



## MATRIX-002 CLINICAL CRF COMPLETION GUIDELINES

**Protocol Name: MATRIX-002 Trial to Assess Acceptability and Safety of Two Placebo Prototype Vaginal Films, Version 1.0 approved 24 May 2023**

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## 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?**

Okay

Ignore and leave record

Ignore and go to next form

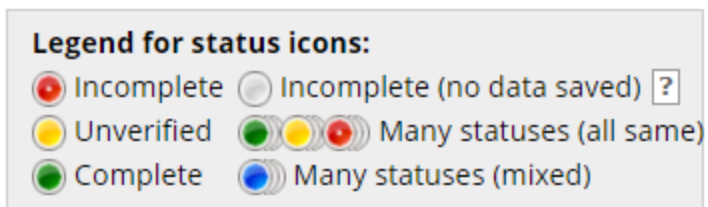
If the information is not available to be entered, use “Not Done” or ‘ND’ in places where, for example, a specimen was not collected. This will help minimize queries. The eCRFs include instructions for what to enter in situations where data is not available.

**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.

The screenshot shows a form field labeled "Complete?". A dropdown menu is open, displaying four options: "Incomplete" (highlighted in blue), "Incomplete", "Unverified", and "Complete". Below the dropdown is a blue button labeled "Save & Go To Next Record" and a grey button labeled "-- Cancel --".

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


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.

**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. Log into RedCap and navigate to the **Record Status Dashboard**. Select the pre-assigned PTID number.

An empty Participant Dashboard will display on your screen:

| Data Collection Instrument                             | V1 Screen<br>SCR start | V2 Enroll<br>(1st film)<br>Rand date | V3 (24-72 hr phone contact) | V4 (wk 1 phone contact) | V5 (wk 2 phone contact) | V6 (wk 4 clinic f/u, 2nd film)<br>V6 date | V7 (24-72 hr phone contact) | V8 (wk 6 phone contact) | V9 (wk 8 clinic f/u)<br>V9 date | V10 (wk 9 final phone contact) | + Add new<br>Interim<br>Use "Add new" button above to add another interim visit | Ongoing Logs<br>Complete as needed | Product Hold/Discontinuation |
|--|------------------------|--------------------------------------|-----------------------------|-------------------------|-------------------------|---|-----------------------------|-------------------------|---------------------------------|--------------------------------|---|------------------------------------|------------------------------|
| ICF Summary  | <input type="radio"/>  |                                      |                             |                         |                         |   |                             |                         |                                 |                                |   |                                    |                              |
| Demographic (DEM) Form                                 | <input type="radio"/>  |                                      |                             |                         |                         |   |                             |                         |                                 |                                |   |                                    |                              |
| Matrix-002 Randomization                               |                        | <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"/>   |                                    |                              |
| Hematology and Chemistry Results                       | <input type="radio"/>  |                                      |                             |                         |                         |   |                             |                         | <input type="radio"/>           |                                |   |                                    |                              |
| HIV, STI and Urine Test Results                        | <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"/>   |                                    |                              |
| Specimen Storage                                       |                        | <input type="radio"/>                |                             |                         |                         | <input type="radio"/>                     |                             |                         | <input type="radio"/>           |                                | <input type="radio"/>   |                                    |                              |
| Visit Summary  |                        | <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 (CO) Form                        |                        | <input type="radio"/>                |                             |                         |                         | <input type="radio"/>                     |                             |                         |                                 |                                |   |                                    |                              |
| Post-Insertion Acceptability (FU1) Form                |                        | <input type="radio"/>                |                             |                         |                         | <input type="radio"/>                     |                             |                         |                                 |                                |   |                                    |                              |
| Brief Acceptability (FU2) Form <small>(survey)</small> |                        |                                      | <input type="radio"/>       | <input type="radio"/>   | <input type="radio"/>   |   | <input type="radio"/>       | <input type="radio"/>   |                                 |                                |   |                                    |                              |
| Follow-up behavioral and acceptability (FU3) Form      |                        |                                      |                             |                         |                         | <input type="radio"/>                     |                             |                         |                                 |                                |   |                                    |                              |
| Final Behavioral and Acceptability (FU4)               |                        |                                      |                             |                         |                         |   |                             |                         | <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"/>   |                                    |                              |
| PRN Targeted Physical Exam                             |                        | <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"/>           | <input type="radio"/>          |   |                                    |                              |

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


## SCREENING VISIT CRFs (V1)

### General 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.

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

|   |
|---|
| <p><b>Date participant signed the ICF</b></p> <input type="text"/>  Today D-M-Y  |
| <p><b>IRB approved ICF version</b></p> <input type="text"/> <p><small>According to site consent process</small></p>   |
| <p><b>IRB approved ICF version date</b></p> <input type="text"/>  D-M-Y  |
| <p><small>According to site consent process</small></p>   |
| <p><b>Addendum Options</b></p>  |
| <p><b>CONSENT FOR LONG-TERM STORAGE AND FUTURE TESTING OF SPECIMENS and RELATED HEALTH INFORMATION</b></p> <p><small>* must provide value</small></p> <p> <input type="radio"/> Agree<br/> <input type="radio"/> Do Not Agree<br/> <input type="radio"/> N/A         </p> |
| <p><b>Date the participant agreed or did not agree to Consent for long term storage of specimens?</b></p> <input type="text"/>  Today D-M-Y  |
| <p><b>CONSENT TO PARTICIPATE IN AN IN-DEPTH INTERVIEW</b></p> <p><small>* must provide value</small></p> <p> <input type="radio"/> Agree<br/> <input type="radio"/> Do Not Agree<br/> <input type="radio"/> N/A         </p>  |

## 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              |   |
|---|---|
|   | <b>V1 Screen</b><br>SCR start<br>05-06-2023 |
| Establish PTID                          |   |
| ICF Summary                             | +   |
| Matrix-002 Randomization                |   |
| Baseline Medical and Menstrual History  | +   |
| Screening Physical Exam and vital signs | +   |
| Pelvic Exam                             | +   |
| Hematology and Chemistry Results        | +   |
| HIV, STI and Urine Test Results         | +   |

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           |  | ICF Summary dated: 05-06-2023 |
| 2           |  | ICF Summary dated: 19-06-2023 |
| + Add new   |  |                               |



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

### 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.

|   |
|---|
| <p><b>Date of assessment</b></p> <p>* must provide value</p> <p><input type="text"/>  Today D-M-Y</p>  |
| <p><b>Do you have any major medical problems?</b></p> <p>* must provide value</p> <p><input type="radio"/> Yes</p> <p><input type="radio"/> No</p> <p><a href="#">Capture medical conditions and diagnoses on the Pre-existing Conditions Log</a></p> <p style="text-align: right;">reset</p>   |
| <p><b>Do you have any allergies?</b></p> <p>* must provide value</p> <p><input type="radio"/> Yes</p> <p><input type="radio"/> No</p> <p><a href="#">Capture all allergies (including but not limited to drug, food, seasonal, environmental) on the Pre-existing Conditions Log</a></p> <p style="text-align: right;">reset</p>                                    |
| <p><b>Do you currently take any medications, including oral, vaginal, herbal, other-the-counter or prescription medications?</b></p> <p>* must provide value</p> <p><input type="radio"/> Yes</p> <p><input type="radio"/> No</p> <p><a href="#">Capture all current medications on the Concomitant Medications Log</a></p> <p style="text-align: right;">reset</p> |
| <p><b>Notes related to medical problems, allergies, concomitant meds</b></p> <div style="border: 1px solid gray; height: 80px; width: 100%;"></div> <p style="text-align: right;">Expand</p>  |


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 15<sup>th</sup> of the month is acceptable).

**Do you know the date of your last menstrual period?**  
*\* must provide value*

Yes  
 No  
 N/A - Amenorrhea

---

**First day of last menstrual period**

 Today D-M-Y

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)  
 Abstinence from penile-vaginal intercourse  
 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

---

**Date you began using abstinence**


 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

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.










| Date of visit:  |             |   |                                  |                                  |
|---|-------------|---|----------------------------------|----------------------------------|
| <input type="text"/>                                      | Today M-D-Y |   |                                  |                                  |
| <b>Physical exam:</b>                                     |             |   |                                  |                                  |
|   |             | <b>Not evaluated</b>  | <b>Normal</b>                    | <b>Abnormal</b>                  |
| <b>General Appearance</b><br>* must provide value         | <br>        | <input checked="" type="radio"/>  | <input type="radio"/>            | <input type="radio"/>            |
|   |             |   |                                  | <a href="#">reset</a>            |
| <b>Heart/Cardiac</b><br>* must provide value              | <br>        | <input type="radio"/>   | <input checked="" type="radio"/> | <input type="radio"/>            |
|   |             |   |                                  | <a href="#">reset</a>            |
| <b>Lung/Respiratory</b><br>* must provide value           | <br>        | <input type="radio"/>   | <input checked="" type="radio"/> | <input type="radio"/>            |
|   |             |   |                                  | <a href="#">reset</a>            |
| <b>Abdomen</b><br>* must provide value                    | <br>        | <input type="radio"/>   | <input checked="" type="radio"/> | <input type="radio"/>            |
|   |             |   |                                  | <a href="#">reset</a>            |
| <b>Other</b><br>* must provide value                      | <br>        | <input type="radio"/>   | <input type="radio"/>            | <input checked="" type="radio"/> |
|   |             |   |                                  | <a href="#">reset</a>            |
| <b>Other abnormality:</b><br>* must provide value         | <br>        | <input type="text"/>  |                                  |                                  |
|   |             | <a href="#">Document abnormal findings on Pre-existing conditions Log</a> |                                  |                                  |
| <b>Vital Signs</b>  |             |   |                                  |                                  |
| <b>Blood Pressure: Systolic</b><br>* must provide value   | <br>        | <input type="text" value="115"/>  |                                  |                                  |
| <b>Blood Pressure: Diastolic</b><br>* must provide value  | <br>        | <input type="text" value="78"/>   |                                  |                                  |
| <b>Height:</b><br>* must provide value                    | <br>        | <input type="text" value="65"/>   |                                  |                                  |
| <b>Height unit of measurement</b><br>* must provide value | <br>        | <input type="radio"/> cm <input checked="" type="radio"/> in              |                                  |                                  |
|   |             | <a href="#">reset</a>   |                                  |                                  |
| <b>Weight:</b><br>* must provide value                    | <br>        | <input type="text" value="136"/>  |                                  |                                  |
| <b>Weight unit of measurement</b><br>* must provide value | <br>        | <input type="radio"/> kg <input checked="" type="radio"/> lb              |                                  |                                  |
|   |             | <a href="#">reset</a>   |                                  |                                  |
| <b>Notes/Comments</b>                                     | <br>        | <input type="text"/>  |                                  |                                  |

## Pelvic Exam CRF (as viewed during Screening Visit)























The questions that appear as the form is opened are all required to be answered:

|  |  |
|--|--|
| <b>Date of pelvic exam</b><br>* must provide value<br><input type="text"/>  Today D-M-Y | <br>        |
| <b>Bleeding on exam?</b><br>* must provide value<br><input type="radio"/> Yes<br><input type="radio"/> No  | <br>        |
| <b>External Genital Exam</b><br>* must provide value<br><input type="radio"/> Normal<br><input type="radio"/> Abnormal<br><input type="radio"/> Not Done                 | <br>        |
| <b>Internal Genital Exam</b><br>* must provide value<br><input type="radio"/> Normal<br><input type="radio"/> Abnormal<br><input type="radio"/> Not Done                 | <br>        |
| <b>Cervical Exam</b><br>* must provide value<br><input type="radio"/> Normal<br><input type="radio"/> Abnormal<br><input type="radio"/> Not Done                         | <br>  |

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:


|  |  |
|--|--|
| <b>Bi-manual Exam</b><br>* must provide value<br><input type="radio"/> Normal<br><input checked="" type="radio"/> Abnormal<br><input type="radio"/> Not Done   | <br>  |
| Only required at Screening   | <a href="#">reset</a>  |
| <b>Mark all bi-manual exam findings:</b><br>* must provide value<br><input type="checkbox"/> Cervical motion tenderness<br><input type="checkbox"/> Uterine tenderness<br><input type="checkbox"/> Adnexal tenderness<br><input checked="" type="checkbox"/> Other | <br>  |
| <b>Other bi-manual exam finding</b><br>* must provide value<br><input type="text"/>  | <br>  |

Vaginal pH and wet prep are available at screening if indicated, though neither are required. 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:

|  |   |
|--|---|
| <p><b>Was vaginal pH done?</b></p> <p>* must provide value</p> <p><input checked="" type="radio"/> Yes<br/><input type="radio"/> No</p> <p>Required at V2, V6 and V9</p> <p style="text-align: right;">reset</p>   | <br><br>       |
| <p><b>Date of vaginal pH collection</b></p> <p>* must provide value</p> <p>29-06-2023  Today D-M-Y</p>  | <br><br>       |
| <p><b>Vaginal pH</b></p> <p>* must provide value</p> <p>4.6</p>  | <br><br>       |
| <p><b>Was vaginal wet prep done?</b></p> <p>* must provide value</p> <p><input checked="" type="radio"/> Yes<br/><input type="radio"/> No</p> <p>Only required if indicated, and/or per local standard of care</p> <p style="text-align: right;">reset</p> | <br><br>       |
| <p><b>Wet prep result</b></p> <p>* must provide value</p> <p><input type="radio"/> Normal<br/><input checked="" type="radio"/> Abnormal</p> <p style="text-align: right;">reset</p>  | <br><br> |
| <p><b>Mark all vaginal wet prep findings</b></p> <p>* must provide value</p> <p><input type="checkbox"/> Buds/hyphae<br/><input type="checkbox"/> &gt;20% clue cells<br/><input type="checkbox"/> Motile trich</p>   | <br><br> |
| <p><b>Notes/Comments</b></p> <div style="border: 1px solid #ccc; height: 100px;"></div>  | <br><br> |

## Hematology and Chemistry Results CRF

This CRF is required for V1 and V9. Units for results are listed in the different measurements used by sites. Creatinine requires a unit to be marked.

|  |
|--|
| <b>Collection Date</b><br><input type="text"/>  Today D-M-Y |
| <b><i>If any result is missing or not done, please mark "ND" in the field</i></b>  |
| <b>WBC</b><br>* must provide value<br><input type="text"/><br>X10E+09/L or 10 <sup>3</sup> cells/ $\mu$ L or 10 <sup>9</sup> /L              |
| <b>Hemoglobin</b><br>* must provide value<br><input type="text"/><br>g/dL  |
| <b>Platelets</b><br>* must provide value<br><input type="text"/><br>x10E+09L or 10 <sup>3</sup> cells/ $\mu$ L or 10 <sup>9</sup> /L         |
| <b>AST</b><br>* must provide value<br><input type="text"/><br>IU/L   |
| <b>ALT</b><br>* must provide value<br><input type="text"/><br>IU/L   |
| <b>Serum Creatinine</b><br>* must provide value<br><input type="text"/><br>Please indicate units below                                       |
| <b>Units for Serum Creatinine result</b><br><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 every in-clinic visit. 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:

| Required HIV testing   |        |
|--|--------|
| <b>Type of HIV Rapid test</b><br>* must provide value  | H<br>M |
| <input checked="" type="radio"/> Saliva<br><input type="radio"/> Blood<br><input type="radio"/> Not Done                                   | reset  |
| Required at every clinic visit   |        |
| <b>HIV Rapid test result (1)</b><br>* must provide value   | H<br>M |
| <input type="radio"/> Negative<br><input type="radio"/> Positive<br><input type="radio"/> Invalid result<br><input type="radio"/> Not Done | reset  |
| A Positive HIV Rapid test requires Confirmatory Testing (document results on HIV Confirmatory CRF)   |        |

If “Blood” is selected:

| Required HIV testing   |        |
|--|--------|
| <b>Type of HIV Rapid test</b><br>* must provide value  | H<br>M |
| <input type="radio"/> Saliva<br><input checked="" type="radio"/> Blood<br><input type="radio"/> Not Done                                   | reset  |
| Required at every clinic visit   |        |
| <b>HIV Rapid test result (1)</b><br>* must provide value   | H<br>M |
| <input type="radio"/> Negative<br><input type="radio"/> Positive<br><input type="radio"/> Invalid result<br><input type="radio"/> Not Done | reset  |
| A Positive HIV Rapid test requires Confirmatory Testing (document results on HIV Confirmatory CRF)   |        |
| <b>HIV Rapid test result (2)</b><br>* must provide value   | H<br>M |
| <input type="radio"/> Negative<br><input type="radio"/> Positive<br><input type="radio"/> Invalid result<br><input type="radio"/> 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 every clinic visit.

|  |                                |
|--|--------------------------------|
| <p><b>Syphilis serology final result</b></p> <p>* must provide value</p> <p><input type="radio"/> Negative</p> <p><input type="radio"/> Positive</p> <p><input type="radio"/> Not Done</p> <p>Only required at Screening</p> | <p>H</p> <p>M</p> <p>reset</p> |
| <p><b>Urine - Required at every scheduled in-person visit; optional for interim visits</b></p>   |                                |
| <p><b>Urine pregnancy test result</b></p> <p>* must provide value</p> <p><input type="radio"/> Negative</p> <p><input type="radio"/> Positive</p> <p>Required at every clinic visit</p>                                      | <p>H</p> <p>M</p> <p>reset</p> |




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.

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

STI testing is required at all in-clinic visits. Once marked YES for “was a sample collected for...testing?” the result variable becomes available to document the test result.

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

The following question is only asked at the Screening Visit:

|   |   |
|---|---|
| <b>Was a Pap Test done?</b><br><i>* must provide value</i>  | <br><br> |
| <input type="radio"/> Yes<br><input type="radio"/> No   | <a href="#">reset</a>   |
| 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 |   |


## ENROLLMENT VISIT CRFs (V2)


### Matrix-002 Randomization CRF

The Randomization CRF should only be activated once the PTID has been randomized (per SOP).

The CRF will automatically pre-fill the dates of when the participant began screening and the final date they can be enrolled. Also when the enrollment date is entered, the “days since SCR began” will be calculated. This must be 45 days or less. Complete the additional variables documenting Randomization Number, film assignment, date and time.

#### Matrix-002 Randomization



Data Access Group: **[No Assignment]** 

 Editing existing PTID **PTID-XXX**.


Event: **V2 Enroll (1st film)**


**PTID** PTID-XXX

**This Participant began the screening process:** 05-06-2023 [View equation](#)

**Final date for this Participant to be enrolled is:** 20-07-2023 [View equation](#)  


**Date of this enrollment Visit**

 Today D-M-Y


**Days since SCR began** 


[View equation](#)

This should not exceed 45 days

**Randomization Number** 

\* must provide value


**This participant is randomized to receive the following film:** 


\* must provide value 


Film A


Film B


[reset](#)


**Date of participant's randomization** 

\* must provide value 

 Today D-M-Y

**Time of participant's randomization** 

\* must provide value 

 Now H:M

## Pelvic Exam CRF (as viewed during Enrollment Visit)

The Pelvic Exam CRF functions the same for enrollment as it does for screening (reference pages 13-14). The only difference is that the bi-manual exam variable is not available at enrollment.





















|   |  |
|---|--|
| <b>Date of pelvic exam</b><br>* must provide value<br><input type="text"/>  Today D-M-Y            | <br><br>                |
| <b>Bleeding on exam?</b><br>* must provide value<br><input type="radio"/> Yes<br><input type="radio"/> No   | <br><br><br>reset       |
| <b>External Genital Exam</b><br>* must provide value<br><input type="radio"/> Normal<br><input type="radio"/> Abnormal<br><input type="radio"/> Not Done                            | <br><br><br>reset       |
| <b>Internal Genital Exam</b><br>* must provide value<br><input type="radio"/> Normal<br><input type="radio"/> Abnormal<br><input type="radio"/> Not Done                            | <br><br><br>reset       |
| <b>Cervical Exam</b><br>* must provide value<br><input type="radio"/> Normal<br><input type="radio"/> Abnormal<br><input type="radio"/> Not Done                                    | <br><br><br>reset |
| <b>Was vaginal pH done?</b><br>* must provide value<br><input type="radio"/> Yes<br><input type="radio"/> No<br>Required at V2, V6 and V9   | <br><br><br>reset |
| <b>Was vaginal wet prep done?</b><br>* must provide value<br><input type="radio"/> Yes<br><input type="radio"/> No<br>Only required if indicated, and/or per local standard of care | <br><br><br>reset |
| <b>Notes/Comments</b>   | <br><br>          |

## HIV, STI and Urine Test Results (Enrollment)

This CRF functions the same as it does for the screening visit. HIV, Urine pregnancy and STI required; Syphilis serology, urine dipstick and urine culture only if indicated or per local standard of care. Guidelines are the same as for screening (as shown on page 16-18 of this document).

## Updated Medical and Menstrual History CRF (Enrollment)

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.

|   |  |
|---|--|
| <b>Date of assessment</b><br><small>* must provide value</small><br><input type="text"/>  Today D-M-Y  | <br>                                  |
| <b>Have there been any changes to your medical history since your last visit/contact?</b><br><small>* must provide value</small><br><input type="radio"/> Yes<br><input type="radio"/> No<br><a href="#">Update Pre-existing Conditions Log as needed</a>   | <br> <br><a href="#">reset</a>        |
| <b>Have there been any changes to your concomitant medications since your last visit/contact? (Including any changes with oral, vaginal, herbal, other-the-counter or prescription medications)</b><br><small>* must provide value</small><br><input type="radio"/> Yes<br><input type="radio"/> No<br><a href="#">Update Concomitant Medications Log as needed</a> | <br> <br><a href="#">reset</a>  |
| <b>Notes related to updated medical history</b><br><div style="border: 1px solid #ccc; height: 80px; width: 100%;"></div>   | <br> <br><a href="#">Expand</a> |
| <b>Have you had a period since your last visit/contact?</b><br><small>* must provide value</small><br><input checked="" type="radio"/> Yes<br><input type="radio"/> No<br><input type="radio"/> N/A (Amenorrhea)  | <br> <br><a href="#">reset</a>  |
| <b>First day of last menstrual period</b><br><input type="text"/>  Today D-M-Y   | <br>                            |

If there have been changes to the PTID's birth control method since the last visit, document that here. In this example, the oral contraceptives will be documented as a new medication on the Concomitant Medications Log, and the Copper IUD insertion date can be documented in the date box that will appear on the eCRF.

**Have you changed your birth control/contraception method since your last visit?** H

*\* must provide value* M

Yes

No

reset

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

*\* must provide value* M

Oral contraceptives

Injectable contraceptives (Depo)

Implant

IUD (non-copper)

Copper IUD

Sterilization of participant

Condoms (for US sites only)

Abstinence from penile-vaginal intercourse

Other

Choose all that apply; document hormonal methods on Con Med Log

**Date of copper IUD insertion** H

M

D-M-Y

Questions regarding vaginal and urinary symptoms complete the form:

**Have you experienced any vaginal symptoms or concerns (including vaginal bleeding) since your last visit?** H

*\* must provide value* M

Yes

No

reset

**Have you experienced any urinary symptoms or concerns since your last visit?** H

*\* must provide value* M

Yes

No

reset

**Mark all urinary symptoms that apply** H

*\* must provide value* M

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

Update Pre-existing Conditions Log or Adverse Event Log as applicable

## Specimen Storage CRF (Enrollment)

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

|  |  |
|--|--|
| <b>PTID</b>  | d2d-test-8002  |
| <b>Plasma storage</b><br><i>* must provide value</i><br><input checked="" type="radio"/> Collected<br><input type="radio"/> Not Collected<br>Only at V2 Enrollment | <br><br><br><br><br><a href="#">reset</a>   |
| <b>Plasma Collection Date</b>  | <br><br><br><input type="text"/><br> Today D-M-Y         |
| <b>Vaginal Gram Stain</b><br><i>* must provide value</i><br><input checked="" type="radio"/> Collected<br><input type="radio"/> Not Collected                      | <br><br><br><br><br><a href="#">reset</a>   |
| <b>Gram stain collection date</b>  | <br><br><br><input type="text"/><br> Today D-M-Y         |
| <b>Vaginal Swabs for microbiota</b><br><i>* must provide value</i><br><input checked="" type="radio"/> Collected<br><input type="radio"/> Not Collected            | <br><br><br><br><br><a href="#">reset</a>   |
| <b>Vaginal swab collection date</b>  | <br><br><br><input type="text"/><br> Today D-M-Y |

## Visit Summary CRF (Enrollment)

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 V2 Enroll (1st film) 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 until V9, 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

### Form Status

Complete?

Data regarding in-clinic required procedures
























## PRN Hematology and Chemistry CRF (Enrollment)

The PRN Hematology and Chemistry CRF is not required but is available if needed; guidelines are the same as for screening. There is a note indicating “ND” should be marked in each field if the lab test was not done.

| Collection Date  |   |
|--|---|
| <input type="text"/>   | Today D-M-Y   |
| <b>If any result is missing or not done, please mark "ND" in the field</b> |   |
| <b>WBC</b>   |   |
| <input type="text"/>   | X10E+09/L or 10 <sup>3</sup> cells/ $\mu$ L or 10 <sup>9</sup> /L |
| <b>Hemoglobin</b>  |   |
| <input type="text"/>   | g/dL  |
| <b>Platelets</b>   |   |
| <input type="text"/>   | x10E+09L or 10 <sup>3</sup> cells/ $\mu$ L or 10 <sup>9</sup> /L  |
| <b>AST</b>   |   |
| <input type="text"/>   | IU/L  |
| <b>ALT</b>   |   |
| <input type="text"/>   | IU/L  |
| <b>Serum Creatinine</b>  |   |
| <input type="text"/>   | Please indicate units below                                       |
| <b>Units for Serum Creatinine result</b>                                   |   |
| <input type="radio"/> mg/dL  | <input type="radio"/> umol/L                                      |
| <input type="radio"/> Not Done   |   |
| <a href="#">reset</a>  |   |

## PRN Targeted Physical Exam CRF (Enrollment)

The PRN Targeted Physical Exam is only needed if an examination is indicated during the visit. Guidelines are the same as for screening. There is a note indicating “ND” should be marked in each field if blood pressure was not done.

| Date of Exam:             |   |  |                       |                       |
|---------------------------|---|--|-----------------------|-----------------------|
| <input type="text"/>      | Today   | M-D-Y                                    |                       |                       |
| Physical exam:            |   |  |                       |                       |
|                           |   | Not evaluated                            | Normal                | Abnormal              |
| General Appearance        | <br><br>       | <input type="radio"/>                    | <input type="radio"/> | <input type="radio"/> |
|                           |   |  |                       | reset                 |
| Heart/Cardiac             | <br><br>       | <input type="radio"/>                    | <input type="radio"/> | <input type="radio"/> |
|                           |   |  |                       | reset                 |
| Lung/Respiratory          | <br><br>       | <input type="radio"/>                    | <input type="radio"/> | <input type="radio"/> |
|                           |   |  |                       | reset                 |
| Abdomen                   | <br><br> | <input type="radio"/>                    | <input type="radio"/> | <input type="radio"/> |
|                           |   |  |                       | reset                 |
| Other                     | <br><br> | <input type="radio"/>                    | <input type="radio"/> | <input type="radio"/> |
|                           |   |  |                       | reset                 |
| Vital Signs               |   |  |                       |                       |
| Blood Pressure: Systolic  | <br><br> | <input type="text"/>                     |                       |                       |
|                           |   | Mark "ND" if blood pressure was Not Done |                       |                       |
| Blood Pressure: Diastolic | <br><br> | <input type="text"/>                     |                       |                       |
|                           |   | Mark "ND" if blood pressure was Not Done |                       |                       |
| Notes/Comments            |   |  |                       |                       |
| <input type="text"/>      |   |  |                       |                       |

**Refer to SBR CCGs for Socio-behavioral CRFs linked to Enrollment and subsequent visits**

## 24 -72 hour phone contact CRFs (V3 and V7)

V3 (and V7) are very short contacts by telephone or SMS messaging. The 24-72 hour phone contact includes the “Brief Acceptability (FU2) form” (included with the Behavioral CRF Completion Guidelines) and the Visit Summary CRF (shown on page 24 of this document).

If the contact is missed, the PRN Missed Visit CRF is to be completed instead.

## PRN Missed Visit CRF (first available at V3, but applicable for Visits 3 thru 10)

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.


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

**Mark the box below, confirming the visit has been missed**

\* must provide value

The Participant has missed V3 (24-72 hr phone contact)

**Date documenting the missed visit in REDCap**

 Today D-M-Y

**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

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

**A note about all phone contacts:**

The Brief Acceptability (FU2) Form begins with a place to enter the date of the phone contact (shown below). This is the variable used to determine if the contact happened and was within the appropriate visit window. Leaving this variable blank will result in the visit showing up on a missed visit report. If transcribing the date from a paper CRF into REDCap, be sure you are capturing the date the contact occurred.

Date of Brief Acceptability contact  
\* must provide value

Today D-M-Y  
If date is missing, visit will show on reports as missed














**Week 1, Week 2, and Week 6 Phone Contact CRFs (V4, V5 and V8)**

These phone contacts include the “Brief Acceptability (FU2) form” designed by D2D (included with the Behavioral CRF Completion Guidelines), the Updated Medical and Menstrual History CRF (shown next on page 29 for visits after enrollment), and the Visit Summary CRF (shown on page 24 of this document).










If the contact is missed, the PRN Missed Visit CRF is to be completed instead (reference page 27)

## Updated Medical and Menstrual History CRF (as viewed in REDCap after Enrollment for visits: V4, V5, V6, V8, V9\* and V10).

Note: V9 includes additional social impact assessment questions (see page 31 of this document.)

|   |   |
|---|---|
| <b>Date of assessment</b><br><small>* must provide value</small><br><input type="text"/>  Today D-M-Y  | <br>                               |
| <b>Have there been any changes to your medical history since your last visit/contact?</b><br><small>* must provide value</small><br><input type="radio"/> Yes<br><input type="radio"/> No<br><br><a href="#">Update Pre-existing Conditions Log as needed</a>   | <br> <br><br><a href="#">reset</a> |
| <b>Have there been any changes to your concomitant medications since your last visit/contact? (Including any changes with oral, vaginal, herbal, other-the-counter or prescription medications)</b><br><small>* must provide value</small><br><input type="radio"/> Yes<br><input type="radio"/> No<br><br><a href="#">Update Concomitant Medications Log as needed</a> | <br> <br><br><a href="#">reset</a> |
| <b>Notes related to updated medical history</b><br><div style="border: 1px solid #ccc; height: 40px; width: 100%;"></div>   | <br>                               |

The following section appears on the eCRF anytime it is utilized after the enrollment visit. The rest of the CRF follows the same outline as previously shown for Enrollment (reference pages 21-22).

|  |   |
|--|---|
| <b><i>The following three protocol adherence questions are only visible in REDCap after Visit 2 Enrollment</i></b>   |   |
| <b>Have you used PrEP or PEP since study enrollment?</b><br><small>* must provide value</small><br><input type="radio"/> Yes<br><input type="radio"/> No<br><br><a href="#">If yes, discontinue per protocol</a>   | <br> <br><br><a href="#">reset</a> |
| <b>Have you used any non-therapeutic injection drugs since study enrollment?</b><br><small>* must provide value</small><br><input type="radio"/> Yes<br><input type="radio"/> No<br><br><a href="#">If yes, discontinue per protocol</a>   | <br> <br><br><a href="#">reset</a> |
| <b>Are you participating in any other studies (includes studies involving drugs, medical devices, vaginal products or vaccines).</b><br><small>* must provide value</small><br><input type="radio"/> Yes<br><input type="radio"/> No<br><br><a href="#">If yes, complete a protocol deviation, update ConMeds as applicable, and consult with PSRT</a> | <br> <br><br><a href="#">reset</a> |

## Week 4 and Week 8 Clinic Follow-up visit CRFs (V6 and V9)

The Clinical CRFs available for use at V6 and V9 are the same as for V2 Enrollment with two exceptions:

- The Randomization CRF is not needed
- Hematology and Chemistry Results are PRN at V6, but required at V9
- Note also that the Behavioral CRFs are different for V6 and V9.

A couple of V6 and V9 CRFs include additional questions, outlined here:

### Pelvic Exam CRF (when viewed at any visit after enrollment: V6, V9 and Interim)

The Pelvic Exam CRF as viewed for V6 and V9 (and interim visits) includes a place to document a film visibility assessment prior to specimen collection. These variables are shown below:

*The following Film Assessment questions are only applicable at V6, V9 and Interim Visits requiring a pelvic exam*

**Is the film visible?**

\* must provide value

Yes  
 No  
 Unsure

**Was film removed prior to specimen collection?**

\* must provide value

Yes  
 No  
 Unsure

**Narrative related to film visibility and removal**

Expand

The Pelvic Exam CRF then proceeds in the same manner as when used at V2 Enrollment.

## Updated Medical and Menstrual History CRF (as viewed for V9)

The Updated Medical and Menstrual History CRF includes an additional prompt. The CRF begins with questions that are the same as previously used:

**Date of assessment** (H) (M)

*\* must provide value*

31 Today D-M-Y

**Have there been any changes to your medical history since your last visit/contact?** (H) (M)

*\* must provide value*

Yes

No

[reset](#)

[Update Pre-existing Conditions Log as needed](#)

**Have there been any changes to your concomitant medications since your last visit/contact? (Including any changes with oral, vaginal, herbal, other-the-counter or prescription medications)** (H) (M)

*\* must provide value*

Yes

No

[reset](#)

[Update Concomitant Medications Log as needed](#)

**Notes related to updated medical history** (H) (M)

The following section regarding social impacts is only available for V9:

*The following two Social Impact questions are only visible in REDCap at Visit 9* (H) (M)

**Have you experienced a negative change, event, or experience in your life related to your study participation?** (H) (M)

*\* must provide value*

Yes

No

[reset](#)

[If yes, complete an entry on the Social Harms and Benefits Assessment Log](#)

**Have you experienced a positive change, event, or experience in your life related to your study participation?** (H) (M)

*\* must provide value*

Yes

No

[reset](#)


[If yes, complete an entry on the Social Harms and Benefits Assessment Log](#)

Note that a social impact may be reported at ANY visit during the study, and should be documented on the Social Harms and Benefits Assessment Log found in the Ongoing Logs Folder on the REDCap Dashboard (Ongoing Logs CCG, next page), however the participants are only asked if they've experienced a social impact at the 8 week Clinic visit (V9).

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

|   |   |
|---|---|
| <b>Form Status</b>  |   |
| <b>Complete?</b>  | <input type="text" value="Incomplete"/> |
| <input type="button" value="Save &amp; Exit Form"/> <input type="button" value="Save &amp; Go To Next Form"/> |   |



## 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.

| Event: <b>Ongoing Logs</b>  |   |
|---|---|
| PTID  | 2006  |
| 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: <input type="text"/> Today D-M-Y   |   |
| <b>Description of condition:</b><br><input type="text"/>  | <b>Start date of condition:</b><br><input type="text"/>             |
| <b>Medications taken for this condition:</b><br><input type="text"/>  | <b>Other treatments for this condition:</b><br><input type="text"/> |
| <b>Severity grade:</b><br><input type="radio"/> Grade 1 - mild<br><input type="radio"/> Grade 2 - moderate<br><input type="radio"/> Grade 3 - severe<br><input type="radio"/> Grade 4 - potentially life-threatening<br><input type="radio"/> Not gradable<br><a href="#">reset</a> |   |
| <b>Is condition ongoing at enrollment?</b><br><input type="radio"/> Yes<br><input type="radio"/> No<br><a href="#">reset</a>  | <b>Stop date of condition:</b><br><input type="text"/>              |
| <b>Comments:</b><br><input type="text"/><br><a href="#">Expand</a>  |   |

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   |   |
|---|---|
| <b>Complete?</b>  | <input type="text" value="Incomplete"/> |
| <input type="button" value="Save &amp; Exit Form"/> <input type="button" value="Save &amp; Go To Next Form"/> |   |

## 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 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.


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


*\* must provide value*

 Today D-M-Y

[Click the Today button](#)

**Date site was informed of AE:** H M

*\* 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:** H M

*\* must provide value*

**AE onset date:** H M

*\* must provide value*

 Today D-M-Y

**Body system:** H M

*\* 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:** H M

*\* 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  
 Visible film 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 vaginal film study product inserted?**

\* must provide value

 Today D-M-Y

**Has participant had 2nd vaginal film study product inserted?**

\* must provide value

- Yes
- No

reset

**Date participant had second vaginal film 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).



|   |
|---|
| <b>Relatedness</b>  |
| <b>Relatedness to Study Product/Procedure:</b><br><i>* must provide value</i><br><input type="radio"/> Not related<br><input type="radio"/> Related<br><span style="float: right;">reset</span>                           |
| <small>Relatedness to be determined by a study clinician</small>  |
| <b>Justification of relatedness (for both related and not related)</b><br><i>* must provide value</i><br><div style="border: 1px solid gray; height: 60px; width: 100%;"></div> <span style="float: right;">Expand</span> |
| <b>Name of Clinician determining relatedness</b><br><i>* must provide value</i><br><div style="border: 1px solid gray; height: 15px; width: 40%;"></div>  |
| 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.                     |
| <b>Comment (1):</b><br><div style="border: 1px solid gray; height: 60px; width: 100%;"></div> <span style="float: right;">Expand</span>   |
| <b>Comment (2):</b><br><div style="border: 1px solid gray; height: 60px; width: 100%;"></div> <span style="float: right;">Expand</span>   |
| <b>Comment (3):</b><br><div style="border: 1px solid gray; height: 60px; width: 100%;"></div> <span style="float: right;">Expand</span>   |
| <b>Comment (4):</b><br><div style="border: 1px solid gray; height: 60px; width: 100%;"></div>   |



## Social Harms and Benefits Assessment Log (Ongoing Logs)

### Social Harms and Benefits Assessment Log

Data Access Group: [No Assignment] 

|   |   |
|---|---|
|  Editing existing PTID <b>PTID-XXX</b> . (Instance #1) |   |
| Event: <b>Ongoing Logs</b>  |   |
| PTID  | PTID-XXX  |
| <b>Document each social harm or benefit as its own entry</b>  |   |
| <b>Date documenting Social Harm or Benefit</b>  |   |
| <input type="text"/>  |  Today D-M-Y |
| <b>Social impact type</b>   |   |
| <input type="radio"/> Social Harm<br><input type="radio"/> 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 10 (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.





#### Participant Disposition




Data Access Group: X - MATRIX-002 TRAINING GROUP 

 Editing existing PTID **1001-TRAIN**.

Event: **Product Hold/Discontinuation**




**PTID** 1001-TRAIN

**Date of study exit**     
  Today D-M-Y

**Primary reason for completion/discontinuation**   




- 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](#)

**Document additional relevant details**     

[Expand](#)

**Form Status**

**Complete?**    

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.

**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](#)

**Is this participant evaluable?** H M

- Yes
- No

[reset](#)

Per protocol, "evaluable" is defined as having completed V6

If “Participant did not meet all eligibility criteria” OR “Participant did not enroll within 45 days of screening” are marked, you are asked to confirm the PTID as a screen failure:

**For reporting purposes, please confirm that PTID is a screen failure ( "screen-out").** H M

- Yes, PTID is a Screen failure

[reset](#)

If this is not accurate, revise the primary reason for study discontinuation above

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** H M

In each case, the question “Is the participant evaluable?” will appear. As indicated in the footnote of the question, per protocol, evaluable is defined as having completed V6. This question is only skipped (not shown in REDCap) if the participant did not enroll.

**Is this participant evaluable?** H  
M

Yes  
 No

Per protocol, "evaluable" is defined as having completed V6 reset

**Document additional relevant details** H  
M

[Expand](#)

For Screen Failures (“Screen-outs”), the eCRF will ask which eligibility criteria prevented the PTID from enrolling (both Inclusion criteria and Exclusion criteria can be marked). Additional questions then populate for more specific information.

**Which eligibility criteria prevented the participant from enrolling?** H  
M

Inclusion criteria  
 Exclusion criteria

Mark all that apply

**Mark the primary reason the participant did not meet the inclusion criteria** H  
M

\* 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/willing 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

Based on Protocol v1.0 dated 24MAY2023 reset

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

## 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.

|  |  |   |
|--|--|---|
| <b>Date of Product Hold/Discontinuation</b>                  | <input type="text"/>  <input type="button" value="Today"/> <span style="margin-left: 10px;">D-M-Y</span>  |       |
| <b>Why is study product being held/discontinued?</b>         | <input type="radio"/> Investigator decision<br><input type="radio"/> Reactive HIV test<br><input type="radio"/> Pregnancy or breastfeeding<br><input type="radio"/> Allergic reaction to study product<br><input type="radio"/> Grade 3 Related or Grade 4 AE<br><input type="radio"/> Use of or need for PrEP or PEP<br><input type="radio"/> Use of Non-therapeutic drugs<br><input checked="" type="radio"/> Other, specify |       |
| <b>Other reason product is being held/discontinued</b>       | <input type="text"/>   |       |
| <b>Date study product last inserted</b>                      | <input type="text"/>  <input type="button" value="Today"/> <span style="margin-left: 10px;">D-M-Y</span>  |     |
| <b>Was PSRT Query form completed?</b>                        | <input type="radio"/> Yes<br><input type="radio"/> No<br><input type="radio"/> N/A   |   |
| <small>Only required for IoR initiated product holds</small> |  | <a href="#">reset</a>   |
| <b>Was study product resumed?</b>                            | <input checked="" type="radio"/> Yes<br><input type="radio"/> No   |   |
| <b>Date the participant resumed study product use?</b>       | <input type="text"/>  <input type="button" value="Today"/> <span style="margin-left: 10px;">D-M-Y</span>  |   |

## 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:

**Was an HIV-1/2 Confirmatory Test collected?** H M

Yes  
 No

[reset](#)

---

**HIV-1/2 Confirmatory Test name** H M

---

**HIV-1/2 Confirmatory Test date** H M

Today D-M-Y

---

**HIV-1/2 Confirmatory Test result** H M

HIV Negative  
 HIV-1 Indeterminate  
 HIV-2 Indeterminate  
 HIV-1 Positive  
 HIV-2 Positive  
 HIV-2 Positive with HIV-1 cross-reactivity  
 HIV Positive undifferentiated (un-typeable)

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

**Was plasma for confirmatory testing collected?** H M

Yes  
 No

[reset](#)

---

**Was plasma stored for HIV Confirmatory testing?** H M

Stored  
 Not stored

[reset](#)

---

**Plasma for confirmatory testing collection date** H M

Today D-M-Y




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.

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

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 V10):

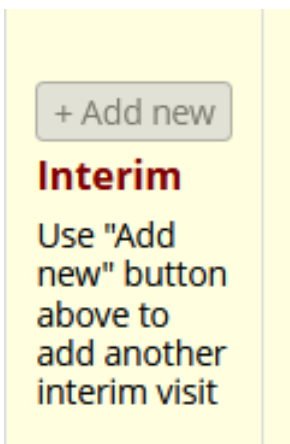


PTID 1001-TRAIN  
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| Data Collection Instrument | V1<br>Screen<br>SCR start | V2<br>Enroll<br>(1st film)<br>Rand date | V3<br>(24-72 hr phone contact) | V4 (wk 1 phone contact) | V5 (wk 2 phone contact) | V6<br>(wk 4 clinic f/u, 2nd film)<br>V6 date | V7<br>(24-72 hr phone contact) | V8 (wk 6 phone contact) | V9<br>(wk 8 clinic f/u)<br>V9 date | V10 (wk 9 final phone contact) | + Add new | Interim<br>Use "Add new" button above to add another interim visit | Ongoing Logs<br>Complete as needed | 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.

| <b>Interim</b><br>Use "Add new" button above to add another interim visit (#1)      | Use "Add new" button above to add another interim visit (#2)                        | <br>(#3) |
|---|---|---|
|   |   |   |
|   |   |   |
|   |   |   |
|   |   |   |
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|   |   |   |
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|  |  |        |
|  |  |        |
|  |  |        |

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.