CRF COMPLETION GUIDELINES

LIST OF CRFs

BEH

BL

COI

COR

DEM

FU1

FU2

FU3

FU4

SPDEM

EXP

SPE

General Guidelines for MATRIX-003 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.
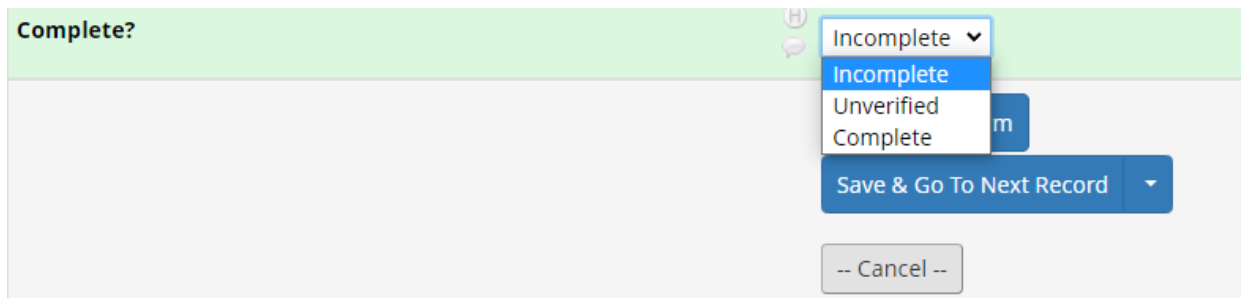
When in the **Record Home Page**, users are able to view the status of all required eCRF by simply noting the color of the eCRF icon. See legend for status icons:
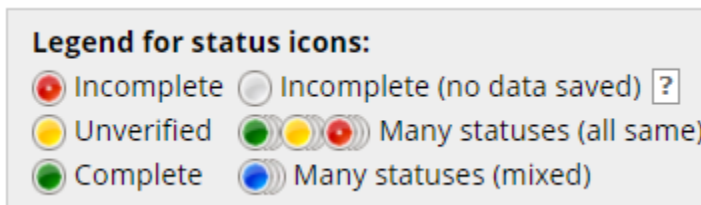
Once missing data are entered into empty fields, or unverified data are confirmed, the eCRF will need to be saved with a "Complete" status.

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	————○——

Now		Done

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-003 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:

					V1 Screen					V2 Enroll (Stage 1, Day 0)										
PTID	Establish PTID	ICF Summary	Demographic DEM Form	Baseline Medical And Menstrual History	Screening Physical Exam And Vital Signs	Pelvic Exam	Hematology And Chemistry Results	HIV, STI and Urine Test Results	Matrix-003 Randomization Assignment	Pelvic Exam	HIV, STI and Urine Test Results	Updated Medical And Menstrual History	Specimen Storage	Baseline Behavioral BEH Form	Baseline Acceptability BL Form	Clinical Observations for Insertion COI Form	Post Insertion Acceptability FU1 Form	Visit Summary	PRN Hematol And Chemis Result
MOCK_PTID Pitt/MWRIF	●	●)) +	●	● +	● +	● +	● +	● +	●	○	○	●	●	●	●	●	●	○	(
PITT_0001 Pitt/MWRIF	●	●)) +	●	● +	● +	● +	● +	● +	●	○	○	●	●	●	●	●	●	○	(
PITT_0002 Pitt/MWRIF	●	●)) +	●	● +	● +	● +	● +	● +	●	○	○	●	●	●	●	●	●	○	(
PITT_0003 Pitt/MWRIF	●	●)) +	●	● +	● +	● +	● +	● +	●	○	○	●	●	●	●	●	●	○	(
PITT_0004 Pitt/MWRIF	●	●)) +	●	● +	● +	● +	● +	● +	●	○	○	●	●	●	●	●	●	○	(
RTI Test	○	○	●	○	○	○	○	○	○	○	○	○	○	●	●	●	●	○	(
TEST-1234	●	● +	●	○	○	○	○	○	○	○	○	○	○	●	○	●	●	○	(
TRAIN_101	●	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	(
TRAIN_989 Aurum Thembisa	●	● +	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	(
TRAIN_991 Aurum Thembisa	●	● +	○	○	○	○	○	○	●	●	○	○	○	○	○	○	○	○	(
TRAIN_992	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	(
TRAIN_993	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	(
TRAIN_994	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	(
TRAIN_995	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	(
TRAIN_996	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	(
TRAIN_997	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	(
TRAIN_998	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	(
US02-3101 Pitt/MWRIF	●	● +	●	● +	● +	● +	● +	● +	○	○	○	○	○	○	○	○	○	○	(
US02-3102 Pitt/MWRIF	●	● +	●	● +	● +	● +	● +	● +	●	●	●	●	●	●	●	●	●	●	(
US02-3103 Pitt/MWRIF	●	● +	●	● +	● +	● +	● +	● +	●	●	●	●	●	●	●	●	●	●	(
US02-3104 Pitt/MWRIF	●	● +	●	● +	● +	● +	● +	● +	○	○	○	○	○	○	○	○	○	○	(
US02-3105	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	(
US02-3106	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	(
US02-3107	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	(

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	RTI Test
Date of assessment: * must provide value	(H) (M) 29-02-2024 📅 [Today] D-M-Y

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.

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? * must provide value	(H) (M) [＿＿＿＿＿] *years*

Question 2 and 3 response options may be modified, as appropriate, for study population and location.

What sex were you assigned at birth? * must provide value	(H) (M)	○ *Female* ○ *Male* ○ *Intersex* ○ *Prefer not to answer* *reset*

What is your gender identity? * must provide value	(H) (M)	○ *Woman* ○ *Man* ○ *Transgender woman* ○ *Transgender man* ○ *Nonbinary, Gender Non-Conforming, or Genderqueer* ○ *A gender not listed here, please specify:* ○ *Prefer not to answer* *reset*

For sites in South Africa and Zimbabwe What is your race or ethnicity? * must provide value	(H) (M)	○ Black ○ Colored ○ Indian ○ Asian ○ White ○ 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
17	Other, specify:

H
M   17
       Language code

* must provide value

Other language, *specify:*   H
                                M

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?		Never
		Rarely (once or twice)
Read options and mark one		Sometimes (3-10 times)
* must provide value		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 live 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

☐ I live alone
☐ Partner
☐ Sibling(s)
☐ Mother and/or father
☐ Other relative(s)
☐ Your child(ren)
☐ Friend(s)/Roommate(s)
☐ 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?   [Incomplete ▼]

[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	RTI Test
Date of assessment: * must provide value	(H) (M) 29-02-2024 🗓 [Today] D-M-Y

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

INTERVIEWER READS: The following are some questions related to your sexual and reproductive health, and your relationship with any sexual partners.

How many sex partners have you had in the last 6 months? * must provide value	(H) (M) [_____] # 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. * must provide value	(H) (M) ○ Yes ○ No reset
In the past 30 days, have you used vaginal lubricant (for any reason)? * must provide value	(H) (M) ○ Yes ○ No reset
In the past 30 days, have you had vaginal sex? * must provide value	(H) (M) ○ Yes ○ No reset
When making choices about HIV prevention, who do you speak with to help you make the decision? Is it... *(Mark all that apply)* * must provide value	(H) (M) ☐ No one, it is my decision ☐ Clinic staff (doctor, nurse, counselor, etc.) ☐ My mother ☐ My sibling/s ☐ My partner ☐ Friend/s ☐ Other, *specify:*

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 family planning. Family planning refers to the various methods that a couple can use to delay or avoid pregnancy.

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 *(e.g. morning after pill)*
☐ Female sterilization (tubal ligation/hysterectomy)
☐ Natural methods (rhythm, fertility awareness, calendar)
☐ NuvaRing
☐ 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.

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... *(Show Response Card 6)*

		Daily	Almost every day	Weekly	Monthly	Never
Manage menses * must provide value	(H) (M)	○	○	○	○	○
						reset
Treat infection * must provide value	(H) (M)	○	○	○	○	○
						reset
Tighten or dry the vagina for sex * must provide value	(H) (M)	○	○	○	○	○
						reset
Clean the vagina * must provide value	(H) (M)	○	○	○	○	○
						reset
Other, *specify:* * must provide value	(H) (M)	○	○	○	○	○
						reset

How comfortable are you with inserting something in your vagina using your fingers? *(Show Response Card 7)*
* must provide value

(H) (M)

○ Very comfortable
○ Somewhat comfortable
○ Somewhat uncomfortable
○ Very uncomfortable

reset

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 *Ease of Use* example below, guide the participant to respond using the 1-10 scale where 1 means extremely difficult and 10 means extremely easy. Follow this format with the appropriate scale for each question where it is indicated.

PTID	RTI Test	
Date of assessment: * must provide value	(H) (M)	[ ] 📅 [Today] D-M-Y

Note: 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 thoughts on the vaginal ring, even though we know you have not yet tried it. We are interested in hearing how you feel about the ring and what you imagine the ring will be like before you try it.

Ease of Use

On a scale of 1 to 10, how difficult or easy do you think it will be to insert the vaginal ring yourself (i.e. put the ring inside your vagina), where 1 means extremely difficult and 10 means extremely easy?

(Show Response Card 1)

* must provide value

(H)
(M)

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

reset

On a scale of 1 to 10, how comfortable do you think it will be to remove the vaginal ring yourself, where 1 means extremely uncomfortable and 10 means extremely comfortable?

(Show Response Card 2)

* must provide value

(H)
(M)

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

reset

Worries and Excitement

On a scale of 1 to 10, how worried are you about using the vaginal ring, where 1 means extremely worried and 10 means not at all worried?

(Show Response Card 3)

* must provide value

(H)
(M)

- ○ 1 - Extremely worried
- ○ 2 - Very worried
- ○ 3
- ○ 4
- ○ 5
- ○ 6
- ○ 7
- ○ 8
- ○ 9 - Not worried
- ○ 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 ring were available for dual purpose pregnancy and HIV prevention, using a vaginal ring 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 ring were available for dual purpose HIV and pregnancy prevention... *[insert item from table]*

		Disagree	Agree somewhat	Agree a lot
Using a vaginal ring on a monthly basis may interfere with my sexual relationships. * must provide value	(H) (M)	○	○	○
				reset
Using a vaginal ring on a monthly basis may enhance/improve my sexual relationships. * must provide value	(H) (M)	○	○	○
				reset
Using a vaginal ring on a monthly basis may give me greater control of my sexual health. * must provide value	(H) (M)	○	○	○
				reset
Using a vaginal ring on a monthly basis may make people think I am at high-risk/that I take sexual risks. * must provide value	(H) (M)	○	○	○
				reset
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.* * must provide value	(H) (M)	○	○	○
				reset

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 important, Somewhat important, Somewhat unimportant, Very unimportant, N/A".

In the future, if vaginal rings were available for dual HIV and pregnancy prevention, how important is it to you that vaginal rings could be used without the following people knowing? *(Show Response Card 5)*						
		Very important	Somewhat important	Somewhat unimportant	Very unimportant	N/A
Spouse/main sexual partner (if not spouse) * must provide value	Ⓗ 💬Ⓜ	○	○	○	○	○
						reset
Casual (other) sexual partner(s) * must provide value	Ⓗ 💬Ⓜ	○	○	○	○	○
						reset
Family, *specify:* * must provide value	Ⓗ 💬Ⓜ	○	○	○	○	○
						reset
Friends * must provide value	Ⓗ 💬Ⓜ	○	○	○	○	○
						reset

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

Clinical Observations for Insertion (COI) 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 ring was **not** inserted, document the circumstance in the "Notes" box.

PTID	RTI Test
Note: To be clinician-completed at every in-clinic visit with product insertion (product initiation and follow-up visit, per protocol). The clinician will be present (behind a curtain) to address questions and concerns. Privacy should be offered to participants.	

Date of assessment: * must provide value	(H) (M) [ ] 📅 [Today] D-M-Y
Was the vaginal ring inserted? * must provide value	(H) (M) ○ Yes ○ No reset

End of Form

Notes:	(H) (M) [ ] Expand

Form Status

Complete?	(H) [Incomplete ▾]

[Save & Exit Form] [Save & ... ▾]

[– Cancel –]

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

Was the vaginal ring inserted?	Ⓗ ⑭	⦿ Yes
* must provide value		○ No
		reset

Was the vaginal ring inserted in the presence of a clinician?	Ⓗ ⑭	⦿ Yes
* must provide value		○ No
		reset

Were you:	Ⓗ ⑭	○ In the same room as participant but behind a curtain or separation
* must provide value		○ In the same room as participant not behind a curtain or separation
		○ Other
		reset

Did the participant require assistance with insertion of the vaginal ring?	Ⓗ ⑭	⦿ Yes
* must provide value		○ No
		reset

Specify type of assistance needed, including any adjustments made to placement of the ring:	Ⓗ ⑭	[ ]
* must provide value		

Did you check placement of the ring?	Ⓗ ⑭	⦿ Yes
* must provide value		○ No
		reset

Based on your perception or observation, how difficult or easy was it for the participant to insert the vaginal ring?	Ⓗ ⑭	○ Very difficult
* must provide value		○ Difficult
		○ Neither difficult nor easy
		○ Easy
		○ Very easy
		reset

Based on your observation, did the participant insert the vaginal ring as per the provided instructions?	Ⓗ ⑭	○ Yes
* must provide value		○ No
		reset

After the insertion, did the participant remove and reinsert the ring?	Ⓗ ⑭	⦿ Yes
* must provide value		○ No
		reset

Please note any challenges or notable circumstances with the removal and reinsertion:	Ⓗ ⑭	[ ]
* must provide value		
		Expand

Based on your observation, how confident did the participant seem inserting the vaginal ring today?	Ⓗ ⑭	○ Very confident
* must provide value		○ Confident
		○ Not confident

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

Clinical Observations for Removal (COR) 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 ring was **not** removed, document the circumstance in the "Notes" box.

PTID	RTI Test

Note: To be clinician-completed at every in-clinic visit with product insertion (product initiation and follow-up visit, per protocol). The clinician will be present (behind a curtain) to address questions and concerns. Privacy should be offered to participants.

Date of assessment: * must provide value	Ⓗ Ⓜ [_____] 🗓 [Today] D-M-Y
Was the vaginal ring removed? * must provide value	Ⓗ Ⓜ ○ Yes ○ No reset

End of Form

Notes:	Ⓗ Ⓜ [_____] Expand

Form Status

Complete?	Ⓗ [Incomplete ˅]

[Save & Exit Form] [Save & ... ▾]

[– Cancel –]

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

Was the vaginal ring removed?	⒣ ⒨	◉ Yes ○ No
* must provide value		
		reset

Was the vaginal ring removed in the presence of a clinician?	⒣ ⒨	◉ Yes ○ No
* must provide value		
		reset

Were you:	⒣ ⒨	○ In the same room as participant but behind a curtain or separation ○ In the same room as participant not behind a curtain or separation ○ Other
* must provide value		
		reset

Did the participant require assistance with removal of the vaginal ring?	⒣ ⒨	◉ Yes ○ No
* must provide value		
		reset

Specify type of assistance needed:	⒣ ⒨	[ ]
* must provide value		

Based on your perception or observation, how difficult or easy was it for the participant to remove the vaginal ring?	⒣ ⒨	○ Very difficult ◉ Difficult ○ Neither difficult nor easy ○ Easy ○ Very easy
* must provide value		
		reset

Explain why it was difficult for the participant to remove the vaginal ring? *(mark all that apply)*	⒣ ⒨	☐ Reluctance to remove the ring herself ☐ Physical discomfort or pain while removing the ring ☐ Discomfort with touching the vagina ☐ Concern that she could not "find" the ring ☐ Discomfort with removing in the presence of clinician ☐ Difficulty with grasping the ring ☑ Other
* must provide value		

Specify:	⒣ ⒨	[ ]
* must provide value		

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. Read the text in the yellow box labeled "Interviewer Reads" aloud. Follow this format with the appropriate scale for each question where it is indicated.

PTID	RTI Test
Date of assessment: * must provide value	(H) (M) [ ] 📅 [Today] D-M-Y
Note: Information in italics is for the interviewer and will not be read aloud to the participant.	
INTERVIEWER READS: I am going to ask you questions about your experiences with insertion and removal of the ring at today's visit.	
Did you insert and remove the ring during this visit? * must provide value	(H) (M) ○ Inserted only, did not remove ◉ Inserted and removed ○ Did not insert or remove reset
Overall, how easy or difficult was it to insert the vaginal ring yourself? **(Show Response Card 8)** * must provide value	(H) (M) ○ Very difficult ○ Difficult ○ Neither difficult nor easy ○ Easy ○ Very easy reset
Overall, how easy or difficult was it to follow the instruction sheet for vaginal ring insertion? **(Show Response Card 8}** * must provide value	(H) (M) ○ Very difficult ○ Difficult ○ Neither difficult nor easy ○ Easy ○ Very easy ○ N/A, instruction sheet not used reset
Overall, how easy or difficult was it to remove the vaginal ring yourself? **(Show Response Card 8)** * must provide value	(H) (M) ○ Very difficult ○ Difficult ○ Neither difficult nor easy ○ Easy ○ Very easy reset
Overall, how easy or difficult was it to follow the instruction sheet for vaginal ring removal? **(Show Response Card 8)** * must provide value	(H) (M) ○ Very difficult ○ Difficult ○ Neither difficult nor easy ○ Easy ○ Very easy ○ N/A, instruction sheet not used 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.

End of Form

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?

Ⓗ
💬

Incomplete ⌄

Save & Exit Form   Save & ...   ▾

– Cancel –

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

STAGE 1, DAY 7 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.

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.

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.

PTID	RTI Test
Date of Brief Acceptability contact * must provide value	(H) [ ] 📅 [Today] D-M-Y (M) *If date is missing, visit will show on reports as missed*

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

Note: To be used when contacting the participant via SMS or phone (or in-person, if preferred) approximately 7 days after the insertion of the each IVR.

These questions are intended to ask participants about their experience with the ring after insertion and to offer support/guidance to address any challenges or concerns they have identified.

Have you noticed, been aware of, or felt the ring since you left the clinic? *Noticed can include if the participant felt, saw, or was aware of the ring* * must provide value	(H) ○ Yes (M) ○ No reset
Have you noticed any changes to your vagina since using the ring? * must provide value	(H) ○ Yes (M) ○ No reset
Has the ring bothered you or caused any type of discomfort? * must provide value	(H) ○ Not at all ○ Some (M) ● Quite a bit reset
If one is needed (such as significant discomfort), complete an AE form.	
In what ways has the ring bothered you or caused discomfort? * must provide value	(H) [ ] (M)

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

Has the vaginal ring been removed or come out since it was inserted during your study visit?	☐ Yes, the ring was removed intentionally
Check all that apply	☑ Yes, the ring came out unintentionally or accidentally
* must provide value	☐ No, the ring has not come out, either accidentally nor intentionally

How many times has the ring come out unintentionally or accidentally since you inserted it?	
* must provide value	times unintentionally

Do you know what caused the ring to come out?	
[Probes: when did this happen? What were you doing when this happened?]	
* must provide value	Expand

Of the times that you mentioned before, what was the longest time that the ring was out?	○ Less than 1 hour
	○ More than 1 hour but less than 3 hours
	○ More than 3 hours but less than 24 hours
* must provide value	○ 24 hours or more
	○ Not sure
	reset

What do you like about the ring so far?	
* must provide value	

What do you dislike about the ring so far?	
* must provide value	

Do you have any concerns about the ring at this time?	○ Yes
* must provide value	○ No
	reset

Do you have any questions for me?	○ Yes
* must provide value	○ No
	reset

End of Form

Notes:	
	Expand

Form Status

Complete?	Incomplete ▾

[Save & Exit Form] [Save & ... ▾]

[– Cancel –]

STAGE 1, DAY 14 CRF (V4)

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.

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	RTI Test

Date of assessment:
(H)
(M) [____] [📅 31] [Today]   D-M-Y
* must provide value

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 vaginal ring you used <u>over the past two weeks</u>. 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 ring <u>in the past two weeks</u>, where 1 means extremely disliked and 10 means extremely well liked?

(H)
(M)

(Show Response Card 11)

* must provide value

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

reset

Please rate how easy or difficult it was for you to use the ring (have it inserted in your vagina) <u>in the past two weeks</u>, from 1-10, where 1 means extremely difficult and 10 means extremely easy.

(H)
(M)

(Show Response Card 12)

* 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.

Expulsion and Removal

Has the vaginal ring been removed or come out since your last study visit? *Check all that apply* * must provide value	Ⓗ 💬Ⓜ	☐ Yes, the ring was removed intentionally ☑ Yes, the ring came out unintentionally or accidentally ☐ No, the ring has not come out, either accidentally or intentionally
Do you know what caused the ring to come out? *[Probes: when did this happen? What were you doing when this happened?]* * must provide value	Ⓗ 💬Ⓜ	 Expand

Burden

Since your last visit, how often did your use of the vaginal ring interfere with any of your regular daily activities? * must provide value	Ⓗ 💬Ⓜ	○ Most of the time ◉ Sometimes ○ Never ○ Ring not used reset
Which daily activities were disrupted by ring use? * must provide value	Ⓗ 💬Ⓜ	 Expand

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

STAGE 1, DAY 28 CRF (V5)

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	RTI Test
Date of assessment: * must provide value	(H) (M) [ ] 📅 [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 vaginal ring you used **over the past month**. 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.

Overall Product Acceptability

On a scale of 1 to 10, how much did you like or dislike using the vaginal ring since your last visit, where 1 means extremely disliked and 10 means extremely well liked? **(Show Response Card 16)** * must provide value	○ 1 - Extremely disliked ○ 2 - Very disliked ○ 3 ○ 4 ○ 5 ○ 6 ○ 7 ○ 8 ○ 9 - Very well liked ○ 10 - Extremely well liked reset
Please rate how easy or difficult it was for you to use the ring since your last visit, from 1-10, with 1 being extremely difficult and 10 being extremely easy. **(Show Response Card 17)** * 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.

MATRIX | MATRIX-003
CRF Completion Guidelines

Protocol Version 1.0 dated 29June2023
Version 1.0

Page 24 of 30
[14 March 2024]

Ease of use

Since the last visit, were you aware of the feeling of the vaginal ring during your normal daily activities? * must provide value	Ⓗ Ⓜ	○ Yes, most of the time ○ Yes, sometimes ○ No reset
Since the last visit, did you notice any of the following changes in your vagina? (Mark all that apply) * must provide value	Ⓗ Ⓜ	☑ More wetness than normal ☑ More dryness than normal ☑ More itchiness than normal ☑ More soreness than normal ☑ Other: ☐ No noticeable changes
Other:	Ⓗ Ⓜ	[_____]

Burden

Since your last visit, how often did your use of the vaginal ring interfere with any of your regular daily activities? * must provide value	Ⓗ Ⓜ	○ Most of the time ○ Sometimes ○ Never ○ Ring not used reset

How, if at all, would the following changes in your vagina affect your use of vaginal rings in the future?

(Show Response Card 21)

More wetness than normal * must provide value	Ⓗ Ⓜ	○ More likely to use ○ No change in use ○ Less likely to use reset
More dryness than normal * must provide value	Ⓗ Ⓜ	○ More likely to use ○ No change in use ○ Less likely to use reset
More itchiness than normal * must provide value	Ⓗ Ⓜ	○ More likely to use ○ No change in use ○ Less likely to use reset
More soreness than normal * must provide value	Ⓗ Ⓜ	○ More likely to use ○ No change in use ○ Less likely to use reset
Other: _____	Ⓗ Ⓜ	○ More likely to use ○ No change in use ○ Less likely to use reset

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

SEXUAL PARTNER IDI VISIT

Sexual Partner Demographic (SPDEM) Form

Document the MATRIX-003 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.

Record ID	WGHI Test 001
What is the MATRIX-003 participant's PTID? * must provide value	Ⓗ ▢ [ ]
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. All response options should be read aloud to the participant unless shown in italics.

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? * must provide value	Ⓗ ▢ [ ] in years
What sex were you assigned at birth? * must provide value	Ⓗ ▢ ○ *Female* ○ *Male* ○ *Intersex* ○ *Prefer not to answer* 　　　　　　　　　　　　reset
What is your gender identity? * must provide value	Ⓗ ▢ ○ *Woman* ○ *Man* ○ *Transgender woman* ○ *Transgender man* ○ *Nonbinary, Gender Non-Conforming, or Genderqueer* ○ *A gender not listed here, please specify:* ○ *Prefer not to answer* 　　　　　　　　　　　　reset
What is your race or ethnicity? * must provide value	Ⓗ ▢ ○ Black ○ Colored ○ Indian ○ Asian ○ White ○ Other, *please specify:* 　　　　　　　　　　　　reset
What is your highest level of school completed? * must provide value	Ⓗ ▢ ○ No schooling ○ Primary school, not complete ○ Primary school, complete ○ Secondary/high school, not complete ○ Secondary/high school, complete ○ Post-secondary education, not complete ○ Post-secondary education, complete 　　　　　　　　　　　　reset
What is your relationship status with your sexual partner in this study? * must provide value	Ⓗ ▢ ○ We are in a casual relationship ○ We are in an exclusive relationship, but not engaged or married ○ We are engaged ○ We are married ○ Other, specify: 　　　　　　　　　　　　reset

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

For each of the following statements, please tell me if you disagree, agree somewhat, or agree a lot. In the future, if the vaginal ring were available... *[insert item from table]*
(Show Response Card 33)

	Disagree	Agree Somewhat	Agree a lot
My partner using a vaginal ring may interfere with our sexual relationship. * must provide value	○	○	○
			reset
My partner using a vaginal ring may enhance or improve our sexual relationship. * must provide value	○	○	○
			reset
My partner using a vaginal ring may make me think that she is at high risk/that she takes sexual risks. * must provide value	○	○	○
			reset
People in my community who are similar to me may want their partners to use a vaginal ring. *"Similar" means people who may share the same life circumstances as you, be in a similar situation in terms of relationships, age, living situation, education* * must provide value	○	○	○
			reset
My partner using a vaginal ring may make me feel safer. * must provide value	○	○	○
			reset

End of Form

Notes:
* must provide value

Expand

Form Status

Complete?   [Incomplete ▾]

[Save & Exit Form] [Save & ... ▾]

[– Cancel –]

PRN (As Needed) Logs

PRN Expulsion Log

Note that this form is not participant-facing and is not meant to be read to the participant. Site staff should gather details about the expulsion or removal event when the participant reports it and record it in this log.

Has the vaginal ring been removed or expelled (intentionally or unintentionally) since the last visit or contact? *Check all that apply*	○ Yes, the ring was removed intentionally ○ Yes, the ring came out unintentionally or accidentally reset
How many times has the ring been removed intentionally since the last visit or contact?	[_____] times intentionally
Why was the vaginal ring removed? *Check all that apply*	☐ It was uncomfortable ☐ It felt like it was falling out ☐ Participant wanted to show partner/ partner wanted to see it ☐ Partner asked participant not to wear it ☐ Participant wanted to clean it ☐ Participant was menstruating ☐ Participant wanted to have sex without it ☐ Participant was sick (e.g. diarrhea) and worried that it would be expelled ☐ Other (specify):
Other, specify:	[_____]
How many times has the vaginal ring come out unintentionally or accidentally since the last visit or contact?	[_____] times unintentionally
What caused the ring to come out?	[_____] Expand Describe
Of the times mentioned above, what was the longest time that the ring was out?	○ Less than 1 hour ○ More than 1 hour but less than 3 hours ○ More than 3 hours but less than 24 hours ○ 24 hours or more ○ Not sure reset
Was the ring re-inserted after it was removed or expelled?	○ Yes ○ No ○ Unsure reset
Please note any further details surrounding the ring removal or expulsion, or surrounding the reinsertion.	[_____]

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

PRN Sexual Partner Events Log

Document the date that site staff was informed of the event being reported. Provide a description of the event. Note that this form is not participant-facing and is not meant to be read to the participant. Site staff should gather details about the event when the participant reports it and record it in this log.

Note: To be used when a sexual partner reports any event or complaint related to the study participant's use of the IVR during the study.	
Date site was informed of sexual partner event:	[　　　] 📅 [Today] D-M-Y
Sexual partner event description:	[text box] Expand
Type of sexual partner event:	○ **Medical event** - Partner reported untoward medical event related to the study product ○ **Personal Relationships (Partner)** - Had negative experiences with significant other, spouse, or sex partner ○ **Personal Relationships (Other)** - Had negative experience with friends, neighbors, or other community members (excluding family) ○ **Personal Relationships (Family)** - Had negative experiences with family (excluding partner) ○ **Housing** - Had trouble getting or keeping housing, had negative experience with landlord, or had other problems related to housing ○ **Other** - Had other problems not covered in the codes above reset
Did this event involve physical harm to the sexual partner?	○ Yes ○ No reset
What impact did this situation have on the sexual partner's quality of life?	○ Minimal disturbance ○ Moderate disturbance; no significant impact ○ Major disturbance with significant impact ○ Unknown reset
Describe what was done by staff and sexual partner to address the event?	[text box] Expand
Current status:	○ Unresolved ○ Unable to resolve; no further action taken ○ Resolved reset

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