision? <i>(Mark all that apply)</i> <i>* must provide value</i>	<input type="checkbox"/> No one, it is your decision <input type="checkbox"/> Clinic staff (doctor, nurse, counselor, etc.) <input type="checkbox"/> Your mother <input type="checkbox"/> Your sibling/s <input type="checkbox"/> Your partner <input type="checkbox"/> Friend/s <input type="checkbox"/> Other, <i>specify:</i>

For questions with the italicized instructions “(insert response option, mark all that apply)” complete the sentence with each answer choice option as you read it to the participant. For the first two options in the example below, you would read: “Have you ever used oral pills? Have you ever used an injectable or shot?”

INTERVIEWER READS: Now, I would like to talk about pregnancy and family planning. Family planning refers to the various methods that a couple can use to delay or avoid pregnancy.

Have you ever been pregnant?

[This includes if you are currently pregnant or have given birth, had an abortion or a miscarriage.]

* must provide value

- Yes
 No

reset

Which of the following methods for family planning have you ever used? Please answer based on your experiences with ALL your partners, both past and present.

Have you ever used... *(insert response option, mark all that apply)*

* must provide value













- Oral pills
 Injectable (or shot)
 Implant
 Male condoms
 Female condoms
 IUD
 Emergency contraception
 Female sterilization (tubal ligation/hysterectomy)
 Natural methods (rhythm, fertility awareness, calendar)
 None
 Other: Is there any other method you have used for family planning? specify:

Use this same format to read the answer choices in questions formatted like the example below, where the participant must select an answer from a range of responses. For the first two answer choices in the example below, you would read: “In the last three months, how often have you inserted anything into your vagina to control menses? In the last three months, how often have you inserted anything into your vagina to treat infection?”

There will also be questions that include the italicized instructions “(Show Response Card X)”. This refers to the numbered Response Booklet that corresponds to each relevant CRF. For questions where the italicized instructions say to show “Response Card X”, show the participant the response card that corresponds to that question using the numbered Response Card Booklet.

At the end of the CRF select a Form Status and save.

(Show Response Card 6) INTERVIEWER READS: The next questions are about products or items you may have inserted into your vagina for health reasons, cleanliness, menstrual control or for pleasure. Even if you might change how you use these products while you are in the study, I would like to know how often you have used them in the past three months. In the last three months, how often have you inserted anything into your vagina to...

		Daily	Almost every day	Weekly	Monthly	Never		
Control menses <i>* must provide value</i>	 	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	reset	
Treat infection <i>* must provide value</i>	 	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	reset	
Tighten or dry the vagina for sex <i>* must provide value</i>	 	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	reset	
Clean the vagina <i>* must provide value</i>	 	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	reset	
Other, specify: <i>* must provide value</i>	 	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	reset	
<i>If participant indicates that they have inserted a product into their vagina, ask: What products or items did you use?</i>							 	<input type="text"/>

Baseline Acceptability (BL) Form

Document the date of assessment. Note that information in italics is for the interviewer and will not be read aloud to the participant. Read the text in the yellow box labeled “Interviewer Reads” aloud. Record the participant’s responses to the questions following the response format indicated in the form.

For questions where the italicized instructions say to show a response card, show the participant the response card that applies to that question. For the *Comfort* example below, guide the participant to respond using the 1-10 scale where 1 means extremely uncomfortable and 10 means extremely comfortable. Follow this format with the appropriate scale for each question where it is indicated.

PTID	d2d-test-8002
Date of assessment: <i>* must provide value</i>	<input type="text"/> Today D-M-Y
<i>Note: Information in italics is for the interviewer and will not be read aloud to the participant.</i>	
INTERVIEWER READS: The following questions ask you about your thoughts on the vaginal film, even though we know you have not yet tried it yet. We are interested in hearing how you feel about the film and what you imagine the film will be like before you try it	
Comfort	
On a scale of 1 to 10, how comfortable do you think the insertion process will be for the vaginal film, where 1 means extremely uncomfortable and 10 means extremely comfortable? <i>(Show Response Card 1)</i> <i>* must provide value</i>	<input type="radio"/> 1 - Extremely uncomfortable <input type="radio"/> 2 - Very uncomfortable <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 5 <input type="radio"/> 6 <input type="radio"/> 7 <input type="radio"/> 8 <input type="radio"/> 9 - Very comfortable <input type="radio"/> 10 - Extremely comfortable reset
Worries and excitement	
On a scale of 1 to 10, how worried are you about using the vaginal film, where 1 means extremely worried and 10 means not at all worried? <i>(Show Response Card 2)</i> <i>* must provide value</i>	<input type="radio"/> 1 - Extremely worried <input type="radio"/> 2 - Very worried <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 5 <input type="radio"/> 6 <input type="radio"/> 7 <input type="radio"/> 8 <input type="radio"/> 9 - Not worried <input type="radio"/> 10 - Not at all worried reset

In the example below, read the first sentence to the participant and finish the second sentence with each of the statements below it. Select the answer choice for each sentence. For the first example below you would read: “For each of the following statements, please tell me if you disagree, agree

somewhat, or agree a lot. In the future, if the vaginal film were available for HIV prevention, using a vaginal film on a monthly basis may interfere with my sexual relationships.”
















Gains and losses

For each of the following statements, please tell me if you disagree, agree somewhat, or agree a lot. In the future, if the vaginal film were available for HIV prevention... [insert item from table]

	Disagree	Agree somewhat	Agree a lot
<p>Using a vaginal film on a monthly basis may interfere with my sexual relationships.</p> <p><small>* must provide value</small></p>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<p>Using a vaginal film on a monthly basis may enhance/improve my sexual relationships.</p> <p><small>* must provide value</small></p>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<p>Using a vaginal film on a monthly basis may give me greater control of my sexual health.</p> <p><small>* must provide value</small></p>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<p>Using a vaginal film on a monthly basis may make people think I am at high-risk for HIV/that I take sexual risks.</p> <p><small>* must provide value</small></p>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<p>People in my community who are similar to me may want to use a vaginal film.</p> <p><i>“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.</i></p> <p><small>* must provide value</small></p>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

This format may also be used with other answer choice variations. In the example below, you would follow the previous example’s instructions but use the answer choices “Very unimportant, Somewhat unimportant, Somewhat important, Very important, N/A”.

How important is it to you that the film could be used without [insert a-d below] knowing? (Show Response Card 5)

		Very unimportant	Somewhat unimportant	Somewhat important	Very important	N/A
Spouse/main sexual partner (if not spouse) * must provide value	  	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
reset						
Casual (other) sexual partner(s) * must provide value	  	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
reset						
Family, specify: * must provide value	  	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
reset						
Friends * must provide value	  	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
reset						
In the future, if you were using an HIV prevention product that could be used without your main partner or other sexual partners knowing, would you tell them anyway?				<input type="radio"/> Yes  <input type="radio"/> No   <input type="radio"/> Unsure		
* must provide value						reset

At the end of the CRF, select a Form Status and save.

Clinical Observations (CO) Form

Document the date of assessment. Record the participant’s responses to the questions following the response format indicated in the form. If the vaginal film was **not** inserted, document the circumstance in the “Notes” box.

Event: V2 Enroll (1st film)	
PTID	d2d-test-8002
Note: To be clinician-completed at every in-clinic visit with product insertion (product initiation and follow-up visit, per protocol). Clinician will be present (behind a curtain) to address questions and concerns. Privacy should be offered to participants.	
Date of assessment:	<input type="text"/> Today D-M-Y
<small>* must provide value</small>	
Was the vaginal film inserted?	<input type="radio"/> Yes <input type="radio"/> No
<small>* must provide value</small>	<small>reset</small>
Was the participant instructed to "tuck in" any visible film following the initial external exam?	<input type="radio"/> Yes <input type="radio"/> No
	<small>reset</small>
Notes	<div style="border: 1px solid #ccc; height: 80px;"></div> <small>Expand</small>
Form Status	
Complete?	<input type="text"/> Unverified
<div style="display: flex; justify-content: space-around;"><div>Save & Exit Form</div><div>Save & ...</div></div> <div style="text-align: center; margin-top: 10px;"><div>- Cancel -</div></div>	

If the vaginal film **was** inserted, more questions will appear on the CRF. Answer these as instructed, and specify in the blank space if prompted.


Was the vaginal film inserted in the presence of a clinician? <i>* must provide value</i>	<input type="radio"/> Yes <input type="radio"/> No	reset
Did the participant require assistance with self-insertion of the vaginal film? <i>* must provide value</i>	<input checked="" type="radio"/> Yes <input type="radio"/> No	reset
Specify type of assistance needed: <i>* must provide value</i>	<input type="text"/>	reset
How many attempts did the participant need to successfully insert the vaginal film? <i>* must provide value</i>	<input type="radio"/> 1 attempt <input type="radio"/> 2 attempts <input type="radio"/> Unsuccessful at self-insertion	reset
Based on your presence in the room, how difficult or easy was it for the participant to insert the vaginal film? <i>* must provide value</i>	<input type="radio"/> Very difficult <input type="radio"/> Difficult <input type="radio"/> Neither difficult nor easy <input type="radio"/> Easy <input type="radio"/> Very easy	reset
Based on your observation, did the participant insert the vaginal film as per the provided instructions? <i>* must provide value</i>	<input type="radio"/> Yes <input type="radio"/> No	reset
What percentage (or amount) of the film was visible outside the vagina at clinical assessment? <i>* must provide value</i>	<input type="radio"/> Most of the film (>50%) <input type="radio"/> About half of the film (50%) <input type="radio"/> Very little of the film (< 50%) <input type="radio"/> None of the film	reset
Was the participant instructed to "tuck in" any visible film following the initial external exam?	<input type="radio"/> Yes <input type="radio"/> No	reset
Based on your observation, how confident did the participant seem inserting the vaginal film? <i>* must provide value</i>	<input type="radio"/> Very confident <input type="radio"/> Confident <input type="radio"/> Not confident	reset

At the end of the CRF select a Form Status and save.

Post-Insertion Acceptability (FU1) Form

Document the date of assessment. Note that information in italics is for the interviewer and will not be read aloud to the participant. Record the participant's responses to the questions following the response format indicated in the form.

For questions where the italicized instructions say to show a response card, show the participant the response card that applies to that question. Follow this format with the appropriate scale for each question where it is indicated.

Event: V2 Enroll (1st film)	
PTID	d2d-test-8002
Date of assessment: <i>* must provide value</i>	<input type="text"/>  Today D-M-Y
How many attempts did it take you to insert the film? <i>* must provide value</i>	<input type="text"/> attempts
How easy or difficult was it to insert the vaginal film? <i>(If the participant had more than 1 attempt) INTERVIEWER READS: Please think about your final insertion as you answer this question. (Show Response Card 8)</i> <i>* must provide value</i>	<input type="radio"/> Very difficult <input type="radio"/> Difficult <input type="radio"/> Neither difficult nor easy <input type="radio"/> Easy <input type="radio"/> Very easy reset
Overall, how easy or difficult was it to follow the instructions in the pamphlet for insertion? <i>(Show Response Card 8)</i> <i>* must provide value</i>	<input type="radio"/> Very difficult <input type="radio"/> Difficult <input type="radio"/> Neither difficult nor easy <input type="radio"/> Easy <input type="radio"/> Very easy reset
Overall, on a scale of 1 to 10, how comfortable was the insertion of the vaginal film, where 1 means extremely uncomfortable and 10 means extremely comfortable? <i>(Show Response Card 9)</i> <i>* must provide value</i>	<input type="radio"/> 1 - Extremely uncomfortable <input type="radio"/> 2 - Very uncomfortable <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 5 <input type="radio"/> 6 <input type="radio"/> 7 <input type="radio"/> 8 <input type="radio"/> 9 - Very comfortable <input type="radio"/> 10 - Extremely comfortable reset

Read the text in the yellow box labeled "Interviewer Reads" aloud.

INTERVIEWER READS: Please rate how acceptable each aspect of the film was for you, on a scale from 1 (not at all acceptable) to 5 (highly acceptable).

How acceptable was the overall process of inserting the film?

(Show Response Card 10)



- Not at all acceptable
- Not acceptable
- Somewhat acceptable
- Acceptable
- Highly acceptable

reset

How acceptable was the texture of the film, how it felt in your hand?

(Show Response Card 10)



- Not at all acceptable
- Not acceptable
- Somewhat acceptable
- Acceptable
- Highly acceptable

reset

How comfortable were you inserting the vaginal film with your finger?

* must provide value



- Very comfortable
- Comfortable
- Uncomfortable
- Very uncomfortable

reset

Do you feel confident that the vaginal film was inserted correctly?

* must provide value



- Yes
- No

reset

Were you able to insert the vaginal film according to the instructions provided?

* must provide value



- Yes
- No, I had to alter something (do something differently) to insert the film

reset

How comfortable would you be inserting this vaginal film on your own now, post-insertion?

* must provide value



- Very comfortable
- Comfortable
- Uncomfortable
- Very uncomfortable
- I would be unable to insert it

reset

On a scale of 1 to 10, how comfortable is the film now that it is inserted, where 1 means extremely uncomfortable and 10 means extremely comfortable?

(Show Response Card 9)

* must provide value



- 1 - Extremely uncomfortable
- 2 - Very uncomfortable
- 3
- 4
- 5
- 6
- 7
- 8
- 9 - Very comfortable
- 10 - Extremely comfortable

reset

Under the “Notes” question, include your own relevant notes including comments from the participant and influences on their responses that have not been captured in the questions so far.

What suggestions do you have for improving the film insertion instructions? What parts were easy to follow? What was unclear?

* must provide value



Expand

Notes

Interviewer to include any relevant notes here about comments the participant made not captured here that may have affected their responses (e.g., if multiple insertion attempts influenced how they responded).



Expand

Form Status

Complete?



Unverified ▾

Save & Exit Form

Save & ... ▾

- Cancel -

At the end of the CRF select a Form Status and save.

24 -72 HOUR PHONE CONTACT CRF (V3)

Brief Acceptability (FU2) Form

Document the date of assessment. Note that information in italics is for the interviewer and will not be read aloud to the participant. Read the text in the yellow box labeled “Interviewer Reads” aloud. Record the participant’s responses to the questions following the response format indicated in the form.

If prompted, describe the participant’s response in the blank response box following the question.

If the participant’s response to the question “Has the film bothered you or caused any discomfort?” is “Some” or “Quite a bit”, this may indicate an AE. If one is needed based on the participant’s response (such as significant discomfort), complete an AE form.

Event: V3 (24-72 hr phone contact)	
PTID	d2d-test-8002
Date of Brief Acceptability contact	<input type="text"/> Today D-M-Y <small>If date is missing, visit will show on reports as missed</small>
<i>* must provide value</i>	
<i>Note: Information in italics is for the interviewer and will not be read aloud to the participant.</i>	
Note: To be used when contacting the participant via SMS or phone (or in-person, if preferred) between 24-72 hours after Visit 2 and Visit 6, as well as when contacting the participant via SMS or phone at 1 and 2 weeks after Visit 2, and 2 weeks after Visit 6.	
These questions are intended to ask participants about their experience with the film after insertion and to offer support/guidance to address any challenges or concerns they have identified.	
Have you noticed the film in the last day/since you left the clinic?	<input type="radio"/> Yes <input type="radio"/> No
<i>Noticed can include if the participant felt, saw, or was aware of the film</i>	<small>reset</small>
<i>* must provide value</i>	
Has the film bothered you or caused any discomfort?	<input type="radio"/> Not at all <input type="radio"/> Some <input checked="" type="radio"/> Quite a bit
<i>* must provide value</i>	<small>reset</small>
<i>If one is needed (such as significant discomfort), complete an AE form.</i>	
In what ways has the film bothered you or caused discomfort?	<input type="text"/>
<i>* must provide value</i>	

At the end of the CRF select a Form Status and save.

Have you noticed any changes to your vagina since using the film?

* must provide value

- Yes
- No

reset

Do you have any concerns about using the film right now?

* must provide value



Expand

Since you left the clinic, have you noticed the film coming out of your vagina, partially or fully?

* must provide value

- Yes, partially
- Yes, fully
- Not sure
- No, not at all

reset

Is there anything you found positive or beneficial about the film so far?

* must provide value

- Yes
- No

reset

Do you have any questions for me?

* must provide value

- Yes
- No

reset

Form Status

Complete?

Save & Exit Form

Save & ...


- Cancel -

WEEK 4 CLINIC FOLLOW-UP CRF (V6)

Follow-up Behavioral and Acceptability (FU3) Form

Document the date of assessment. Note that information in italics is for the interviewer and will not be read aloud to the participant. Read the text in the box labeled “Interviewer Reads” aloud. Record the participant’s responses to the questions following the response format indicated in the form.

For questions where the italicized instructions say to show a response card, show the participant the response card that applies to that question. Follow this format with the appropriate scale for each question where it is indicated.

Event: V6 (wk 4 clinic f/u, 2nd film)	
PTID	d2d-test-8002
Date of assessment: <i>* must provide value</i>	<input type="text"/>  Today D-M-Y
<i>Information in italics is for the interviewer and will not be read aloud to the participant.</i>	
INTERVIEWER READS: The following questions ask you about your opinions and experiences with the 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.	
Overall Product Acceptability	
On a scale of 1 to 10, how much did you like or dislike using the vaginal film this past month, where 1 means extremely disliked and 10 means extremely well liked? (Show Response Card 11) <i>* must provide value</i>	<input type="radio"/> 1 - Extremely disliked <input type="radio"/> 2 - Very disliked <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 5 <input type="radio"/> 6 <input type="radio"/> 7 <input type="radio"/> 8 <input type="radio"/> 9 - Very well liked <input type="radio"/> 10 - Extremely well liked reset
Worries and excitement	
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 12) <i>* must provide value</i>	<input type="radio"/> 1 - Extremely difficult <input type="radio"/> 2 - Very difficult <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 5 <input type="radio"/> 6 <input type="radio"/> 7 <input type="radio"/> 8 <input type="radio"/> 9 - Very easy <input type="radio"/> 10 - Extremely easy reset

If prompted, provide details in the open response box.

How acceptable to you was the overall process of inserting the film? (Show Response Card 15)	<input type="radio"/> Not at all acceptable <input type="radio"/> Not acceptable <input type="radio"/> Somewhat acceptable <input type="radio"/> Acceptable <input type="radio"/> Highly acceptable	reset
How confident were you that the film was inserted correctly? (Show Response Card 16)	<input type="radio"/> Not at all confident <input type="radio"/> Somewhat confident <input type="radio"/> Fairly confident <input type="radio"/> Very confident	reset
How confident were you that the film stayed in place over the past month? (Show Response Card 16)	<input type="radio"/> Not at all confident <input type="radio"/> Somewhat confident <input type="radio"/> Fairly confident <input type="radio"/> Very confident	reset
The next statements are about things that you may have experienced when you were using the vaginal film this month.		
The vaginal film came out, or did not stay correctly in place <small>* must provide value</small>	<input checked="" type="radio"/> Yes (Agree) <input type="radio"/> No (Disagree)	reset
What do you think caused that? <small>* must provide value</small>		Expand
The vaginal film felt uncomfortable during normal activities <small>* must provide value</small>	<input type="radio"/> Yes (Agree) <input type="radio"/> No (Disagree)	reset

Ease of use

How long do you think it took for the film to dissolve in your vagina after insertion?

Days

- Do not think it dissolved fully
 Not sure

reset

How often were you aware of the feeling of the vaginal film during your normal daily activities?



- Most of the time
 Sometimes
 Never

* must provide value

reset

Over the last month, did you check to see if the vaginal film was still present in the vagina?



- Yes
 No

* must provide value

reset

Since the last visit, did you notice any of the following changes in your vagina?



- More wetness than normal
 More dryness than normal
 More itchiness than normal
 More soreness than normal
 Other: *specify*
 No noticeable changes

(Mark all that apply)

* must provide value

Burden

Since your last visit, how often did your use of the vaginal film interfere with any of your regular daily activities?



- Most of the time
 Sometimes
 Never
 Film not used

* must provide value

reset

Read the text in the yellow box labeled “Interviewer Reads” aloud. Responses to the following questions may impact whether later questions are shown or hidden for the rest of the CRF. Be sure to respond to all questions accurately and select all relevant responses for “mark all that apply” questions.

Adherence

INTERVIEWER READS: I know you were counseled to abstain from sex during the first month of product use, and I know sometimes sex doesn't only happen when we plan it. I'm going to ask some questions about what you did in the past month, and it is important that we know what really happened - even if it is not what you were instructed to do. This will help us understand the results we get from this study. Your answers to these questions will not change your involvement in this study.

Have you had any sex during the first month of film use, including oral, vaginal, or anal sex?

Select all that apply

* must provide value

- Oral
 Vaginal
 Anal
 None
 Other, specify:

Impact on Sex

INTERVIEWER READS: I will now ask you some questions about sex, menstruation, and other vaginal practices in the last month. I know it can be awkward to talk about some of these things; I hope you feel comfortable to answer freely, and you can always skip questions if you would prefer.

Did using the film affect...

How often you had any type of sex?

* must provide value

- Yes
 No

reset

Your overall desire to have sex?

* must provide value

- Yes
 No

reset

Your feelings of intimacy or emotional closeness with your partner during sex?

* must provide value

- Yes
 No

reset

The types of sex you had?

* must provide value

- Yes
 No

reset

How did the film affect your sexual pleasure?

* must provide value

- It was not affected
 I had less sexual pleasure than usual
 I had more sexual pleasure than usual

reset

How did the film affect your partner(s)' sexual pleasure?

* must provide value

- It was not affected
 They had less sexual pleasure than usual
 They had more sexual pleasure than usual
 I do not know

reset

Use during menses

In the past month, have you had any vaginal bleeding or spotting? Yes No
* must provide value

Product attributes For each of the following, what is your opinion of... (show Response Card 19)

	I liked it/No problem	Neutral/No opinion	I did not like it/It was a problem
a. How the vaginal film is inserted <small>* must provide value</small>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
b. How the vaginal film felt during insertion <small>* must provide value</small>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
c. How the vaginal film felt after it was inserted <small>* must provide value</small>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
d. The size of the vaginal film <small>* must provide value</small>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

At the end of the CRF select a Form Status and save.

Satisfaction

Please rate on a scale of 1-10 how satisfied you are, overall, with using the vaginal film, where 1 means extremely dissatisfied and 10 means extremely satisfied.

(Show Response Card 20)
* must provide value

1 - Extremely dissatisfied
 2 - Very dissatisfied
 3
 4
 5
 6
 7
 8
 9 - Very satisfied
 10 - Extremely satisfied

Form Status

Complete?

Save & Exit Form Save & ... - Cancel -

WEEK 9 FINAL PHONE CONTACT CRF (V10)

Final Behavioral and Acceptability (FU4) Form

Document the date of assessment. Note that information in italics is for the interviewer and will not be read aloud to the participant. Read the text in the box labeled “Interviewer Reads” aloud. Record the participant’s responses to the questions following the response format indicated in the form.

For questions where the italicized instructions say to show a response card, show the participant the response card that applies to that question. Follow this format with the appropriate scale for each question where it is indicated.


Responses to certain questions may impact whether later questions are shown or hidden for the rest of the CRF. Be sure to respond to all questions accurately and select all relevant responses for “mark all that apply” questions.

PTID

d2d-test-8002

Date of assessment:

* must provide value

 Today D-M-Y

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

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.

Overall Product Acceptability

On a scale of 1 to 10, how much did you like or dislike using the second vaginal film this past month, where 1 means extremely disliked and 10 means extremely well liked?

(Show Response Card 21)

* must provide value

- 1 - Extremely disliked
- 2 - Very disliked
- 3
- 4
- 5
- 6
- 7
- 8
- 9 - Very well liked
- 10 - Extremely well liked

reset

Worries and excitement

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)

* must provide value

- 1 - Extremely difficult
- 2 - Very difficult
- 3
- 4
- 5
- 6
- 7
- 8
- 9 - Very easy
- 10 - Extremely easy

reset

If prompted, provide details in the open response box.

Burden

Since your last visit, how often did your use of the vaginal film interfere with any of your regular daily activities?

* must provide value

- Most of the time
 Sometimes
 Never
 I didn't use the vaginal film

reset

Which daily activities were disrupted by film use?

* must provide value



Expand

Discreetness and product use

INTERVIEWER READS: The next questions ask about your views of whether the vaginal film can be used discreetly (without others knowing) and whether you have let others know about your product use or not.

How involved was your main partner when you were deciding whether to join this study?

* must provide value

- Not at all involved
 A little involved
 Very involved
 I don't have a partner

reset

Is your main partner aware that you used the vaginal film?

* must provide value

- Yes, I chose to tell them about it
 Yes, they found out from someone else
 Yes, they discovered the film some other way
 No, they don't know I'm using the film

reset

At the end of the CRF select a Form Status and save.

Film as a dual-purpose product

INTERVIEWER READS: We're now going to talk about a film being developed that can prevent both HIV and pregnancy at the same time. The film would deliver two different types of medicine: one to prevent HIV and one to prevent pregnancy and be a "2-in-1" product.

In the future, if a dual-purpose film were available for HIV prevention AND pregnancy, how interested would you be in using it?
* must provide value

Very interested
 Somewhat interested
 Not sure
 Somewhat uninterested
 Very uninterested

reset

Thinking about your current circumstances, what type of film would you prefer?
* must provide value

HIV prevention film
 Pregnancy prevention film
 "2 in 1" film that protects against both HIV and pregnancy
 Not sure
 None, I don't like the film

reset

Form Status

Complete?

SEXUAL PARTNER IDI VISIT

















Sexual Partner Demographic (SPDEM) Form

Document the MATRIX-002 participant’s PTID. Note that information in italics is for the interviewer and will not be read aloud to the participant. Read the text in the box labeled “Interviewer Reads” aloud. Record the participant’s responses to the questions following the response format indicated in the form.

Sexual Partner PTID	KE01-240
<i>What is the MATRIX-002 participant's PTID?</i> <small>* must provide value</small>	<input type="text"/>
<i>Information in italics is for the interviewer and will not be read aloud to the participant.</i>	
INTERVIEWER READS: The following are some questions regarding your background to help us describe the people who participated in this study. All the information you provide will be kept confidential and will not be shared with anyone else besides the research study staff.	
How old are you?	<input type="text"/> <small>in years</small>
What sex were you assigned at birth?	<input type="radio"/> Female <input type="radio"/> Male <input type="radio"/> Intersex <input type="radio"/> Prefer not to answer <small>reset</small>
What is your gender identity?	<input type="radio"/> Woman <input type="radio"/> Man <input type="radio"/> Transgender woman <input type="radio"/> Transgender man <input type="radio"/> Nonbinary, Gender Non-Conforming, or Genderqueer <input type="radio"/> A gender not listed here, please specify: <input type="radio"/> Prefer not to answer <small>reset</small>
What is your highest level of school completed?	<input type="radio"/> No schooling <input type="radio"/> Primary school, not complete <input type="radio"/> Primary school, complete <input type="radio"/> Secondary school, not complete <input type="radio"/> Secondary school, complete <input type="radio"/> College or university, not complete <input type="radio"/> College or university, complete <small>reset</small>
What is your relationship status?	<input type="radio"/> Single <input type="radio"/> In a relationship, not married <input type="radio"/> Married <input type="radio"/> Other, specify: <small>reset</small>

Who are the people you live with now?



Mark all that apply

		Yes	No	
a. I live alone	 	<input type="radio"/>	<input type="radio"/>	reset
b. Partner	 	<input type="radio"/>	<input type="radio"/>	reset
c. Sibling(s)	 	<input type="radio"/>	<input type="radio"/>	reset
d. Mother and/or father	 	<input type="radio"/>	<input type="radio"/>	reset
e. Other relative(s)	 	<input type="radio"/>	<input type="radio"/>	reset
f. Your child(ren)	 	<input type="radio"/>	<input type="radio"/>	reset
g. Friend(s)/Roommate(s)	 	<input type="radio"/>	<input type="radio"/>	reset
h. Other, please specify:	 	<input type="radio"/>	<input type="radio"/>	reset
Have you ever been tested for HIV?		<input type="radio"/> Yes	<input type="radio"/> No	reset

At the end of the CRF select a Form Status and save.

Form Status

Complete?

  Incomplete ▾

I certify that I have ensured the accuracy and completeness of the data reported in the Case Report Forms. Nyaradzo M. Mgodzi, MBChB, MMed

 Lock

Save & Exit Form

Save & ... ▾

- Cancel -

Delete data for THIS FORM only

NOTE: To delete the entire record (all forms/events), see the record action drop-down at top of the [Record Home Page](#).