



MATRIX-003 CLINICAL CRF COMPLETION GUIDELINES

Protocol Name: MATRIX-003: Trial to Assess Acceptability and Safety of Two Placebo Intravaginal Ring (IVR) Designs, Version 1.0 approved 29 Jun 2023

Author: Tracy Zamborsky, Data Manager, zambtx@upmc.edu

Approved by: Leslie Meyn, Protocol Statistician, meynla@mwri.magee.edu

Version 1.0 Approved 18JAN2024

TABLE OF CONTENTS:

Guidelines for direct data entry	page 2
Data Entry/Corrections	page 3
Date and Time Fields	page 4
REDCap Dashboard	page 5
Establish PTID CRF	page 6
ICF Summary CRF	page 7
Matrix-003 Randomization Assignment CRF	page 9
Baseline Medical and Menstrual History CRF	page 10
Screening Physical Exam and Vital signs CRF	page 13
Pelvic Exam CRF	page 14
Hematology and Chemistry CRF	page 16
HIV, STI and Urine results CRF	page 17
Updated Medical and Menstrual History CRF	page 20
Visit Summary CRF	page 23
PRN Missed Visit CRF	page 24
<i>Ongoing Logs section:</i>	
Concomitant Medications Log	page 25
Pre-existing Conditions Log	page 26
Protocol Deviation Log	page 27
Adverse Event Log	page 29
Social Harms and Benefits Assessment Log	page 34
<i>Product Hold/Discontinuation Folder section:</i>	
Participant Disposition CRF	page 37
Study Product Hold/Discontinuation Log CRF	page 40
HIV Confirmatory CRF	page 41
Pregnancy Report and Outcome CRF	page 43
Interim Visit Section	page 44

Guidelines for Direct Data Entry into REDCap utilizing eCRFs

Introduction: When entering data directly into REDCap, eCRFs are programmed to only show variables relevant to the specific visit. This includes skip patterns for subsequent questions that are only relevant if the leading question is answered in a manner that requires additional information. Leading questions typically follow a Yes/No (or normal vs abnormal) format. Site staff should familiarize themselves with the skip patterns on the eCRFs to ease data capture on occasions when they may need to use a paper CRF.

Forms that begin with “PRN” should be used only when needed.

Required Variables:

Many variables on the eCRFs include the ***must provide value** notation. Example shown below.

Is this the first or second screening attempt for the participant?
** must provide value*

First
 Second

If the variable is not answered when the user saves the eCRF, an auto-generated system query pop-up alert (as shown below) will display on the screen. The eCRF will be saved despite the missing data, however you should make a note to return to the eCRF to enter the data once you have the information.

NOTE: Some fields are required! ✕

Your data was successfully saved, but you did not provide a value for some fields that require a value. Please enter a value for the fields on this page that are listed below.

Provide a value for...

- **Is this the first or second screening attempt for the participant?**

If the information is not available to be entered, use “Not Done” or ‘ND” in places where, for example, a specimen was not collected. This will help minimize queries. The eCRFs include instructions for what to enter in situations where data is not available.

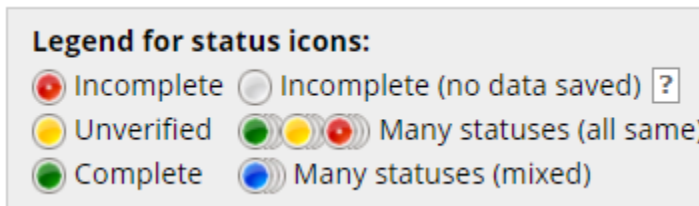
Data Entry/Corrections: After an eCRF has been completed, the user has the ability to save it with a status of “complete”, a status of “incomplete” or a status of “unverified”. Ultimately, the expectation is that eCRFs submitted will be in their “Complete” state, but at the time of data entry some data 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

It is required to mark the “Complete?” variable for every eCRF submitted in REDCap. Note that this is used to signal completeness on the Participant’s dashboard; the variable is not included on paper CRFs.



When in the **Record Home Page**, users are able to view the status of all required eCRFs by 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 affect 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: DD-MM-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 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. Please note that the randomization time entered in REDCap should match the time on the paper randomization form.

Date of participant's randomization
* must provide value

 Today D-M-Y

Time of participant's randomization
* must provide value

 Now H:M

REDCap Dashboard

Entering a New Screening Participant: A unique PTID (participant ID) is assigned to participants who have completed an informed consent. Login to RedCap and navigate to the **Record Status Dashboard**. Select the pre-assigned PTID number.

An empty Participant Dashboard will display on your screen:

PTID TEST-1234

Data Collection Instrument	V1 Screen	V2	V3	V4	V5	V6	V7	V8	V9	+ Add new	Interim Visit	Ongoing Logs	Product Hold/Discontinuation
		Enroll (Stage 1, Day 0)	(Stage 1, Day 7)	(Stage 1, Day 14)	(Stage 1, Day 28)	(Stage 2, Day 0)	(Stage 2, Day 7)	(Stage 2, Day 14)	(Stage 2, Day 28)				
Establish PTID	<input checked="" type="radio"/>												
ICF Summary	<input type="radio"/>												
Demographic DEM Form	<input type="radio"/>												
Matrix-003 Randomization Assignment		<input type="radio"/>											
Baseline Medical And Menstrual History	<input type="radio"/>												
Screening Physical Exam And Vital Signs	<input type="radio"/>												
Pelvic Exam	<input type="radio"/>	<input type="radio"/>		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>		<input type="radio"/>	<input type="radio"/>		<input type="radio"/>		
Hematology And Chemistry Results	<input type="radio"/>												
HIV, STI and Urine Test Results	<input type="radio"/>	<input type="radio"/>		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>		<input type="radio"/>	<input type="radio"/>		<input type="radio"/>		
Updated Medical And Menstrual History		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>		<input type="radio"/>		
Specimen Storage		<input type="radio"/>		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>		<input type="radio"/>	<input type="radio"/>		<input type="radio"/>		
Baseline Behavioral BEH Form		<input type="radio"/>											
Baseline Acceptability BL Form		<input type="radio"/>											
Clinical Observations for Insertion COI Form		<input type="radio"/>				<input type="radio"/>							
Clinical Observations for Removal COR Form					<input type="radio"/>				<input type="radio"/>				
Post Insertion Acceptability FU1 Form		<input type="radio"/>				<input type="radio"/>							
Brief Acceptability FU2 Form			<input type="radio"/>				<input type="radio"/>						
Followup Behavioral And Acceptability FU3 Form				<input type="radio"/>				<input type="radio"/>					
Final Behavioral And Acceptability FU4 Form									<input type="radio"/>				
Visit Summary			<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>		<input type="radio"/>		
Concomitant Medications Log												<input type="radio"/>	
Preexisting Conditions Log												<input type="radio"/>	
Protocol Deviation Log												<input type="radio"/>	
Adverse Events Log												<input type="radio"/>	
Social Harms And Benefits Assessment Log												<input type="radio"/>	
Participant Disposition													<input type="radio"/>
Study Product Hold/Discontinuation Log													<input type="radio"/>
HIV Confirmatory													<input type="radio"/>
Pregnancy Report And Outcome													<input type="radio"/>
PRN Hematology And Chemistry Results		<input type="radio"/>		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>		<input type="radio"/>	<input type="radio"/>		<input type="radio"/>		
PRN Symptom-directed Physical Exam		<input type="radio"/>		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>		<input type="radio"/>	<input type="radio"/>		<input type="radio"/>		
PRN Missed Visit			<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>				
Delete all data on event:	<input checked="" type="checkbox"/>												


To begin entering data, click the bubble for the “Establish PTID” CRF in the top left corner of the grid.

Note for all Screening CRFs

If over the course of the 45 day Screening window, the participant needs to be re-examined or have samples collected again, a new instance of the relevant CRF can be added. This is done by clicking on the “+” button on the dashboard next to the CRF access bubble. Or clicking the “+ Add new” button below the existing instance of the CRF in the Repeating Instrument Section located under the PTID’s dashboard. The option to add a new instance only becomes available after one instance is already entered. Additional explanation and visuals included in next section.

Establish PTID CRF

Choose the site at which this participant is screening, then document the date, and whether this is the first or second screening attempt for the participant. Sites are responsible for tracking this, as participants are only allowed per protocol to be screened twice for the study. If this is the second attempt, the previously used PTID should be entered for the “Enter the PTID assigned to the participant at first screening attempt” question. Then mark the form complete, and continue to the next eCRF.

PTID	<input type="text"/>
Screening Site: <small>* must provide value</small>	<input type="radio"/> Aurum Thembisa <input type="radio"/> CAPRISA Vulindlela <input type="radio"/> HHRC/Zengeza <input type="radio"/> Pitt/MWRIF <input type="radio"/> Wits RHI
	reset
Date Consent was signed <small>* must provide value</small>	<input type="text"/>  Today D-M-Y <small>The 45 day window to Enrollment begins with this date</small>
Is this the first or second screening attempt for the participant? <small>* must provide value</small>	<input type="radio"/> First <input type="radio"/> Second
	reset
Enter the PTID assigned to the participant at first screening attempt	<input type="text"/>




ICF Summary CRF

The ICF Summary CRF captures the ICF version/date and the consent addendum options that the participant agreed or did not agree to.

From section 4 SSP Informed Consent: Informed consent is a dynamic process that should continue throughout the duration of study to ensure participant understanding of protocol requirements. Site staff should review protocol requirements and processes at study visits/contacts as applicable and as deemed necessary. Study participants are free to withdraw consent at any time during participation.

This CRF is repeatable. The ICF Summary CRF is to be updated anytime there is a new ICF version. Also, participants may change their minds about consent during the 45 day screening process OR even after they have been enrolled/randomized. Changes to the ICF version or the addendums the participant agreed to will necessitate a new entry of the ICF Summary CRF. The previously recorded data should NOT be written over.

Below is a section of the ICF Summary CRF as it appears in REDCap:

Date participant signed the ICF <input type="text"/>  Today D-M-Y
IRB approved ICF version <input type="text"/> <small>According to site consent process</small>
IRB approved ICF version date <input type="text"/>  D-M-Y <small>According to site consent process</small>
Addendum Options If a participant changes their mind about any of the consent addendum options after signing consent, create a new instance of the eCRF (instructions in CRF Completion Guidelines document). Do not write over data in REDCap.
CONSENT FOR LONG-TERM STORAGE AND FUTURE TESTING OF SPECIMENS and RELATED HEALTH INFORMATION <small>* must provide value</small> <input type="radio"/> Agree <input type="radio"/> Do Not Agree <input type="radio"/> N/A reset
Date the participant agreed or did not agree to Consent for long term storage of specimens? <input type="text"/>  Today D-M-Y
CONSENT TO PARTICIPATE IN AN IN-DEPTH INTERVIEW <small>* must provide value</small> <input type="radio"/> Agree <input type="radio"/> Do Not Agree <input type="radio"/> N/A reset

How to add an updated instance of the ICF Summary:

If there are changes to be recorded for a participant on the ICF Summary, a new instance of the CRF must be created. This is done by clicking the “+” button on the dashboard next to the CRF access bubble:

The dashboard example shown below indicates that the PTID already has multiple ICF Summary CRF instances entered (the access bubble has a 3-dimensional effect).

Data Collection Instrument	V1 Screen
Establish PTID	<input checked="" type="radio"/>
ICF Summary	<input checked="" type="radio"/> +
Demographic DEM Form	<input type="radio"/>
Matrix-003 Randomization Assignment	

Alternately, you may use the “Repeating instruments” section below the PTID’s dashboard. Clicking the “+ Add new” button below the existing ICF Summary CRF(s) will activate another instance of the ICF Summary to be entered.




Repeating Instruments

ICF Summary		▼
V1 Screen		
(2)		
1	<input checked="" type="radio"/>	Date ICF updated: 05-12-2023
2	<input checked="" type="radio"/>	Date ICF updated: 14-12-2023
<input type="button" value="+ Add new"/>		

Demographic (DEM) Form – refer to Behavioral CCG document for DEM Form

Matrix-003 Randomization Assignment CRF


The Randomization Assignment CRF in REDCap will alert you as the user if the participant has surpassed the 45 day window period for enrolling. All variables on this CRF must be completed for the participant to be considered randomized and enrolled. Be sure that the randomization time entered in REDCap matches the time on the paper randomization form.

Date of this enrollment Visit <input type="text"/>  Today D-M-Y
Days since SCR began <input type="text"/> View equation This should not exceed 45 days
ALERT: **It has been more than 45 days since this participant's screening process started**
Randomization Envelope Number * must provide value <input type="text"/>
This participant is randomized to the following IVR use sequence: * must provide value <input type="radio"/> A followed by B <input type="radio"/> B followed by A reset
Date of participant's randomization * must provide value <input type="text"/>  Today D-M-Y
Time of participant's randomization * must provide value <input type="text"/>  Now H:M

Baseline Medical and Menstrual History CRF

This CRF establishes a baseline for existing medical conditions, allergies, current Rx and OTC medications; as well as capturing family planning methods currently being used by the PTID. Most of the questions are Yes/No answer format, with notes reminding staff to document conditions and medications on the appropriate logs.

Date of assessment
* must provide value

 Today D-M-Y

Do you have any major medical problems?
* must provide value

Yes
 No

[Capture medical conditions and diagnoses on the Pre-existing Conditions Log](#) [reset](#)

Do you have any allergies?
* must provide value

Yes
 No

[Capture all allergies \(including but not limited to drug, food, seasonal, environmental\) on the Pre-existing Conditions Log](#) [reset](#)

Do you currently take any medications, including oral, vaginal, herbal, other-the-counter or prescription medications?
* must provide value

Yes
 No

[Capture all current medications on the Concomitant Medications Log](#) [reset](#)

Notes related to medical problems, allergies, concomitant meds

[Expand](#)

Participants will be asked if they know the date of their last period, and then asked to provide the date. Even if the participant has not had a period in months or even years, if they know the date, it should be entered. If the participant recalls their last period was “sometime in June of 2021” enter 15-6-2021 (as a default, if the participant cannot remember the exact date, using the 15th of the month is acceptable). There is a place to answer exact date, and a separate place if entering an estimated date

Do you know the date of your last menstrual period?

* must provide value

- Yes
- No
- N/A - Amenorrhea

First day of last menstrual period

  D-M-Y

Answer here only if you know the EXACT date; otherwise answer with an estimated date below

Estimated first day of last menstrual period

In the family planning section, all of the acceptable methods the participant is currently using should be marked. If a non-hormonal method of birth control is marked, REDCap will ask for the start date of that method, as shown in the example below:

What acceptable contraception method(s) are you using to prevent pregnancy?

* must provide value

- Oral contraceptives
- Injectable contraceptives (Depo)
- Implant
- IUD (non-copper)
- Copper IUD
- Sterilization of participant
- Condoms (for US sites only)
- Other

Choose all that apply; document hormonal methods on [Concomitant Medications Log](#)

Date of copper IUD insertion

  D-M-Y

Date of sterilization of participant

  D-M-Y

Date you began using condoms

  D-M-Y

Other Contraception, specify

Date you began using other contraception

  D-M-Y

An assessment of vaginal and urinary symptoms is done, and all symptoms that apply are to be marked. If “other” is marked, a text box to specify the other symptoms will appear in REDCap. If “other” is not marked, the text box will not appear in REDCap:

Are you currently experiencing any vaginal symptoms or concerns?
** must provide value*

Yes
 No

Mark all vaginal symptoms that apply

Itching or irritation
 Abnormal discharge (different than fluctuations in discharge with participant's menstrual cycle or contraception)
 Abnormal odor (outside of normal)
 Discomfort or Pain
 Unexpected vaginal bleeding
 Other

Other vaginal symptom(s), specify

Are you currently experiencing any urinary symptoms or concerns?
** must provide value*

Yes
 No

Mark all urinary symptoms that apply

Burning with urination
 Frequency (urinating more than normal and not explained for instance by increased water intake)
 Urgency (feeling the urge or need to urinate but not being able to go)
 Other


Other urinary symptom(s), specify

Note: This CRF (Baseline Medical and Menstrual History) references utilizing The Pre-existing Conditions Log and the Concomitant Medications Log, which are Ongoing Logs to be reviewed at every in-clinic visit.

Screening Physical Exam and vital signs CRF (PRN Symptom-directed physical exam)

A physical examination is required at Screening (all variables require an answer). If “Abnormal” is marked for any of the specific body systems, an additional data entry box will appear to document the abnormality (shown below for “Other”). Indicate unit of measurement for height and weight.

The PRN Symptom-directed physical exam is available at all in clinic visits, though not required.

Date of visit:
  M-D-Y

Physical exam:

	Not evaluated	Normal	Abnormal	
General Appearance <small>* must provide value</small>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	reset
Heart/Cardiac <small>* must provide value</small>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	reset
Lung/Respiratory <small>* must provide value</small>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	reset
Abdomen <small>* must provide value</small>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	reset
Other <small>* must provide value</small>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	reset

Other: Specify body system and associated abnormality:
* must provide value
 Document abnormal findings on Pre-existing conditions Log

Vital Signs

Blood Pressure: Systolic
* must provide value

Blood Pressure: Diastolic
* must provide value

Height:
* must provide value
 Use up to 2 decimal places

Height unit of measurement
* must provide value
 cm in [reset](#)

Weight:
* must provide value
 Use up to 2 decimal places


Weight unit of measurement
* must provide value
 kg lb [reset](#)

Notes/Comments

Pelvic Exam CRF

Intravaginal Ring placement should be confirmed at all in person visits after screening. This question will not appear in REDCap when completing the eCRF, and there are clear directions on the paper CRF to skip it during screening.

Date of pelvic exam
* must provide value

 Today D-M-Y

Skip this question for Visit 1 Screening

Was IVR placement confirmed?
* must provide value

Yes
 No

If no, please explain in notes/comments at end of CRF reset

The CRF continues with the standard pelvic exam

Bleeding on exam?
* must provide value

Yes
 No reset

External Genital Exam
* must provide value

Normal
 Abnormal
 Not Done reset


Mark all external genital exam findings
* must provide value

Edema
 Erythema
 Ulcer
 Blister
 Pustule
 genital warts
 Other

Other external genital exam finding
* must provide value


If “Abnormal” is marked for any section of the pelvic exam, another question will ask the user to mark all of the findings. If “other” is then chosen, a text box will populate asking you to indicate the finding:

Vaginal pH and wet prep are available at screening if indicated, though neither are required. Vaginal pH is required at all in clinic visits after screening. If “yes” is marked indicating that vaginal pH was done, then additional data will need to be entered (date of vaginal pH collection and vaginal pH value). Similarly, if “yes” is marked indicating vaginal wet prep was done, questions will populate to document the wet prep result. If “abnormal” is noted, you are then asked for a more detailed description of findings:

Was vaginal pH done? <i>* must provide value</i> <input type="radio"/> Yes <input type="radio"/> No PRN at V1 Screen visit, required at all scheduled in clinic visits after screening reset
Date of vaginal pH collection <i>* must provide value</i> <input type="text"/>  Today D-M-Y
Vaginal pH <i>* must provide value</i> <input type="text"/>
Was vaginal wet prep done? <i>* must provide value</i> <input type="radio"/> Yes <input type="radio"/> No Only required if indicated, and/or per local standard of care reset
Wet prep result <i>* must provide value</i> <input type="radio"/> Normal <input type="radio"/> Abnormal reset
Mark all vaginal wet prep findings <i>* must provide value</i> <input type="checkbox"/> Buds/hyphae <input type="checkbox"/> >20% clue cells <input type="checkbox"/> Motile trich
Notes/Comments <div style="border: 1px solid #ccc; height: 80px; width: 100%;"></div> Expand

Hematology and Chemistry Results CRF (and PRN Hematology and Chemistry Results)

This CRF is required for V1 screening. Units for results are listed in the different measurements used by sites. Creatinine requires a unit to be marked. The **PRN Hematology and Chemistry Results CRF** is linked with all other in clinic visits but should only be used if necessary.

Collection Date <input type="text"/>  Today D-M-Y
<i>If any result is missing or not done, please mark "ND" in the field</i>
WBC <i>* must provide value</i> <input type="text"/> X10E+09/L or 10 ³ cells/ μ L or 10 ⁹ /L
Hemoglobin <i>* must provide value</i> <input type="text"/> g/dL
Platelets <i>* must provide value</i> <input type="text"/> x10E+09L or 10 ³ cells/ μ L or 10 ⁹ /L
AST <i>* must provide value</i> <input type="text"/> IU/L
ALT <i>* must provide value</i> <input type="text"/> IU/L
Serum Creatinine <i>* must provide value</i> <input type="text"/> Please indicate units below
Units for Serum Creatinine result <input type="radio"/> mg/dL <input type="radio"/> umol/L <input type="radio"/> Not Done

HIV, STI and Urine Test Results CRF

An HIV test is required at V1, V2, V6 and V9. For sites that have CLIA certification for saliva testing, there is one place to document a rapid test result. If a blood test is collected, there are two places to capture results. Both options are shown below as they appear on the CRF during data entry.

If “Saliva” is selected:

HIV testing - Required at V1 Screening, V2 Enrollment, V6 and V9, or if indicated per local standard of care

Type of HIV Rapid test H
** must provide value* M

Saliva
 Blood
 Not Done

reset

HIV Rapid test result (1) H
** must provide value* M

Negative
 Positive
 Invalid result
 Not Done

reset

A Positive HIV Rapid test requires Confirmatory Testing (document results on HIV Confirmatory CRF)

If “Blood” is selected:

HIV testing - Required at V1 Screening, V2 Enrollment, V6 and V9, or if indicated per local standard of care

Type of HIV Rapid test H
** must provide value* M

Saliva
 Blood
 Not Done

reset

HIV Rapid test result (1) H
** must provide value* M

Negative
 Positive
 Invalid result
 Not Done

reset

A Positive HIV Rapid test requires Confirmatory Testing (document results on HIV Confirmatory CRF)







HIV Rapid test result (2) H
** must provide value* M

Negative
 Positive
 Invalid result
 Not Done













reset

A Positive HIV Rapid test requires Confirmatory Testing (document results on HIV Confirmatory CRF)
















As indicated on the eCRF, Syphilis serology is only required at screening; whereas urine pregnancy testing is required at V1, V2, V6 and V9.

Syphilis serology final result <small>* must provide value</small> <input type="radio"/> Negative <input type="radio"/> Positive <input type="radio"/> Not Done <small>Only required at Screening</small>	   <small>reset</small>
Urine - Required at V1 Screening, V2 Enrollment, V6 and V9, or if indicated per local standard of care	
Urine pregnancy test result <small>* must provide value</small> <input type="radio"/> Negative <input type="radio"/> Positive <input type="radio"/> Not done	   <small>reset</small>




Additional urine tests may be collected but are not required. This includes urine dipstick and urine culture. Note that there is not a field to capture the urine culture result in REDCap. Relevant results should be captured as Adverse Events.

Urine - Optional tests	
Was a urine dipstick test done? <small>* must provide value</small> <input checked="" type="radio"/> Yes <input type="radio"/> No <small>Not Required; only if indicated and/or per local standard of care</small>	   <small>reset</small>
Nitrates <small>* must provide value</small> <input type="radio"/> Negative <input type="radio"/> Positive	   <small>reset</small>
Leukocyte esterase <small>* must provide value</small> <input type="radio"/> Negative <input type="radio"/> Positive	   <small>reset</small>
Was a Urine Culture done? <small>* must provide value</small> <input type="radio"/> Yes <input type="radio"/> No <small>Not Required; only if indicated and/or per local standard of care</small>	   <small>reset</small>

STI testing is only required at V1 Screening, but available if indicated at all in-clinic visits.


STI testing - Required at all scheduled in-person visits	
Was a vaginal sample collected for Trichomonas testing? <i>* must provide value</i>	  
<input checked="" type="radio"/> Yes <input type="radio"/> No	reset
Trichomonas test result <i>* must provide value</i>	  
<input type="radio"/> Negative <input type="radio"/> Positive <input type="radio"/> Invalid result <input type="radio"/> Not Done	reset
Was a vaginal sample collected for NAAT for GC/CT? <i>* must provide value</i>	  
<input checked="" type="radio"/> Yes <input type="radio"/> No	reset
N. gonorrhoea <i>* must provide value</i>	  
<input type="radio"/> Negative <input type="radio"/> Positive <input type="radio"/> Invalid result <input type="radio"/> Not Done	reset
C. trachomatis <i>* must provide value</i>	  
<input type="radio"/> Negative <input type="radio"/> Positive <input type="radio"/> Invalid result <input type="radio"/> Not Done	reset

The following question is only asked at the Screening Visit:

Was a Pap Test done? <i>* must provide value</i>	  
<input type="radio"/> Yes <input type="radio"/> No	reset
Only asked at Screening, and Only indicated if participant is unable to provide documentation of a normal Pap test within 3 years prior to enrollment	

Updated Medical and Menstrual History CRF

This form allows the participant to report updates to their current medications, LMP, birth control method(s), and urinary and vaginal symptoms. The CRF follows the same line of questioning as the Screening Medical and Menstrual History CRF, except the questions are framed with “Have you... since your last visit?” Abide the notes to update concomitant meds and pre-existing conditions as needed.

Date of assessment <small>* must provide value</small> <input type="text"/>  Today D-M-Y
Have there been any changes to your medical history since your last visit/contact? (Including changes with medical problems previously reported). <small>* must provide value</small> <input type="radio"/> Yes <input type="radio"/> No reset <small>Update Pre-existing Conditions Log as needed</small>
Have there been any changes to your concomitant medications since your last visit/contact? (Including any changes with oral, vaginal, herbal, over-the-counter or prescription medications) <small>* must provide value</small> <input type="radio"/> Yes <input type="radio"/> No reset <small>Update Concomitant Medications Log as needed</small>
Notes related to updated medical history <div style="border: 1px solid #ccc; height: 80px; width: 100%;"></div>

The following sections are questions related to protocol adherence and social impacts. They only appear in REDCap when they are relevant to the visit:

The following three protocol adherence questions are only visible in REDCap after Visit 2 Enrollment

Have you used PrEP or PEP since study enrollment?

* must provide value

- Yes
- No

reset

If yes, discontinue per protocol

Have you used any non-therapeutic injection drugs since study enrollment?

* must provide value

- Yes
- No

reset

If yes, discontinue per protocol

Are you participating in any other studies (includes studies involving drugs, medical devices, vaginal products or vaccines).

* must provide value

- Yes
- No

reset

If yes, complete a protocol deviation, update Con Med Log as applicable, and consult with PSRT

The following Social Impact question is visible in REDCap at Visits 2, 4, 5, 6, 8 and 9

Have you experienced a negative change, event, or experience in your life related to your study participation?

* must provide value

- Yes
- No

reset

If yes, complete an entry on the Social Harms and Benefits Assessment Log

The following Social Impact question is visible in REDCap at Visits 5 and 9

Have you experienced a positive change, event, or experience in your life related to your study participation?

* must provide value

- Yes
- No




reset

If yes, complete an entry on the Social Harms and Benefits Assessment Log

Changes to the PTID's birth control method or new vaginal/urinary symptoms since the last visit, are documented on this CRF as well.

Specimen Storage CRF

Document the specimens collected at this visit. A collection date should also be entered.

Plasma storage <i>* must provide value</i> <input type="radio"/> Collected <input type="radio"/> Not Collected Only at V2 Enrollment	reset
Plasma Collection Date <input type="text"/>  Today D-M-Y	
Vaginal Gram Stain <i>* must provide value</i> <input type="radio"/> Collected <input type="radio"/> Not Collected	reset
Gram stain collection date <input type="text"/>  Today D-M-Y	
Vaginal Swabs for microbiota <i>* must provide value</i> <input type="radio"/> Collected <input type="radio"/> Not Collected Only at V2 Enrollment	reset
Vaginal swab collection date <input type="text"/>  Today D-M-Y	

Visit Summary CRF

The Visit Summary CRF is a review of what happened during the visit. Any “yes” answer indicates an expectation that a new entry would be documented on a CRF linked to Ongoing Logs or within the Product Hold/Discontinuation Folder on the Dashboard. The date entered here will be the date used by Data Management to determine if the regular study visits are within window.

Do not mark the "Form Status" as complete until the entire visit is complete.

Date of [event-label] Visit

* must provide value

 Today D-M-Y

If for any reason, the entire visit was not completed in one day, this date should indicate the day the visit began

Was study product held/discontinued (scheduled or early) at this visit?

* must provide value

Yes No

reset

Did participant exit/terminate the study at this visit?

* must provide value

Yes No

reset

Were any new adverse events (AEs) reported at this visit?

* must provide value

Yes No

reset

Were any new concomitant medications (or changes to concomitant medications) reported at this visit?

* must provide value

Yes No

reset

Were any protocol deviations reported at this visit?

* must provide value

Yes No

reset

Were any social impacts (benefits or harms) reported at this visit?

* must provide value

Yes No

reset

NOTE: Participants are not asked about social impacts at all visits, however they may report an impact unprompted

Did the participant sign an updated ICF and/or change their mind about a previous consent addendum?

* must provide value

Yes No

reset

If yes, update the ICF Summary


PRN Missed Visit CRF

The PRN missed visit CRF is only to be used if the participant missed a visit. The CRF is linked to all regularly scheduled visits after Enrollment. Note that missed visits do not require an entry on the Protocol Deviation Log CRF. If a Missed Visit is captured on a paper CRF, data should be entered into REDCap as soon as possible. Ideally, within 1-2 days of the visit, though up to 7 days is acceptable.

The visit that has been missed will auto-populate in the place of “[event-label]” below.

This CRF is to be used only if the participant has missed this Study Visit

REDCap entry date

 Today D-M-Y
Click the Today button

Mark the box below, confirming the visit has been missed

* must provide value

The Participant has missed [event-label]

Reason visit was missed

* must provide value

unable to contact participant
 unable to schedule appointment(s) within allowable window
 participant refused visit
 participant incarcerated
 participant admitted to a health care facility
 participant withdrew from study
 participant deceased
 other

[reset](#)

Specify Other reason


Steps taken to address the reason for the missed visit (corrective action plan)

[Expand](#)

ONGOING LOGS – CRFs to be used and updated as needed



Concomitant Medications Log

All medications the participant is currently taking should be documented on the “Con Meds Log” shown below. To add more medications, use the “+” button on the dashboard next to the bubble, or the “+ Add new” button in the Repeating Instruments section below the dashboard.

Date documenting medication:  Today D-M-Y

Medication name: <input type="text"/>	Indication: <input type="text"/>	Was med taken for a reported AE? <input type="radio"/> Yes <input type="radio"/> No reset
Dose: <input type="text"/>		
Units: <input type="radio"/> Grams <input type="radio"/> Micrograms <input type="radio"/> Milligrams <input type="radio"/> Millileters <input type="radio"/> Capsules <input type="radio"/> Drops <input type="radio"/> Puffs <input type="radio"/> Sachets <input type="radio"/> Suppository <input type="radio"/> Tablets <input type="radio"/> Units <input type="radio"/> Unknown <input type="radio"/> Other (If "Other", specify) reset	Frequency: <input type="radio"/> prn <input type="radio"/> once <input type="radio"/> qd <input type="radio"/> bid <input type="radio"/> tid <input type="radio"/> qid <input type="radio"/> qm <input type="radio"/> qh <input type="radio"/> unknown <input type="radio"/> other (If "Other", specify) reset	Route: <input type="radio"/> Oral <input type="radio"/> Subdermal <input type="radio"/> Intramuscular <input type="radio"/> Intravenous <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Inhalation <input type="radio"/> Vaginal <input type="radio"/> Rectal <input type="radio"/> Intrauterine <input type="radio"/> Epidural <input type="radio"/> Unknown <input type="radio"/> Other (If "Other", specify) reset
Other unit:	Other frequency:	Other route:
Date med started: <input type="text"/>	Continuing at end of study? <input type="radio"/> Yes <input type="radio"/> No reset	Date med stopped: <input type="text"/>

Start and Stop Dates are open entry text fields to accommodate participants who may only remember the month and/or year. Medications documented at Screening can be left with an “Incomplete” form status, as they are to be reviewed at the participant’s final visit.

Form Status	
Complete?	 <input type="text" value="Incomplete"/>
<div style="display: flex; justify-content: flex-end; gap: 10px;"> Save & Exit Form Save & Go To Next Form  </div>	

Pre-existing Conditions Log (Ongoing Logs)

All conditions or diagnoses the participant reports should be documented on the Pre-existing Conditions Log shown below. To add additional entries, use the “+” button on the dashboard next to the CRF status bubble, or the “+Add new” button in the Repeating Instruments section below the dashboard.

Document pre-existing conditions at screening, then review at enrollment. Each entry should be reviewed, marked as ongoing or not, and marked COMPLETE at Enrollment Visit

Date documenting pre-existing condition: Today D-M-Y

Description of condition: <input type="text"/>	Start date of condition: <input type="text"/>
Medications taken for this condition: <input type="text"/>	Other treatments for this condition: <input type="text"/>
Severity grade: <input type="radio"/> Grade 1 - mild <input type="radio"/> Grade 2 - moderate <input type="radio"/> Grade 3 - severe <input type="radio"/> Grade 4 - potentially life-threatening <input type="radio"/> Not gradable reset	
Is condition ongoing at enrollment? <input type="radio"/> Yes <input type="radio"/> No reset	Stop date of condition: <input type="text"/>

Comments:

[Expand](#)

Start and Stop Dates are open entry text fields to accommodate participants who may only remember the month and/or year. These entries can have form status left as “incomplete” in the form status section, as all Pre-existing Conditions should be reviewed at enrollment, and marked “complete” then.

Form Status

Complete?

Protocol Deviations Log (Ongoing Logs)

Use this repeatable CRF to document each Protocol Deviation (other than missed visits which will be tracked with the "PRN Missed Visit" CRF). As Protocol Deviations are time-sensitive, please enter each one into REDCap as soon as possible. Please click the TODAY button on the eCRF to capture the entry date (this should not be back-dated if a deviation was first documented on a paper CRF).

Missed Visits are not captured on the Protocol Deviation Log; Please complete the PRN Missed Visit CRF linked with the visit which was missed

REDCap entry Date

* must provide value

 Today D-M-Y

Click the Today button

Deviation Date

* must provide value

 Today D-M-Y

Site Awareness Date

* must provide value

 Today D-M-Y

Description of Deviation

* must provide value

Type of Deviation

* must provide value

- Inappropriate enrollment
- Failure to follow randomization or blinding procedures
- Study product management deviation
- Study product dispensing error
- Study product use/non-use deviation
- Conduct of non-protocol procedure
- Missed required procedure at visit
- Visit completed outside of window
- Counseling deviation
- Unreported AE
- Breach of confidentiality
- Physical assessment deviation
- Lab assessment deviation
- Mishandled lab specimen
- Staff performing duties that they are not qualified or delegated to perform
- Questionnaire administration deviation
- Use of non-IRB/EC-approved materials
- Use of excluded concomitant medications, devices, or non-study products
- Informed consent process deviation
- Other

reset


"Other" type of deviation, specify:


If “other” is chosen for type of deviation, a place to enter the “other” type is provided. Additional variables to enter long-form descriptions and action plans are then available and each should be completed for every deviation entered.

"Other" type of deviation, specify:
<input type="text"/>
Additional Details of Deviation (if applicable)
<input type="text"/>
Expand
Plans and/or action taken to address the deviation
<input type="text"/>
Expand
Plans and/or action taken to prevent future occurrences of the deviation
<input type="text"/>
Expand
Additional details, if needed
<input type="text"/>
Expand

Adverse Event Log (Ongoing Logs)


Adverse Events are time-sensitive and should be entered into REDCap as soon as possible. To track the date of entry, please click the TODAY button to capture the entry date (this should not be back-dated if AE was first documented on a paper CRF). Complete the CRF as best as possible, and update as needed.

REDCap entry Date
* must provide value
  Today D-M-Y
Click the Today button

Date site was informed of AE:
* must provide value
  Today D-M-Y

The Adverse Event Description should be kept brief. If symptoms led to a diagnosis, the diagnosis should be entered as the Adverse Event Description rather than the symptom(s).

Adverse Event Description:
* must provide value

AE onset date:
* must provide value
  Today D-M-Y

Body system:
* must provide value

- Constitutional
- Cardiovascular
- Digestive
- Endocrine
- Hemic/Lymphatic
- Metabolic/Nutritional
- Musculoskeletal
- Nervous
- Respiratory
- Skin/Appendages
- Special Senses (5 senses + equilibrium)
- Urogenital
- Infection
- HEENT
- Other

[reset](#)

Severity:
* must provide value

- Grade 1 - Mild
- Grade 2 - Moderate
- Grade 3 - Severe
- Grade 4 - Life threatening
- Grade 5 - Death

[reset](#)

Was this AE a worsening of a pre-existing condition? H
M
 * must provide value

Yes
 No reset


Study Product Administration: H
M
 * must provide value

No change
 Held (2nd film not administered)
 Permanently discontinued
 Not applicable reset

Status: H
M
 * must provide value

Continuing
 Continuing at end of study participation
 Death
 Severity/frequency increased
 Resolved/Stabilized reset

Status/Outcome Date H
M
 * must provide value

 Today D-M-Y

The Status/Outcome Date field is available if “Death” or “Resolved/Stabilized” is marked as the Status.

Treatment: Mark 'none' or all that apply
 * must provide value

None
 Ring removed
 Medications
 New/Prolonged hospitalization
 Procedure/Surgery
 Other

Medications, specify

New/Prolonged hospitalization, specify

[Brief details](#)

Procedure or surgery, specify

Other treatment, specify

Some treatment options require additional specification.

This AE was first reported at:

* must provide value

- Visit 2 (enrollment)
- Visit 3 (phone call)
- Visit 4 (phone call)
- Visit 5 (phone call)
- Visit 6 (clinic visit)
- Visit 7 (phone call)
- Visit 8 (phone call)
- Visit 9 (clinic visit)
- Visit 10 (final phone call)
- Interim Visit
- Unscheduled phone contact
- Other

reset

Other, specify

Is this AE serious according to ICH guidelines?

* must provide value

- Yes
- No

reset

SAE Category

* must provide value

- Death
- Life-threatening (immediate risk of death)
- Hospitalization/Prolongation of existing hospitalization
- Important Medical Event
- Persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions
- Other

Mark all that apply

Other SAE category:

* must provide value

Hospitalization admission date

  Today M-D-Y

Hospitalization discharge date

  Today M-D-Y

The SAE Category Field is only visible if Yes is marked for “Is this AE serious according to ICH guidelines?” If the SAE Category is “Other,” indicate the other category. If the SAE is a Hospitalization, additional details regarding admission and discharge dates are required. Next, there is a section for Diagnostic testing/labs.

Has the participant had any diagnostic testing or labs done related to this SAE?

* must provide value

- Yes
- No

reset

Indicate diagnostic tests and labs done, including results if known

Expand

Update as needed

(Additional space for notes, if needed)

Indicate diagnostic tests and labs done, including results if known

Dates of film use help safety physicians when reviewing SAEs and Grade 3 or higher related AEs.

Date participant had first intravaginal ring study product inserted?

* must provide value

Today

 D-M-Y

Has participant had 2nd intravagina ring study product inserted?

* must provide value

- Yes
- No

reset

Date participant had second intravaginal ring study product inserted?

* must provide value

Today

 D-M-Y

Relatedness is to be determined by a Clinician. An ongoing narrative documenting testing and outcomes is to be updated as more information becomes available. Each comment is to be initialed and dated (next section).

Relatedness

Relatedness to Study Product/Procedure:

* must provide value

- Not related
- Related

[reset](#)

Relatedness to be determined by a study clinician

Justification of relatedness (for both related and not related)

* must provide value

[Expand](#)

Name of Clinician determining relatedness

* must provide value

Please include a narrative documenting any additional treatment, hospitalization, or outcomes for this AE/SAE. Add additional notes as needed. End each note with your name or initials and the date.

Comment (1):

[Expand](#)

Comment (2):

[Expand](#)

Comment (3):


[Expand](#)

Comment (4):

Social Harms and Benefits Assessment Log (Ongoing Logs)

Social Harms and Benefits Assessment Log

Data Access Group: [No Assignment] ?


 Editing existing PTID **PTID-XXX**. (Instance #1)

Event: **Ongoing Logs**

PTID	PTID-XXX
------	----------

Document each social harm or benefit as its own entry

Date documenting Social Harm or Benefit

 Today D-M-Y

Social impact type

Social Harm

Social Benefit

Social impact type: Indicate whether you are documenting a social harm or a social benefit.

Definition of Social Harm: Social harms are non-medical adverse consequences experienced by study participants that are related to their participation in the study. This includes psychological, physical, sexual, legal, and economic harm.

Definition of Social benefit: Social benefits are positive impacts experienced by study participants that are related to their participation in the study. This includes psychological or physical benefits, relationship improvements, and general well-being benefits to self or community.

Depending on which is marked (harm vs benefit), the CRF will skip to the appropriate and relevant questions.

When documenting a **social harm**, follow these prompts:

Concisely describe the social harm including date(s) H M

Expand

How was the participant impacted by the social harm? H M

- Personal Relationships (Family) - Had negative experiences with family (excluding partner)
- 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
- Travel/Immigration - Had problems obtaining formal permission to travel to or enter another country
- Employment - Was turned down for a job, lost a job, study visits interfering with work/work performance or experienced other problems at work
- Education - Was turned down by an educational program, told to leave an educational program, study visits interfering with school attendance/performance, or experienced other problems at school
- Medical/Dental - Was refused medical or dental treatment, or treated negatively by a health care provider
- 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

Mark all that apply

Did this involve physical harm to the participant? H M

Yes
 No

reset

What impact did this situation have on the participant's quality of life? H M

Minimal disturbance
 Moderate disturbance; no significant impact
 Major disturbance with significant impact
 Unknown

reset

Describe what was done by staff and participant to address social impact H M

Expand

Current status: H M

Unresolved
 Unresolved at end of study
 Unable to resolve; no further action taken
 Resolved

reset

When documenting a **social benefit**, follow these prompts:

Concisely describe the social benefit including date(s) H M

Expand

The social benefit was related to H M

- Pride about project participation: Feels pride about participation in research
- Feeling better about oneself: Improved self-esteem or feeling of empowerment
- Education: The study educated the participant or inspired /enabled participant to restart school or improve school performance.
- Housing: The participant obtained better or improved her housing situation
- Nutrition/food: The participant was able to improve nutrition or amount of food intake for self or family.
- Improved communication: Participant learned more effective ways of communicating with family, friends, employers or others
- Work: Obtained or improved employment situation (includes informal work)
- Income: Obtained or increased income (includes getting study reimbursement)
- HIV testing: The participant received regular HIV testing
- Treatment of STIs: The participant was able to treat STIs
- Treatment of other illnesses: The participant was able to treat/consult with a doctor about other illnesses (non-STIs)
- Family Planning/Contraception: The participant was able to access contraception and family planning services
- Preventative care services: The participant was able to receive preventative health care such as pap smears.
- Staying HIV free: study provided more effective ways for the participant to avoid becoming infected with HIV
- Altruism: Participant helping community/others by participating in research
- Activities: Participant became involved in community activities
- Peer Support: Participant felt supported by or was able to provide support to peers
- New relationships: Participant created new relationships
- Other

What impact did this situation have on the participant's quality of life? H M

- Minimal
- Moderate - no significant impact
- Major - significant impact
- Unknown

reset

Did this involve social benefit to someone other than the participant? H M

- Yes
- No

reset

Indicate who else benefitted H M

Product Hold/Discontinuation Folder (CRFs available for completion as needed)

Participant Disposition CRF

All participants who have been assigned a “PTID” in REDCap must have this CRF completed once their participation in the study has ended. Usually this will occur at Visit 9 (Study Exit Visit), unless the participant exits the study prior to completion.

Shown below as viewed upon opening in REDCap. Additional questions populate based on the answer to the Primary reason for completion/discontinuation. If the participant has completed the study, the only other question to complete is related to evaluability, with an option to document additional relevant details below.


Participant Disposition

Status of Participant: H M

Did not enroll
 Enrolled but did not complete study
 Enrolled and completed all study visits

reset

Date of study exit H M

 Today D-M-Y

Primary reason for completion/discontinuation H M

Scheduled exit visit/end of study
 Participant did not meet all eligibility criteria
 Participant did not enroll within 45 days of screening
 Participant refused further participation/Participant is unwilling or unable to comply with required study procedures
 Participant refused further study product use
 Lost to follow-up
 Investigator decision
 Early study closure
 Study terminated by sponsor
 Protocol deviation
 AE/SAE
 Product Hold/Discontinuation (reason documented on that form)
 Other

reset

If AE/SAE is marked as the reason, there is an additional question to indicate which AE:

If "AE/SAE" indicate applicable adverse event term/description H M

And if Other is marked, specify other reason:

If "Other" specify

If the participant did enroll, the question “Is the participant evaluable?” will appear. As indicated in the footnote of the question, per protocol, evaluable is defined as having completed V5. This question is only skipped if the participant did not enroll.

Is this participant evaluable?

Yes
 No

Per protocol, "evaluable" is defined as having completed V5

reset

If “Participant did not meet all eligibility criteria” from above, the following question is to be answered:

Which eligibility criteria prevented the participant from enrolling?

Inclusion criteria
 Exclusion criteria

Mark all that apply

If “Inclusion criteria” is marked, the following question asks the primary reason, and there is a place to indicate a secondary reason, if applicable:

Mark the primary reason the participant did not meet the inclusion criteria

* must provide value

Not aged 18-45 y/o
 Not assigned female sex at birth
 Did not provide consent
 Inadequate locator information
 Not able/willing to comply with protocol requirement: sex and vaginal product restrictions in month 1
 Not able/willing to refrain from participation in other research studies for the duration of the study
 Not able/wiling to respond to scheduled phone/short message service contacts, or attend all clinic follow-up visits.
 Not HIV-uninfected
 Not in monogamous relationship, or has a partner with HIV or STI
 Positive urine pregnancy test
 Could not provide documentation of a Grade 0 Pap smear within the past 3 years (if over age 21), or required treatment for pap smear at screening
 Not protected from pregnancy, or not on an effective contraceptive method

reset

Based on Protocol v1.0 dated 29JUN2023

If there is a secondary reason the participant did not meet inclusion criteria, specify

If “Exclusion criteria” is marked, the following question asks the primary reason, and there is a place to indicate a secondary reason, if applicable:

Mark the primary reason the participant did not pass the exclusion criteria

* must provide value

- Participant intends to become pregnant
- Participant intends to breastfeed
- Participant intends to relocate from study site
- Participant intends to travel during study period and would interfere with participation
- HIV + at screen or enrollment
- STI at screening or past 12 months
- UTI, PID, or RTI at enrollment
- Grade 2 or higher pelvic exam finding at enrollment
- Spotting/bleeding greater than what is expected from contraceptive use
- Known study product adverse reaction
- Hysterectomy
- Pelvic surgical procedures within 30 days of enrollment
- Use of diaphragm, NuvaRing, or spermicide in two weeks prior to screening
- Antibiotic or antifungal (oral or intravaginal) therapy within 7 days of Enrollment
- Prior use of PEP or PrEP in the 4 weeks, or any prior use of long-acting systemic PrEP ever
- Use of non-therapeutic drugs in past 12 months as defined in the protocol
- Significant uncontrolled active or chronic issue at screening or enrollment as determined by IoR/Designe
- Grade 2 or higher AST
- Grade 2 or higher ALT
- Grade 2 or higher Creatinine
- Grade 2 or higher hemoglobin
- Any other condition per IoR precluding informed consent or safe study participation

reset

Based on Protocol v1.0 dated 29JUN2023

If there is a secondary reason the participant did not pass exclusion criteria, specify

























Additional details can be added in a narrative note box:

Document additional relevant details

Expand

Study Product Hold/Discontinuation Log (repeatable CRF to be used as needed)

Use this CRF if study product has been held/discontinued. If study product is not resumed, then complete the Participant Disposition CRF as well.

Date of Product Hold/Discontinuation	  
<input type="text"/>  Today D-M-Y	
Why is study product being held/discontinued?	  
<p><input type="radio"/> Investigator decision</p> <p><input type="radio"/> Reactive HIV test</p> <p><input type="radio"/> Pregnancy or breastfeeding</p> <p><input type="radio"/> Allergic reaction to study product</p> <p><input type="radio"/> Grade 3 Related or Grade 4 AE</p> <p><input type="radio"/> Use of or need for PrEP or PEP</p> <p><input type="radio"/> Use of Non-therapeutic drugs</p> <p><input checked="" type="radio"/> Other, specify</p>	reset
Other reason product is being held/discontinued	  
<input type="text"/>	
Date study product last inserted	  
<input type="text"/>  Today D-M-Y	
Was PSRT Query form completed?	  
<p><input type="radio"/> Yes</p> <p><input type="radio"/> No</p> <p><input type="radio"/> N/A</p>	reset
<small>Only required for IoR initiated product holds</small>	
Was study product resumed?	  
<p><input checked="" type="radio"/> Yes</p> <p><input type="radio"/> No</p>	reset
Date the participant resumed study product use?	  
<input type="text"/>  Today D-M-Y	

HIV Confirmatory CRF

If a participant tests positive for HIV, this CRF documents the confirmation of the positive test.

When YES is marked for “Was an HIV Confirmatory Test Collected?” additional questions appear in REDCap:

The screenshot displays a series of form fields for HIV-1/2 confirmatory testing. The first field, "Was an HIV-1/2 Confirmatory Test collected?", is highlighted in green and has radio buttons for "Yes" (selected) and "No". Below it is a text input field for "HIV-1/2 Confirmatory Test name". The next field is "HIV-1/2 Confirmatory Test date", which includes a date picker set to "Today" and a "D-M-Y" format indicator. The final field is "HIV-1/2 Confirmatory Test result", which contains six checkboxes: "HIV Negative", "HIV-1 Indeterminate", "HIV-2 Indeterminate", "HIV-1 Positive", "HIV-2 Positive", and "HIV-2 Positive with HIV-1 cross-reactivity". A seventh checkbox, "HIV Positive undifferentiated (un-typeable)", is also present. Each field has a "reset" link and help icons.

Additional questions also appear if a plasma confirmatory test was collected:


The screenshot shows a series of form fields for plasma confirmatory testing. The first field, "Was plasma for confirmatory testing collected?", is highlighted in green and has radio buttons for "Yes" (selected) and "No". Below it is a text input field for "Was plasma stored for HIV Confirmatory testing?", with radio buttons for "Stored" and "Not stored". The final field is "Plasma for confirmatory testing collection date", which includes a date picker set to "Today" and a "D-M-Y" format indicator. Each field has a "reset" link and help icons.

And if an HIV RNA PCR test was completed:

Was HIV RNA PCR testing completed?

Yes
 No

HIV RNA PCR collection date

 Today D-M-Y

HIV RNA PCR result

Greater than
 Equal to
 Less than

Enter HIV RNA PCR result (copies/mL)

If target not detected, mark below

HIV RNA PCR (copies/mL)

Target Not Detected

HIV RNA PCR kit

Abbott M2000
 Rouche Taqman
 Gene Xpert
 Other

HIV RNA PCR kit lower limit of detection

20
 40



OR write in lower limit of detection below

HIV RNA PCR kit lower limit of detection (copies/mL)

Most importantly, the Final HIV Status field must be completed:

Final HIV Status

HIV Uninfected
 HIV infected
 Pending





















reset

Pregnancy Report and Outcome CRF

This CRF is only used if a participant becomes pregnant

- This form is used to report a pregnancy and pregnancy outcome(s) reported post-enrollment.
- Every effort should be made to follow the pregnancy to outcome.
- Complete this form when information about a pregnancy outcome becomes available to study staff or when it is determined that the outcome is unobtainable.
- A pregnancy outcome can be an infant or a fetus. The conception of twins should result in reporting of two outcomes. If a pregnancy results in more than two outcomes, contact the Data Manager for guidance on how to complete this form.

First day of last menstrual period	  
<input type="text"/>	
<small>Enter "UNK" if LMP is unknown</small>	
Estimated Date of Delivery	  
<input type="text"/>  D-M-Y	
Method used to determine EDD	  
<input type="text"/>	
Does the participant have a history of pregnancy complications or fetal/infant congenital anomalies?	  
<input type="radio"/> Yes <input type="radio"/> No	
	reset
Is the outcome of this pregnancy obtainable?	  
<input type="radio"/> Yes <input type="radio"/> No	
	reset

Additional questions related to the pregnancy outcome will populate in REDCap, once “Is the outcome of this pregnancy obtainable?” is answered. As pregnancy and pregnancy outcome information may be limited, it is expected that many of the variables on the Pregnancy Report and Outcome CRF will be blank. The CRF should be completed as thoroughly as possible when the pregnancy is first reported. Updates to the CRF can be made with each follow-up attempt as appropriate.

Interim Visits

Interim Visits can occur at any time once the participant is randomized. Each instance of an Interim Visit allows access to all clinical follow-up CRFs, though only those CRFs needed should be used. However, the Updated Medical and Menstrual History CRF should be completed for every Interim instance (unless the CRF was completed at a regularly scheduled study visit within the past 24 hours). The Visit Summary CRF should also be completed for all instances of an Interim Visit.

Interim Visits have their own folder on the REDCap participant Dashboard (after V19):

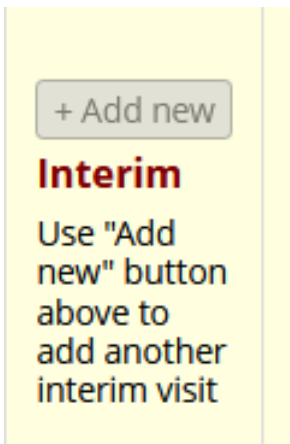


PTID TEST-1234

Data Collection Instrument	V1 Screen	V2 Enroll (Stage 1, Day 0)	V3 (Stage 1, Day 7)	V4 (Stage 1, Day 14)	V5 (Stage 1, Day 28)	V6 (Stage 2, Day 0)	V7 (Stage 2, Day 7)	V8 (Stage 2, Day 14)	V9 (Stage 2, Day 28)	+ Add new	Interim Visit	Ongoing Logs	Product Hold/Discontinuation
----------------------------	--------------	--	------------------------------	-------------------------------	-------------------------------	------------------------------	------------------------------	-------------------------------	-------------------------------	-----------	------------------	-----------------	---------------------------------

















Enlarged View:

To add another interim visit instance, you click the “+Add new” button at the top of the Dashboard Folder.



Each Interim Visit must be documented as its own instance.

This partial screen grab of the PTID’s dashboard indicates 2 Interim visits have already occurred, and another (#3) is about to be entered into REDCap. Each Interim visit has its own column on the PTID’s dashboard in REDCap.

Interim Use "Add new" button above to add another interim visit (#1)	Use "Add new" button above to add another interim visit (#2)	 (#3)
		
		
		
		
		

Remember, regardless of what CRFs are needed to document the procedures completed at an Interim Visit, the Visit Summary CRF must be completed for each instance of an Interim Visit.

DocuSigned by:

 Signer Name: Leslie Meyn
 Signing Reason: I approve this document
 Signing Time: 1/19/2024 | 11:41:59 AM EST
 B4E1CC5F63DF4052A48978550B4DCB6D