CRF Completion Guidelines (CCGs)

Protocol #: MTN-034

Version 5.0 (July 22nd, 2020)

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Completion Guidelines for Standard CRFs

The following instructions are study-specific data completion instructions intended to assist site staff when completing Case Report Forms (CRFs) (referred to as 'forms' throughout this document) for MTN-034. Detailed guidance on general data collection, entry, navigation and general use of Medidata Rave is provided in the Medidata Rave Electronic Data Capture (EDC) Training Manual, which is posted on the MTN-034 Atlas web page: https://atlas.scharp.org/cpas/project/MTN/034/begin.view?.

General Guidelines – Medidata Rave Forms

- All data entered onto each study form should correspond accurately with source documentation.
- Complete all required fields on the screens. Ensure all entries are in English and are accurate, consistent, complete and medically logical.
- Ensure there are no missing data on the form. Where requested to 'specify' for an item, ensure that a specific entry is made.
- Avoid using abbreviations and symbols wherever possible. Do not use special characters unless explicitly stated or hit the Return key in text fields.
- Log (or repeating) forms have been provided. Log forms allow you to enter multiple items on one form, and to switch between portrait and log formats for ease of viewing or data entry. The following are log forms or have the log format within the form for this study: Adverse Events, Concomitant Medications, Protocol Deviations, Social Impact, Social Benefit, Pregnancy Outcome, Medical History, Eligibility Criteria, Product Hold, and Family Planning.

Add Event

- The **Add Event** drop-down menu can add select forms and visits to a participant's casebook.

- The following folders can be added to a participant's casebook:
  - Interim Visits (see section on "Interim Visits" on how to add interim visits to a participant's casebook.
  - Pregnancy (includes the Pregnancy Report and Pregnancy Outcome Log) Pregnancy History (includes the Pregnancy History CRF)
- The STI Test Results CRF can be added, if needed, at the Enrollment by selecting the form from the Add Event drop-down menu.

Interim Visits

- Should unscheduled assessments be required for a non-routine visit or procedure, add the visit by clicking on the **Add Event** button. Select "Interim Visit". An Interim Visit folder will appear in the participant's casebook.

- Open the Interim Visit folder to access the "Interim Visit Summary" form. On the Interim Visit Summary form, select "Yes" for each assessment that was performed. The selected forms will be populated automatically within the applicable Interim Visit folder.

- On the Interim Visit Summary form, enter the visit date as the earliest date visit procedures performed at the visit began.

Auto-population of Medidata Rave Forms

- Medidata Rave will dynamically add forms to a visit folder within a participant's casebook based on specified responses on the forms. Below are a few examples:

  - Example 1: Follow up Visit Summary Form
    - If item "Was this visit completed" is marked 'no', the Missed Visit form will be added to the visit folder and required forms for that visit will not appear in the visit folder.
    - Selecting 'Yes' for various study procedures completed at this visit will dynamically add the applicable forms to the visit folder.

  - Example 2: Adverse Events Summary form
    - Selecting 'Yes' for "Has the participant experienced any adverse events (AEs)?" will dynamically add the Adverse Events Log form to the Ongoing Logs folder.

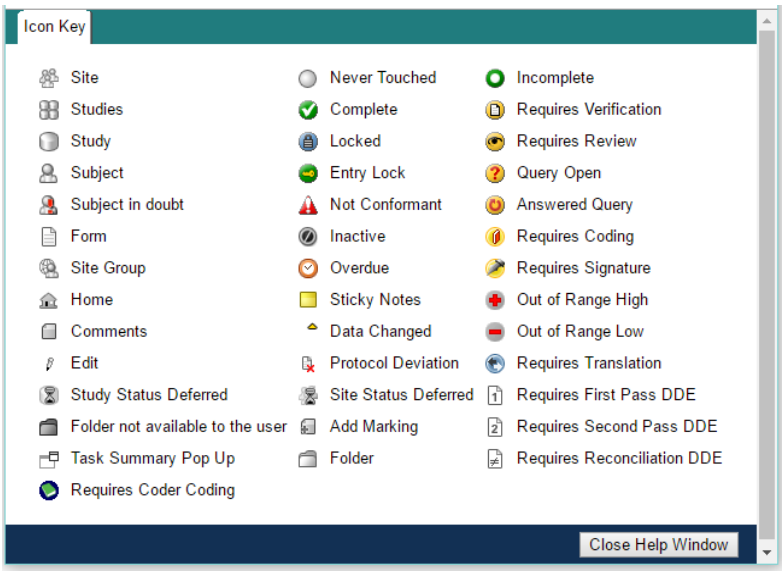
Dynamic Search List Functionality

- Dynamic searchlist functionality is used to look up Adverse Events data *(AE log line, start date, and term, e.g. "05JAN2018-FEVER")*.
- Dynamic searchlist functionality is present on the following forms: Concomitant Medications, Local Laboratory Results, Pelvic Exam, Product Hold, Product Discontinuation, and Study Termination
- For Example:
  - An AE of '*FEVER*' started on 05JAN2018 and is reported on the Adverse Events form
  - On the Concomitant Medications form, if a listed medication was used for this AE, a dynamic searchlist can be used to select the applicable AE record from the dropdown list.
  - The dynamic search list for 'AE log line, start date, and term' shows records entered on the AE form
  - Your selection can be manually deleted if entered in error
    - **Note:** If the original data (e.g., AE term and/or start date, MH term) changed or the log line was inactivated, the previous selection becomes non-conformant. You will need to correct the item by re-selecting from the search list to correspond with the latest data.

Icon Key

Within Rave, an Icon Key is available. The key contains a description and picture of the commonly used icons. To access the Icon Key, click on the Icon Key hyperlink. The Icon Key will open in a separate pop-up window. Below is a screen shot of the Icon Key.

Figure 1. Icon Key

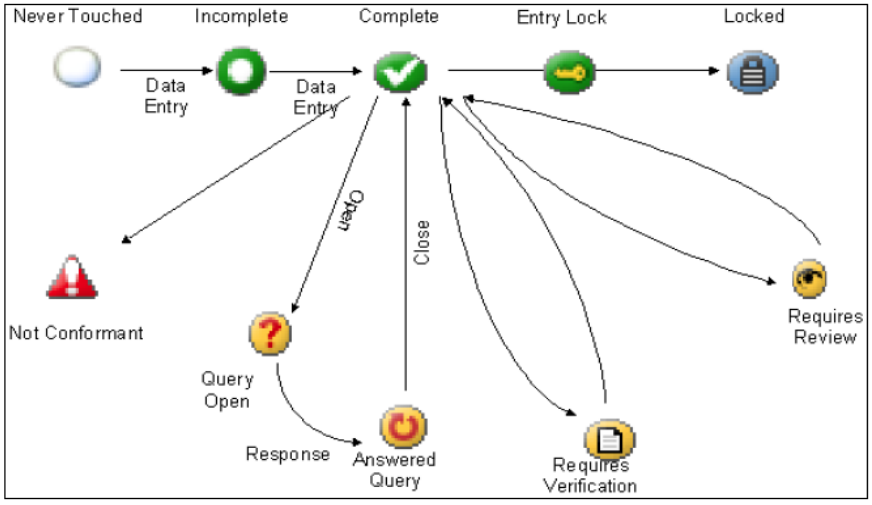


Icon Progressions

The life cycle of folders, forms, fields, etc., follows a logical progression starting with never touched and moving toward complete and locked. Graphical icons are used throughout Rave to visually denote status.

The following figure illustrates the status represented by each icon, and the progression of icons through the life cycle.

Figure 2. Icon Progression



Task Summary

- The Task Summary Listing displays all pending tasks for a study. At the Site level, it displays the number of participants within the site that contain the selected item (see Figure 3). For example, 8 participants within the site have open queries. If the “Open Queries task is expanded, the 8 participants are displayed (see Figure 4).

Figure 3. Site-Level Task Summary

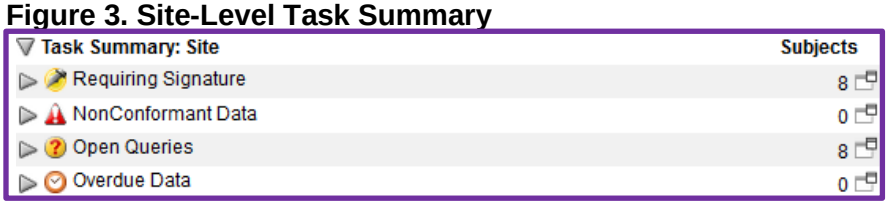
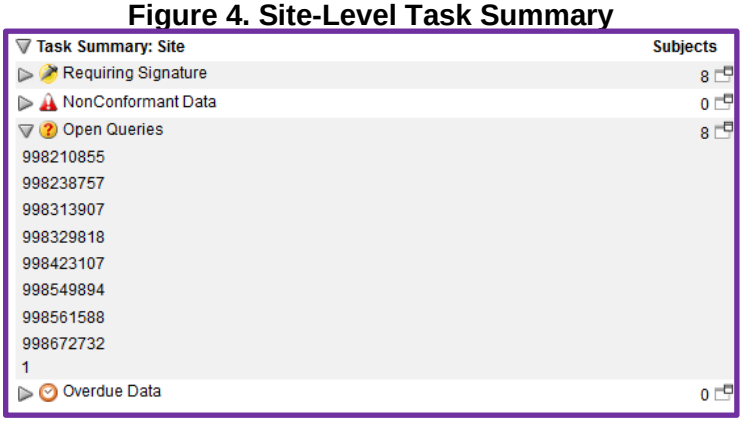
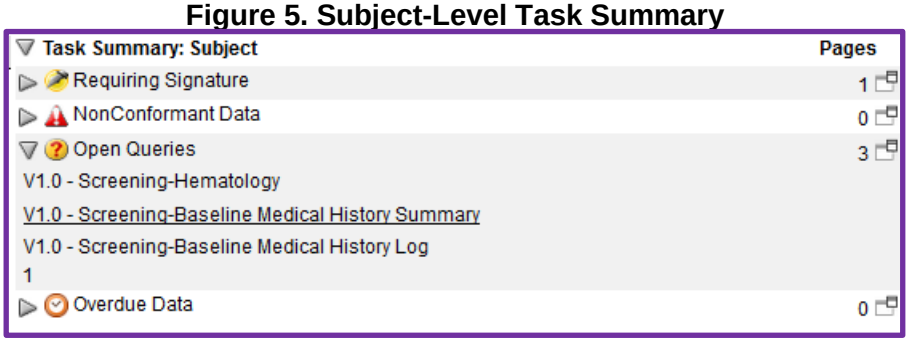


Figure 4. Site-Level Task Summary



- At the Subject (participant) level, the Task Summary displays the number of pages/forms for the participant that contain the selected item. In Figure 5 below, there are 3 open queries on 3 forms. In the expanded task summary view, if a form name is clicked that form is displayed.

Figure 5. Subject-Level Task Summary



General Guidelines – Paper CRF Completion

When completing a paper form, refer to detailed instructions on data collection pertaining to the specific form and fields on that form in this document.

Based on Good Clinical Practices (GCPs), the following guidelines should be used for completing paper forms:

- Use a black or dark blue medium ballpoint pen. Do not use any other type of writing tool.
- Press firmly when recording data or writing comments.
- Print all data and comments legibly by hand. Entries that cannot be read may result in incorrect data entry.
- Do not use cursive/script handwriting, as it can be difficult to read.
- Write numbers as large as possible on the line specified.

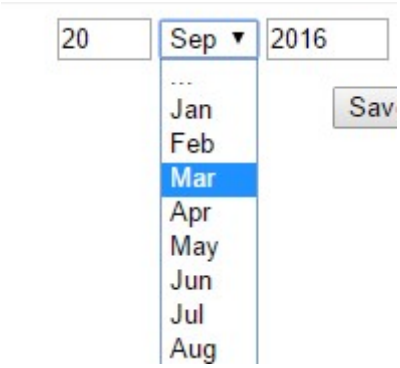
- Record data on the front of forms only.
- If the lines provided for written responses are not long enough, continue in another blank area of the form (within the page margins).
- Mark only one answer except when given the instruction “Mark/Select all that apply.”
- A response is required for every item unless instructed otherwise by a skip pattern, as noted in the CCGs.
- **Never** use correction fluid (“white-out”) or correction tape on forms.

How to Record Dates - Electronic and/or Paper

Dates are entered using the “dd MMM yyyy” format, where “dd” represents the two-digit day, “MMM” represents the three-letter abbreviation of the month (in capital letters), and “yyyy” represents the four digits of the year.
The month field must be entered with the three-letter abbreviation in English. Abbreviations are shown below. In the study database, these abbreviations will be selected from a drop-down list in the month field.

Month	Abbreviation	Month	Abbreviation
January	**JAN**	July	**JUL**
February	**FEB**	August	**AUG**
March	**MAR**	September	**SEP**
April	**APR**	October	**OCT**
May	**MAY**	November	**NOV**
June	**JUN**	December	**DEC**
Unknown	**UNK**		

For example, September 20, 2016 is recorded as:



Some items allow for partial dates. When recording partial dates, the following guidance applies:

- Enter UN for the day
- Select “UNK” for the month from the drop-down menu.

How to Record Time - Electronic and/or Paper

Time is recorded on forms using the 24-hour clock (00:00-23:59), in which hours are designated from 0–23. For example, in the 24-hour clock 2:25 p.m. translates to 14:25 (2 p.m. = 14), which would be recorded as follows:

14 25 24-hour clock

Midnight is recorded as 00:00, not 24:00.

The following chart shows equivalencies between the 12- and 24-hour clocks:

12-hour clock (a.m.)	24-hour clock	12-hour clock (p.m.)	24-hour clock
Midnight	00:00	**Noon**	12:00
1:00 a.m.	01:00	**1:00 p.m.**	13:00
2:00 a.m.	02:00	**2:00 p.m.**	14:00
3:00 a.m.	03:00	**3:00 p.m.**	15:00
4:00 a.m.	04:00	**4:00 p.m.**	16:00
5:00 a.m.	05:00	**5:00 p.m.**	17:00
6:00 a.m.	06:00	**6:00 p.m.**	18:00
7:00 a.m.	07:00	**7:00 p.m.**	19:00
8:00 a.m.	08:00	**8:00 p.m.**	20:00
9:00 a.m.	09:00	**9:00 p.m.**	21:00
10:00 a.m.	10:00	**10:00 p.m.**	22:00
11:00 a.m.	11:00	**11:00 p.m.**	23:00

How to Record Numbers (non-dates)

When recording numbers, please enter the whole number without leading zeros. Instead of '00', this should be recorded as '0'. 3 should be recorded as 3, not '03' and so on.

Data Corrections and Additions - Electronic and/or Paper

Sometimes, data on a form (paper or electronic) may need to be changed, clarified, or amended. There are many reasons why data may need to be changed, such as in response to a query or as a result of site review.

If the electronic form is source, it is sufficient to make data updates in the study database itself. If a paper form is completed, it is important to make changes to the original form first, then enter the updated data into the study database.

Note for paper forms: Never write over an entry once it is recorded. Use the standards outlined in the following paragraphs when changing, clarifying, or amending data.

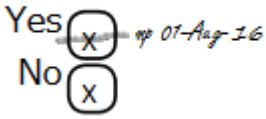
Whenever an entry on a paper form is changed, do the following:

- draw a single horizontal line through the incorrect entry (do not obscure the entry or make it un-readable with multiple cross-outs),
- place the correct or clarified answer near the box, and

If an **X** is marked in the wrong response box, correct it by doing the following:

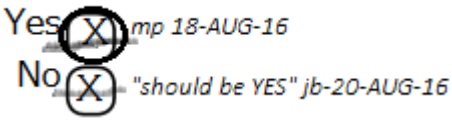
- draw a single horizontal line through the incorrectly marked box,
- mark the correct box, and

- initial and date the correction as shown below:



If the correct answer has previously been crossed out, do the following:

- circle the correct item,
- write an explanation in the white space near the item, and
- initial and date all corrections as shown below:



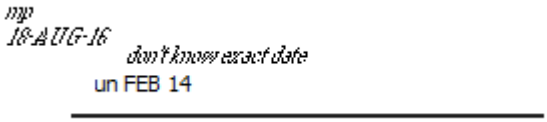
The standards above must ***always*** be followed whenever a paper form is changed, clarified, or amended.

How to Handle Missing and Unknown Data

If the answer to an item is not known, is not available, or if the participant refuses to answer for a required item:

- On paper forms: draw a single horizontal line through the applicable item and initial and date the item for which the data is unknown. It is helpful to write “don’t know,” “refuses to answer,” “UNK” (unknown), “N/A” (not applicable), or “REF” (refused) near the fields.

  For example, when recording a date, if the exact day is not known, write “un” to designate the “dd” (or date) and write “don’t know” next to the response, as shown below. Initials and date are required for any data item that is refused, missing, unknown, or not applicable, regardless of whether it is marked as such during the initial paper form completion, or as an update to the form.



- On electronic forms: enter “UN” or select the “UNK” option from the drop-down list of the applicable field for which the data is missing/unknown.

A skip pattern, as noted in the CCGs, is the **only** valid reason to leave a response blank.

ACASI Summary

Purpose:
This form is used to document participant completion of the (Audio) Computer-assisted Self Interview (A/CASI) questionnaires at Enrollment and during follow-up.
.

General Instructions:
Complete this form at Enrollment, quarterly visits, and Visit 23/PUEV.

Field	Instructions
Was an ACASI questionnaire completed at this visit?	Select 'Yes' or 'No' to indicate whether an ACASI or CASI questionnaire was completed at this visit. If 'Yes' is selected, the "ACASI Tracking" form appears dynamically for completion. If an ACASI questionnaire was completed by a participant, this item should be marked 'Yes' regardless of whether the questionnaire was eventually uploaded to SCHARP. If 'No' is selected, then record the reason why it was not done in the text field below. An "ACASI Tracking" form does not need to be completed.
If no, please explain:	Record the reason why an ACASI questionnaire was not completed in the text field.

ACASI Tracking

Purpose:
This form is used to document participant completion of the (Audio) Computer-assisted Self Interview ((A)CASI) questionnaires at Enrollment and during follow-up.
.

General Instructions:
Selecting 'Yes' on the ACASI Tracking Summary form will open up the ACASI Tracking form. Complete this form at Enrollment, Months 6, 9, 13, 16, 20, 23, and at the participant's Product Use End Visits (PUEV) or early termination visit.

Additionally, complete this form (and the Early PUEV/Discontinuers questionnaire) if the participant is permanently discontinued from both study products prior to the scheduled PUEV (as documented by the Product Discontinuation log). Complete this form for participants who become pregnant at the same visit as the positive pregnancy test. For participants who become infected with HIV, complete this form at the visit immediately following confirmation of HIV infection.

Field	Instructions
Were there any problems or issues related to the	Reasons to mark "Yes" include technical errors occurring during the administration, storing, or uploading of an ACASI questionnaire; multiple ACASI questionnaires being completed at a single visit; the

administration or completion of the questionnaire?	incorrect ACASI questionnaire being completed at a visit; incomplete ACASI questionnaire uploaded; question without appropriate response option.
If yes, please describe:	Describe the problem or issue that occurred in this field

Adherence Counseling

Purpose: To document Dapivirine and FTC/DPV drug levels available for the participant during each adherence counseling session, adherence counseling topics discussed, and barriers or challenges explored during the session.

General Instructions:
Complete this form at Enrollment and all follow-up scheduled study visits through PUEV.
Complete this form at any interim visit at which where adherence counseling is done.
This form should be completed immediately following the counseling session (rather than during the session) whenever possible.

Item-specific Instructions:

Field	Instructions
Visit of counseling session	Select the visit code of the visit at which the counseling session is completed. If the counseling session was complete at an interim, select "interim visit" and specify the interim visit code in the space provided.
Is the participant currently using the ring or tablets?	Indicate the study product that the participant was randomized to receive at that visit. The intent of this question is to indicate the study product that the participant was assigned to and was provided at each study visit. The response "Neither" should only be marked if the participant chooses to not use product or if the participant has been placed on clinical product hold.
Are drug levels available for counseling?	Indicate whether Dapivirine or FTC/DPV are available for the testing lab. If new results are not available, skip to the instruction, "Indicate which topics were covered during the session. Mark all that apply." Lab results are expected to be available at Visits 5, 8, 12, 15, 19, and 22.

Field	Instructions
Which drug levels are available?	If drug levels are available, mark the appropriate drug level that is available, and complete the following: 'Date specimen collected', 'What is the drug level concentration', 'Drug Level Unit', and 'For counseling, which category does the drug level correspond to'. If there is more than one drug level available, add another log line by clicking on "Add a new log line" which will create another log line to enter the next drug level available. If the "Drug Level Unit" is BLQ (below the level of quantification), "What is the drug level concentration?" would be expected to be entered as '16.6'.
Indicate which topics were covered during the session. Mark all that apply	At least one item needs to have a response. If "Other", then specify relevant details in the "If, Other, specify" text field provided.
Indicate which barriers/challenges were explored during this session: *Mark all that apply or "None could be identified".*	Only mark barriers/challenges that were identified by the participant during this session. If "None could be identified" all other responses should be left blank. If "Other", then specify relevant details in the "If, Other, specify" text field provided. Refer to MTN-034 SSP section 10 for additional guidance.
Indicate which adherence strategies/facilitators were chosen during this session: *Mark all that apply or "None could be identified".*	Mark all the adherence strategies or facilitators that were identified by the participant during this session. If "None could be identified" all other responses should be left blank. For example, mark 'carrying case' if the participant identifies this strategy to overcome a barrier. If "Other", then specify relevant details in the "If, Other, specify" text field provided. Refer to MTN-034 SSP section 10 for additional guidance.

Additional Study Procedures

Purpose:

This form is used to identify additional 'as-needed' study procedures conducted during study visit and to add the applicable forms to the participant's visit folder for completion.

General Instructions:

Select the applicable procedures that were completed at the study visit. The applicable form(s) will be added to the participant's visit folder. For example, if a pelvic exam is performed as

indicated, select the checkbox for “Pelvic Exam?”. Additional procedures that were not completed at this visit can be left blank.

Note: The Tablet Assessment form and the Ring Assessment form will **not** be added via the Additional Study Procedures form. These will be added via the Ring Insertion and Removal form or the PrEP provisions and return form at each applicable visit.

You will also use this CRF to populate the **COVID-19 Behavioral Assessment CRF** by marking “COVID-19 Behavioral Assessment” in the list of CRFs on this form, which will then populate the COVID-19 Behavioral Assessment CRF into the appropriate visit folder for completion.

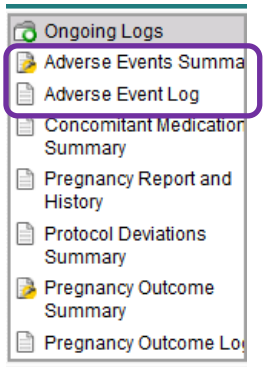
Adverse Events Summary

Purpose:
This form documents if an adverse event was experienced by the participant during the study.

General Instructions:
This form is located within the “Ongoing Logs” folder.

Item-specific Instructions:

Field	Instructions
Has the participant experienced any adverse events (AEs)?	Select ‘Yes’ or ‘No’. Within the “Ongoing Logs” folder, if ‘Yes’ is selected, then the “Adverse Event” log form appears dynamically and can then be completed. Complete as many Adverse Event forms as needed.



Adverse Event Log

Purpose:
To document any Adverse Event (AE) reported by the participant or clinically observed as defined by the protocol.

General Instructions:

Complete a separate entry (e.g., a new log line) for each adverse event when entering into the study database. Use the "Add a new Log line" button to add an additional adverse event in Medidata Rave.

Whenever possible, report a diagnosis instead of listing a cluster of symptoms. If no diagnosis is identified, each symptom must be recorded as separate AE log entries as applicable. If a cluster of symptoms reported on separate AE Log pages is later attributed to a single diagnosis, change/update the earliest reported symptom page to the diagnosis. In the study database, these other symptoms can be deleted by clicking "Inactivate" and selecting the applicable rows that should be inactivated.

Do not record a condition as an AE if it existed at enrollment as a pre-existing condition, unless it increases in severity or frequency.

Item-specific Instructions:

Field	Instructions
Date Reported to Site	Record the date the site became aware of the AE. For lab AEs, record the date the lab result was received. A complete date is required.
Adverse Event (AE)	Use medical terminology to describe the AE. Record a diagnosis if available. Include the anatomical location if applicable. Do not include text on the relationship to study product or timing of AE onset with regard to product use. For lab abnormalities, record the lab name with the direction (i.e., increased or decreased). For example, "increased ALT".
Onset Date	At a minimum, a month and year are required. Record one of the following, as appropriate: the date on which the participant reports first experiencing the AE (onset of first symptom if diagnosis has multiple associated symptoms); date of the study visit/study exam (for physical or pelvic exam findings); specimen collection date (for lab abnormality AEs).
Is the AE still ongoing?	Select 'Yes' if the AE is continuing at the time it is first reported. If 'Yes', leave the Outcome Date blank.
Outcome Date	If the AE is not ongoing, record the outcome date. For the Outcome Date, a month and year are required, at a minimum. Record one of the following, as appropriate: the date on which the participant reports no longer experiencing the AE or associated symptoms, or the date of the study visit or specimen collection at which it is first noted the AE has resolved or returned to baseline status.
Toxicity (Severity) Grade	Record the severity grade using the current version of the *Division of AIDS (DAIDS) Table for Grading the Severity of Adult and Pediatric Adverse Events* (including relevant appendices/addendums).
Relationship to Study Product	Select 'related' if there is a reasonable possibility that the AE may be related to the study agent. Select 'not related' if there is not a reasonable possibility that the AE is related to the study agent. Provide the clinical rationale (the reason) the AE is judged to be 'related' or 'not related' in the applicable Comments section/text field provided for each reported AE.

Field	Instructions
If related, which product is the AE thought to be related to?	Choose the product that the AE is thought to be related to per clinical judgement. Only one product can be chosen.
If related to the DPV vaginal ring, is the AE related to the drug (dapivirine) or the device (ring itself or ring insertion)	A response is required for this item if the AE is deemed "related" to study product and "DPV vaginal ring" is chosen. Select 'Drug (dapivirine)' if the AE is believed to be related only to the product (dapivirine) within the ring. Select 'Device (ring)' if the AE is believed to be related only to the ring OR insertion of the ring, and not related to the study product (dapivirine). Select 'Cannot distinguish between drug-device components' if it cannot be determined what component the AE can be related to. **If Oral Truvada is chosen as the related product, this item should be skipped.**
Action Taken with Study Product	***Dose not changed**:* Select if there is no change to the participant's planned use of study product as a result of the AE. This option should be marked if the participant is still in the product use period and the AE does not result in a clinician-initiated product hold or permanent discontinuation of study product. ***Dose reduced:*** This option does not apply and should not be selected in MTN-034. ***Dose increased:*** This option does not apply and should not be selected in MTN-034. ***Drug withdrawn*:** Select if the AE results in permanent discontinuation of study product. If multiple AEs are reported at the same visit, mark "drug withdrawn" for each AE contributing to the permanent discontinuation. Ensure a Product Discontinuation form is completed with item "Did the participant complete study product use through the Visit 24?" selected as 'No'. ***Drug interrupted**:* Select if the AE results in a clinician-initiated product hold. If multiple AEs are reported at the same visit, select 'drug interrupted' for each AE contributing to the hold. ***Not applicable*:** Select if the AE's onset date is on or after the date the participant permanently discontinues study product use.

Field	Instructions
Other treatment(s) taken	Select 'None' or check all that apply. *Medication*: Select 'Medication' only if the participant reports taking the medication. Report the medication(s) on the "Concomitant Medications Log" form. If medication is indicated, but not yet used, select 'Other' and describe the medication indicated in the "Other, specify" text field provided; update this item to 'Medication' once the medication has been used and report on the "Concomitant Medications Log". If "New/prolonged hospitalization", "Therapeutic procedure/surgery", or "Diagnostic procedure" is selected, then record applicable details in the Comments section at the bottom of the form. If 'Other', then specify relevant details in the "Other, specify" text field provided.
Status/Outcome	***Recovered/resolved:*** AE is no longer present, has returned to baseline severity/frequency, or has increased in severity/frequency. Note that if a participant started taking medication once enrolled to control an AE, the AE is not considered resolved while the medication is still indicated. ***Recovering/resolving****:* AE is continuing and has not yet resolved or returned to baseline severity/frequency. ***Resolved with sequelae:*** Participant has recovered from the AE, but with remaining effects or impairment. These remaining effects can be temporary, but are still present at the time of the report. ***Not recovered/resolved****:* Select this option whenever an AE is continuing at the time of participant termination from the study. ***Fatal****:* Select only if the severity grade of this AE is Grade 5. Any other AEs continuing at the time of death should be changed to "not recovered/resolved". ***Severity/frequency increased:*** If an AE increases in severity/frequency, a new AE should be reported. The original AE should be marked "Severity/frequency increased" and have an Outcome Date equal to the Onset Date of the new AE. Note that decreases in severity (AE improvements) are not recorded as new AEs.
Is this a Serious Adverse Event?	If the AE is a Serious Adverse Event (SAE), complete the subsequent SAE criteria questions. Mark all of the SAE criteria that apply. If the AE is not an SAE, skip to "Has or will this AE be reported as an EAE?".
SAE Onset Date	Provide the date the adverse event first meets ICH criteria for seriousness. A complete date is required.

Field	Instructions
Has or will this AE be reported as an EAE? If yes, EAE Number	For questions about ICH guidelines and EAE reporting, refer to the current *Manual for Expedited Reporting of Adverse Events to DAIDS.* If this AE was/is reported as an EAE (indicated as 'yes'), provide the EAE number and complete any subsequent updates to this form on the applicable EAE form.
Comments	This is a required field and is used to be document the relationship to study product.

Baseline Medical History Summary

Purpose:

To document any baseline medical history conditions/events reported at the Screening visit or recalled by the participant during follow-up.

General Instructions:

This form is present within the "Ongoing Logs" folder and is complete at the Screening Visit.

Item-specific Instructions:

Field	Instructions
Does the participant have any medical history to report?	Select 'Yes' or 'No'. If 'Yes' is marked, then the "Baseline Medical History" log form appears dynamically within the Ongoing Logs folder. Complete entries within the Baseline Medical History Log form as needed. If 'No' is selected, no further action is required. If the participant reports any baseline medical history conditions/events after the Screening visit, update the response to this field to 'Yes' and complete the Baseline Medical History Log as needed.

Baseline Medical History Log

Purpose:

This form is used to document information on the participant's baseline medical history, including but not limited to: history of hospitalizations, surgeries, allergies, any condition that required prescription or chronic medication (that is, more than 2 weeks in duration), and acute conditions ongoing at screening and/or that occur between screening and enrollment.

This form will appear in the Ongoing Logs folder after the "Baseline Medical History Summary" prompt has been answered as 'Yes'. Use the "Add a new Log line" button to add an additional baseline medical history condition/event in Medidata Rave.

General Instructions:

- At the Screening Visit, record relevant baseline medical history. This includes conditions and symptoms reported by the participant during the baseline medical/menstrual history as well as any conditions identified via pelvic exam, physical exam, or laboratory testing.
- At the Enrollment Visit, review and update as needed. Those conditions that are ongoing at the time of enrollment (including ongoing chronic conditions) are considered the participant's pre-existing conditions.
- If a medical condition increases in severity or frequency during follow-up and is captured as an AE, the medical history **should not** be updated to include an End Date.
- Do record baseline medical conditions identified during follow-up. Write a chart note to explain why the entry was added after the Enrollment Visit.
- Complete a separate entry (e.g., log line) for each baseline medical history condition/event when entering into the study database.

Item-specific Instructions:

Field	Instructions
Date medical history collected	Record the date the medical history condition/event was reported by the participant. A complete date is required.
Description of medical history condition/event	Whenever possible, provide a diagnosis instead of listing a cluster of symptoms. If no diagnosis is identified, each symptom must be recorded as a separate term. If an abnormal lab value is reported at the Enrollment visit, record the lab assay with the direction (i.e., increased or decreased) of the abnormality. For example, "decreased hematocrit" or "increased ALT". Additional information on the frequency and duration of chronic condition outbreaks can also be provided within this description.
Is condition/event gradable?	If a condition is not gradable (below Grade 1), select 'No'. Review and update as needed for conditions that are ongoing during the study. If a condition is gradable, select 'Yes' and complete the Toxicity (Severity) Grade.

Field	Instructions
Toxicity (Severity) Grade	This item is required if 'Is condition/event gradable?' is 'Yes'. Select from the options provided in the drop-down list. Review and update as needed for conditions ongoing at the Enrollment Visit. The toxicity grade reported in Baseline Medical History should reflect the status at baseline. • If the severity grade has increased or decreased in severity or frequency during the study AE reporting period, then this should be reported as an AE and the Toxicity Grade should remain unchanged on this form. However, this should be updated as needed if the severity grade and increased or decreased on or prior to the Enrollment Visit. • If the item improves severity or resolves during the study, then the Toxicity Grade should remain unchanged on this form. For each condition, grade the severity using the current version of the *Division of AIDS (DAIDS) Table for Grading the Severity of Adult and Pediatric Adverse Events* (including relevant appendices/addendums).
Date medical condition/event started	Record the date the medical condition was first diagnosed or the date the surgery/procedure was performed as applicable. If the participant is unable to recall the exact date, obtain her best estimate. At a minimum, a year is required. If the exact day is unknown, enter 'UN' for the day field. If the exact month is unknown, then select 'UNK' for the month field. For example, a partial date may be recorded as: UN-Jan-2010 or UN-UNK-2010.
Is the condition ongoing?	Select 'Yes' for chronic conditions, as well as any other conditions that are currently ongoing. During each follow-up visit, routinely follow-up on any and all ongoing conditions. If the condition resolves during follow-up, this item should not be updated. If this item is selected 'Yes', then this is the end of form and the "Date medical condition/event ended/resolved" should be left blank.

Field	Instructions
Date medical condition/event ended/resolved	A date is required if required if 'Is the condition ongoing?' is 'No'. If the exact day is unknown, enter 'UN' for the day field. If the exact month is unknown, then select 'UNK' for the month field. At a minimum, a year is required. Record the date the medical condition was considered resolved. For surgeries/procedures, record the date the surgery/procedure was completed. If the condition resolves during the study, the Baseline Medical History form should not be updated with a resolution or end date for the medical condition.

Concomitant Medications Summary

Purpose:
This form documents if any concomitant medications were reported the participant during the study.

General Instructions:
This form is located within the "Ongoing Logs" folder.

Item-specific Instructions:

Field	Instructions
Is the participant taking any concomitant medications?	Select 'Yes' or 'No'. If 'Yes' is selected, then the "Concomitant Medications" log form appears dynamically within the "Ongoing Logs" folder and complete as many Concomitant Medication forms as needed.

Concomitant Medications Log

Purpose:
This form is used to document all medications taken by the participant starting at the Screening Visit. This includes, but is not limited to: prescription medications, non-prescription (i.e., over-the-counter) medications, contraceptive hormonal medications, preventive medications and treatments (e.g., allergy shorts, flu shots, and other vaccinations), herbal preparations, vitamin supplements, and naturopathic preparations.

General Instructions:
Complete a separate entry (e.g., log line) for each reported concomitant medication when entering into the study database. Use the "Add a new Log line" button to add an additional concomitant medication in Medidata Rave.

Item-specific Instructions:

Field	Instructions
Medication Name	Record the trade or generic name of the medication based on exactly what the participant is taking. If a trade name is not available or not reportable per national guidelines, record the generic name of the medication. A combination medication can be recorded as one entry.
Indication	For health supplements, such as multivitamins, record 'general health'. For preventive medications, record 'prevention of [insert condition]" (e.g., for flu shot, record "prevention of influenza"). In most instances (excluding nutritional supplements and/or prophylactic treatments), the indication should correspond to an item on the Baseline Medical History and/or Adverse Event form(s).
Date Started	If the participant is unable to recall the exact date of medication initiation, obtain participant's best estimate. At a minimum, the year is required. For injections, record each injection as a separate entry, with the same date used for start and stop date. **Oral contraceptive birth control pills**: Record each pill pack confirmed by the participant to have been taken on a new log line. Indicate the start date as the date the first pill of the pack was taken. **Implants/IUD**: Record each implant/IUD on a new log line. The start date should be the date of implant or insertion.
Date stopped	Enter the stop date of this medication if known. At a minimum, the month and year is required. This item can be completed at any time during study participation when the stop date is known. At the participant's Study Exit/Termination Visit, the "Date Stopped" must be recorded for each medication OR the "Ongoing" box must be checked. **Oral contraceptive birth control pills**: Indicate the stop date as the date the last pill of the pack was taken. **Implants/IUD**: The stop date should be the date the implant/IUD is removed.
Taken for a reported AE?	If the concomitant medication was taken for a reported AE, select 'Yes'. The relevant AE log form must be completed to link the concomitant medication to the AE log form entered. Choose the applicable AE from the drop-down list.

Frequency	Select the frequency from options provided in the drop-down list. Below is a list of common frequency abbreviations: QD: every day BID: twice daily TID: three times daily QID: four times daily QM: once a month QH: each hour ONCE: one time Other: alternative dosing schedule or unknown If 'Other' is selected, specify in the corresponding "If other frequency, specify" text field provided. **Implants/IUD**: Indicate the frequency as "Other" and write "continuous" in the text field.
Route	Select the route from options provided in the drop-down list. If 'Other' is selected, specify in the corresponding "If other route, specify" text field provided. **Implants/IUD**: For IUD route, select "Other" and write "intrauterine" in the text field. For Implant route, select "Other' and write "sub-dermal" in the text field.
Dose	Record the dose. If the participant does not know the exact dose units (e.g., "250 mg"), record an estimate (e.g., "1 tablet"). For combination drugs, use the '/' or '-' to distinguish the different doses (i.e., hydrocodone/acetaminophen 5/500). For multivitamin tablets or liquids, record the number of tablets or liquid measurement (e.g. "1" pill or "1" tablespoon") if the exact dosage is unknown. If the dose is unknown, mark the "Unknown" checkbox provided. When documenting medical devices with no active medication, such as an IUCD, enter the dose as "1", the dose unit as "Other", and indicate "device" in the text field.

Dose Units	Select/record the applicable dose units provided in the drop-down list. If the participant does not know the exact dose units (e.g., “250 mg”), record an estimate (e.g., “1 tablet”). If no information on units is known, select the ‘Unknown’ option. When documenting medical devices with no active medication, such as an IUCD, mark the Dose Unit as ‘Other’ and specify “device” in the “If other dose units, specify” text field provided.
Taken for a reported AE?	If the concomitant medication was administered to treat a reported AE, select ‘Yes’. The relevant AE log form must be completed to link the concomitant medication to the AE log form entered. Choose the applicable AE from the drop-down list. Up to 4 AEs can be selected. If the medication was not administered to treat an AE, select ‘No’, and end the form.

COVID-19 Behavioral Assessment

Purpose:
This form is used to collect information about participants’ experiences during the COVID-19 pandemic and local measures to contain the pandemic. To understand how COVID-19-related changes may have impacted participants’ use of study product and study participation overall.

General Instructions:
Complete this form and the initial assessment as soon as possible. The form will also be administered at a second time point which will be approximately 3 months from the initial assessment. All questions and response options should be read aloud and read word-for-word unless otherwise indicated. The only text not to be read aloud is in *italics.*

Since this CRF will be administered at different time points for participants, depending on where they are at in their visit schedule, you will need to populate this CRF into the correct visit folder by choosing this CRF on the “Additional Study Procedures” CRF and/or Interim visit CRF. This will then populate it in that visit folder for completion.

Item-specific Instructions:

Field	Instructions
1. Date of assessment	Full date is required.
2. How many people do you know personally are (or have been) infected with COVID-19?	Enter a number, up to 3 digits. Only numeric characters are allowed.
6. Between getting COVID-19 and getting HIV, which is more concerning to you right now?	Interviewer may prompt participant to consider which they are most scared of (COVID-19 or HIV)

Field	Instructions
7. How has COVID-19 influenced your interest in preventing HIV?	Interviewer may prompt participant to consider whether their motivation to prevent HIV has increased or decreased since the COVID-19 pandemic started.
Questions 10a-q	For this series of questions, there is no "N/A" option. If the question is N/A, the interviewer should select "Has not changed."
10i. How often you use condoms when you have sex	The interviewer may further explain that the question refers to any change in the number of times she has used condoms when having sex.
11. Due to COVID-19, did you experience a time when you were unable to get your [Ring/Tablets] as planned, and therefore could not use it/them?	If "No" skip to item 14.
13d. I switched to other types of sex (e.g. oral/anal)	If "I switched to other types of sex (e.g. oral/anal)" is marked "Agree", specify the other types of sex in the If "Other, specify" text field provided.
14. Due to COVID-19, did you receive more than one month's supply of your [Ring/Tablets]?	If "No" skip to item 18.
19l. If "Other", specify	If "Other" is selected, then specify the adherence support that has been the most helpful in the text field space provided.
20l. If "Other", specify	If "Other" is selected, then specify the adherence support that has been missed the most in the text field space provided.

Demographics

Purpose:
This form is used to document a participant's demographics and socioeconomic information.

General Instructions:
This form is completed at the Screening Visit. Responses should reflect the participant's status at screening and should not be changed after screening unless correction is needed. Items 25 and 26 are translated and should be read aloud word for word to the participant.

Item-specific Instructions:

Field	Instructions
What is the participant's date of birth	Please provide the date of birth. At a minimum, the year is required.
Age	This field is automatically derived by Medidata Rave based on the participant's date of birth and the screening date of visit. No data entry is required.

<table>
<tr><th>Field</th><th>Instructions</th></tr>
<tr><td>What is the participant's sex at birth?</td><td>This field has been pre-selected as "Female" per protocol Inclusion Criteria. This field is locked and cannot be edited.</td></tr>
<tr><td>Ethnic group or tribe</td><td>Select one option based on participant self-report. If the participant does not identify with any of the ethnic groups or tribes listed, select 'other' and provide the name of her ethnic group or tribe in the 'If other, specify' field.
<table>
<tr><th>South Africa</th><th>Uganda</th><th>Zimbabwe</th></tr>
<tr><td>Zulu</td><td>Baganda</td><td>Shona</td></tr>
<tr><td>Xhosa</td><td>Iteso</td><td>Ndebele</td></tr>
<tr><td>Indian</td><td>Basoga</td><td>Other African Tribe</td></tr>
<tr><td>Colored</td><td>Banyankore</td><td>White</td></tr>
<tr><td>Other African Tribe</td><td>Banyaruanda</td><td>Other</td></tr>
<tr><td>White</td><td>Bakiga</td><td></td></tr>
<tr><td>Other</td><td>Lango</td><td></td></tr>
<tr><td></td><td>Bagisu</td><td></td></tr>
<tr><td></td><td>Acholi</td><td></td></tr>
<tr><td></td><td>Lugbara</td><td></td></tr>
<tr><td></td><td>Banyoro</td><td></td></tr>
<tr><td></td><td>Batoro</td><td></td></tr>
<tr><td></td><td>Karamojong</td><td></td></tr>
<tr><td></td><td>Other</td><td></td></tr>
</table></td></tr>
<tr><td>What is the participant's marital status?</td><td>If the participant is single or cohabitating, skip to item 7.</td></tr>
<tr><td>Age at first marriage</td><td>If the participant has been married more than once, enter her age when she was married the first time.</td></tr>
<tr><td>Is the participant currently attending school?</td><td>If "Yes", skip to item 10.</td></tr>
<tr><td>Has the participant ever attended school?</td><td>If "No", skip to item 13.</td></tr>
<tr><td>What age did she leave school?</td><td>Enter the age of the participant when she stopped attending school altogether.</td></tr>
<tr><td>What is the highest level of school attended?</td><td>If the participant attended or completed a post-secondary diploma or certificate program, mark/select the 'Higher (e.g., college or university') box.</td></tr>
<tr><td>What is the highest level (class/form/standard/grade/year) she completed at that level?</td><td>Enter the number indicating the highest year the participant completed within the level of schooling answered in question 10.

For example, fourth form in secondary school should be recorded as '4' year three in primary school should be recorded as '3'. Grade ten in secondary school should be recorded as '10'.</td></tr>
</table>

Field	Instructions
How many grades has she repeated?	Enter the number of times the participant has had to retake a year of schooling. If never, enter "0".
What is the participant's religion?	If "Other", then specify relevant details in the "If, Other, specify" text field provided (13a). If "No religion" is selected, skip to item 15.
What were her sources of income or other financial or material support in the past month?	Mark all that apply (16a through 16f. If "Other", then specify relevant details in the "If, Other, specify" text field provided (16f1).
How many times has the participant been pregnant?	If the participant has never been pregnant (i.e., if "0" is entered), skip to Item 20.
Specify outcome of last pregnancy	If "Other", then specify relevant details in the "If, Other, specify" text field provided (18a).
Date of last pregnancy outcome	At a minimum, the year is required.
For how many children is she the primary caregiver?	Indicate the number of biological or non-biological children for whom the participant is the primary caregiver.
Does the participant's have a mobile phone?	If "No" is selected, skip to item 24.
I am going to read aloud a list of reasons why women may choose to participate in REACH. Please tell me all of the reason(s) that apply to you. *Reach each response aloud.*	If "Other", then specify relevant details in the "If, Other, specify" text field provided (26k1).

Eligibility Criteria

Purpose:

This form is used to document participant eligibility for enrollment in MTN-034, and if applicable, type of ineligibility.

General Instructions:

Complete this form for each participant screened in MTN-034. Complete this form when it is determined whether the participant will enroll in the study. If a participant completes a second screening attempt, update this form with data from the second screening attempt (do not complete a new form).

Item-specific Instructions:

Field	Instructions
Eligibility Status	If the participant is eligible, but did not enroll in the study, select "Eligible, but participant declined enrollment" and specify the reason in the text field provided. Select "Incomplete Screening" if the participant did not complete all screening procedures.
Select reason why participant is ineligible	If the participant is not enrolled, select the applicable reason from the drop-down menu. Add a log line for each reason why the participant is ineligible.
If "Investigator decision", specify (max 200 comments)	This field is required if "E7. Has a condition that, per IoR/designee, preclude informed assent/consent, make study participation unsafe, complicate interpretation of outcome data or interfere with achieving study objectives" is selected for the reason why the participant is ineligible. A maximum 200 characters is allowable.

Enrollment

Purpose:

This form is used to document a participant's study enrollment. This form is completed at Enrollment for participants who have provided informed consent and who are eligible to participate in the study.

General Instructions:

Complete this form for each participant who is enrolled into MTN-034. This form is completed at the V2.0 – Enrollment visit.

Item-specific Instructions:

Field	Instructions
Date the participant marked or signed the study screening and enrollment consent form	A complete date is required. If a separate screening consent form and enrollment consent form are completed, indicate the date that the screening informed consent date was signed.
Did the participant and parent/guardian, if applicable, consent to long-term specimen storage and future testing?	Select 'Yes' or 'No'. Consent for long-term specimen storage can be changed if the participant and/or parent/guardian changes her consent decision after enrollment. Update as needed if the participant and/or parent/guardian changes her consent during the study.
HIV Status	Record the participant's HIV status as determined by testing performed on the day of enrollment. If 'Positive', do not enroll the participant.

Field	Instructions
Pregnancy Status	Record the participant's pregnancy status as determined by testing performed on the day of enrollment. If 'Positive', do not enroll the participant.
Has the participant received an HPV vaccination prior to enrollment?	Indicate if the participant has received an HPV vaccination prior to her study participation by selecting "Yes" to this item. If the participant receives an HPV vaccination at her Enrollment visit, select "No" and document this vaccination on the Concomitant Medications Log CRF.
Has the participant received an HBV vaccination prior to enrollment?	Indicate if the participant has received an HBV vaccination prior to her study participation by selecting "Yes" to this item. If the participant receives an HBV vaccination at her Enrollment visit, select "No" and document this vaccination on the Concomitant Medications Log CRF.
Was the participant randomized to participate in serial IDI (In Depth Interview)?	Refer to the SSP procedures to determine whether the participant has been randomized to participant in serial IDI.
Was the participant invited to participate in Serial IDI?	Indicate whether the participant was invited to participate in Serial IDI if randomized. Refer to the MTN-034 SSP for guidance. This item should be completed for all enrolled participants regardless of randomization.
Will this participant participate in serial IDIs?	Indicate whether the participant will participate in serial IDIs during REACH.

Enrollment Menstrual History

Purpose:

This form is used to document information on the participant's menstrual history since the Screening Visit.

General Instructions:

Complete this form at the V2.0 – Enrollment Visit.

Item-specific Instructions:

Field	Instructions
Date of assessment	Record the date the menstrual history was reported by the participant. A complete date is required.
Since the Screening Visit, has the participant had her menses?	Select 'Yes' or 'No'. Ideally, menses must not coincide with the 14 days of product use.
First day of last menstrual period	Record the first day of the participant's most recent menstrual period. At a minimum, the month and the year are required.

Last day of menstrual period	Enter the last day of the last menstrual period (last day of bleeding). At a minimum, the month and the year are required. If the participant is currently on her menses, check "Ongoing" and leave the last day of last menstrual period blank.
Have there been any changes to the participant's baseline menstrual bleeding pattern since her Screening Visit?	If "Yes", indicate how acceptable the new pattern is to the participant is the text field provided. If "No", end the form.

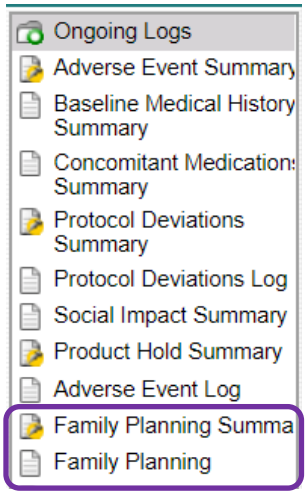
Family Planning Summary

Purpose:
This form documents if any family planning methods were used by the participant during the study.

General Instructions:
This form is located within the "Ongoing Logs" folder.

Item-specific Instructions:

Field	Instructions
Were any family planning methods used by the participant during study participation?	Select 'Yes' or 'No'. Within the "Ongoing Logs" folder, if 'Yes' is selected, then the Family Planning log form appears dynamically and can then be completed.



Family Planning Log

Purpose:
This form is used to document the methods of contraception/family planning used by the participant starting at the Enrollment Visit and during study follow-up, per participant self-report. If a participant initiates a family planning method at Screening, this method should be added to the Family Planning at her Enrollment Visit, should the participant enroll into MTN-034.

General Instructions:
This form is present within the Ongoing Logs folder and should be completed each time a participant starts or stops using a contraceptive or family planning method during the study. Only current methods should be recorded. Methods that the participant is planning to use should not be recorded on this form.

<table>
<tr><th>Field</th><th>Instructions</th></tr>
<tr><td>Date of Completion</td><td>Enter the date this form is completed whenever a method(s) of contraception/family planning is added. A complete date is required.</td></tr>
<tr><td>What method(s) of contraception/family planning is the participant currently using?</td><td>Record the method of contraception/family planning the participant reports currently using. For each specific method reported, a new form or log line will need to be completed. When adding in Medidata Rave, click the “Add a new Log line” to add an additional method of contraception/family planning and complete the form as appropriate.

Record any hormonal methods used on the Concomitant Medications Log as well using the trade name of the contraceptive if possible. (Concomitant Medications records individual methods, while the Family Planning Log records the regimen). The family planning/contraception methods are as follows:

<table>
<tr><th colspan="2">Contraceptive Methods</th></tr>
<tr><td>Spermicide</td><td>Diaphragm</td></tr>
<tr><td>Sponge</td><td>Copper IUD</td></tr>
<tr><td>Hormonal IUD (e.g., Mirena, Lilette, Skyla)</td><td>Injectable contraceptive – Depo</td></tr>
<tr><td>Oral contraceptive birth control pills</td><td>Injectable contraceptive – NET-EN</td></tr>
<tr><td>(Ortho Evra) – The Patch</td><td>Injectable contraceptive – Cyclofem</td></tr>
</table>
</td></tr>
</table>

	Implants	Injectable contraceptive – Other
	Female Condoms	Natural methods such as the withdrawal or rhythm method
	Male Condoms	Sex with partner who had vasectomy
	Sterilization (tubal ligation/hysterectomy/laparoscopy/ other surgical procedure that causes sterilization)	Emergency contraception
	Other	
If "Other", specify	If a contraceptive/family planning method is selected as 'Other', then specify the contraceptive/family planning method in the text field space provided.	
Date Regimen Started	Record the date the participant started using the current contraceptive **regimen**. At a minimum, a month and year is required. For hormonal methods, record the date that the participant started using that particular method. For example: • If a participant reports that she started using "Injectable contraceptive – Depo" every 3 months, starting in October 2017, the date regimen started is October 2012 (month and year required) and should be entered as "UN-OCT-2017". Use this as the start date even if the participant missed an occasional injection. Do not record the date of her last injection as date regimen started. • If a participant reports starting oral contraceptives on 13-MAR-2017, record this as the date regimen started (even if she missed pills or an occasional pill pack during that time). Do not record the start date of her most recent/current pill pack. • For a participant with implants inserted most recently 3 months ago, and has had implants inserted starting 3 years prior (January 2015), record "Un-JAN-2015" as the date regimen started.	
Date Regimen Stopped	If a participant has stopped a contraceptive/family planning method since her last visit, record the stop date. At a minimum, a month and year are required. If a participant has stopped a contraceptive/family planning method since her last visit, provide the reason(s) for changing or stopping the family planning method.	

	If a participant reports that she has defaulted on her family planning method, do not close out the family planning/contraceptive entry on the log form (i.e., do not enter the stop date for this method).
Ongoing	Select 'ongoing' by checking the applicable box if the participant is currently using the applicable contraceptive/family planning method. If the method is not ongoing, leave this item blank and complete the Date Regimen Stopped.
Reason(s) for changing or stopping the family planning method	For ongoing family planning methods, leave this item blank. If a participant discontinues a contraceptive/family planning method during the study and a regimen stop date has been provided, provide the reason(s) that the participant is changing or stopping the family planning method. Select all reasons that apply. If 'bleeding concerns' is selected, then specify the type(s) of vaginal bleeding. If 'medical contraindication' or 'other reason' is selected, then specify the reason in the text field space provided.

Family Planning History

Purpose:
This form is used to document the methods of contraception/family planning used by the participant prior to her study participant (i.e., prior to Screening), age of sexual debut, and age of first contraceptive used.

General Instructions:
This form should be completed one time at the Screening Visit. Only methods that were discontinued prior to the Screening Visit should be recorded (not methods that the participant is planning to use, initiates or is ongoing at Screening).

Field	Instructions
Date of Completion	Enter the date this form is completed whenever a method(s) of contraception/family planning is added. A complete date is required.

<table>
<tr><td>Age at which the participant first used a contraceptive method</td><td>Enter the age of the participant when she first used her first method of contraceptive/family planning.

If the participant initiates her first her first method of family planning at the Screening Visit, enter her age at Screening.</td></tr>
<tr><td>Did the participant use any contraceptive method(s) prior to the screening visit?</td><td>If “No”, end of form.

Any family planning/contraceptive method started at the Screening Visit should be recorded on the Family Planning Log.</td></tr>
<tr><td>Did the participant discontinue use of at least one contraceptive method prior to the screening visit?</td><td>If “No”, end of form.

If “Yes”, complete the remaining items on the log form>.</td></tr>
<tr><td>Of the family planning/contraception method(s) used prior to screening, which method(s) has the participant discontinued?</td><td>Record the method of contraception/family planning the participant has used on the past, but has discontinued prior to the Screening Visit.

For each specific method reported, a new log line will need to be completed. When adding in Medidata Rave, click the “Add a new Log line” to add an additional method of contraception/family planning and complete the log line as appropriate.

Record any hormonal methods used on the Concomitant Medications Log as well using the trade name of the contraceptive if possible. (Concomitant Medications records individual methods, while the Family Planning Log records the regimen). The family planning/contraception methods are as follows:

<table>
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<tr><td>Implants</td><td>Injectable contraceptive – Other</td></tr>
<tr><td>Female Condoms</td><td>Natural methods such as the withdrawal or rhythm method</td></tr>
</table>
</td></tr>
</table>

	<table><tr><td>Male Condoms</td><td>Sex with partner who had vasectomy</td></tr><tr><td>Sterilization (tubal ligation/hysterectomy/laparoscopy/ other surgical procedure that causes sterilization)</td><td>Emergency contraception</td></tr><tr><td>Other</td><td></td></tr></table>
If “Other”, specify	If a contraceptive/family planning method is selected as ‘other’, then specify the contraceptive/family planning method in the text field space provided.
Date Regimen Started	Record the date the participant started using the current contraceptive **regimen**. At a minimum, a month and year is required. For hormonal methods, record the date that the participant started using that particular method. For example: • If a participant reports that she started using “Injectable contraceptive – Depo” every 3 months, starting in October 2012, the date regimen started is October 2012 (month and year required) and should be entered as “Un-OCT-2012”. Use this as the start date even if the participant missed an occasional injection. Do not record the date of her last injection as date regimen started. • If a participant reports starting oral contraceptives on 13-MAR-2012, record this as the date regimen started (even if she missed pills or an occasional pill pack during that time). Do not record the start date of her most recent/current pill pack. • For a participant with implants inserted most recently 3 months ago, and has had implants inserted starting 3 years prior (January 2009), record “Un-JAN-2009” as the date regimen started.
Date Regimen Stopped	Indicate the date that the participant stopped each contraceptive/family planning method. At a minimum, a month and year are required.
Reason(s) for changing or stopping the family planning method prior to screening	Provide the reason(s) that the participant discontinued or stopped the family planning method prior to Screening. Select all reasons that apply. If ‘bleeding concerns’ is selected, then specify the type of vaginal bleeding.

	If 'medical contraindication' or 'other reason' is selected, then specify the reason in the text field space provided.

Follow-up Y/N

Purpose:
This form is documents whether a follow-up visit was completed.

General Instructions:
This form is completed for each scheduled visit and is present in each follow-up visit folder, starting at Visit 3.0 – Week 1 through Visit 24 – Week 73.

Item-specific Instructions:

Field	Instructions
Was this visit completed?	Select 'Yes' or 'No'. If 'No', then leave remaining items blank and save the form. A Missed Visit form will automatically add to the participant's visit folder to be completed.

Follow-up Visit Summary

Purpose:
This form is used to summarize information from each participant follow-up study visit.

General Instructions:
This form is completed for each scheduled visit and is present in each follow-up visit folder, starting at Visit 3 – Week 4 through Visit 24 – Week 73.

Item-specific Instructions:

Field	Instructions
Visit Date	A complete date is required.
Was study product held at this visit?	Select 'Yes' or 'No'. If 'Yes', then complete a Product Hold form within the Ongoing Logs folder.
Was study product use permanently discontinued (scheduled or early) at this visit?	Select 'Yes' or 'No'. If 'Yes', then complete a Product Discontinuation form within the Discontinuations Logs folder.
Did the participant exit/terminate the study at this visit?	Select 'Yes' or 'No'. If 'Yes', then complete a Study Discontinuation form within the Discontinuations folder.

Field	Instructions
Were any new adverse events (AEs) reported at this visit?	Select 'Yes' or 'No'. Select 'Yes' if at least one Adverse Event (AE) was newly completed for this visit. Navigate to the Ongoing Logs folder to complete a log line for the applicable AE(s).
Is the participant taking any concomitant medications that have not been previously reported?	Select 'Yes' or 'No'. Select 'Yes' if at least one concomitant medication was newly completed for this visit. Navigate to the Ongoing Logs folder to complete a log line for the applicable medication(s).
Have any protocol deviations been reported at this visit? If yes, complete the Protocol Deviations Log.	Select 'Yes' or 'No'. Select 'Yes' if at least one protocol deviation was newly completed for this visit. Navigate to the Ongoing Logs folder to complete an entry for the applicable protocol deviation(s).
Were any additional study procedures completed at this visit:	If additional 'as-needed' study procedures were completed at this visit, select "Yes". The Additional Study Procedures form will dynamically be added to the visit folder to be completed. Mark this if the COVID-19 Behavioral Assessment needs to be added to a study visit, since this CRF is expected at different time points for participants, depending on their visit schedule, this will be populated via the Additional Study Procedures CRF.
What study product will the participant initiate at the start of Period 3 (Visit 16)	This question should be completed at the Period 3: Study Initiation Visit/Visit 16/Week 48 visit only.

HIV Confirmatory Results

Purpose:
This form is used to document HIV confirmatory results from local lab confirmatory HIV testing.

General Instructions:
Record HIV test results on this form as they become available.

Item-specific Instructions:

Field	Instructions
Geenius HIV-1/2 confirmatory test	Record the Geenius Confirmatory Assay results as determined by the Geenius reader and software.
Was plasma stored for HIV confirmatory testing?	If plasma was not stored or was not required to be stored, skip to the HIV RNA PCR item.
Plasma for HIV confirmatory testing collection date:	A complete date is required if plasma for HIV confirmatory testing was stored.

Field	Instructions
HIV RNA PCR	Note that the ">" symbol is "greater than", the "<" symbol is "less than" and the "=" is "equal to" the result provided. When completing this item on the form within Rave, select the "greater than", "equal to", or "less than" from the drop down menu.
HIV RNA PCR	Record the participant's HIV RNA PCR result exactly as it appears on the lab report source documentation, regardless of whether the result is more or less than the limit of detection for the assay. If the HIV RNA PCR target is not detected, mark the "target not detected" box and leave the HIV RNA PCR field blank. If the HIV RNA PCR result is below the limit of detection, indicate that the results is "less than" the value provided. If HIV RNA PCR testing is not done/not collected, skip to the Seroconverter Plasma Storage items.
HIV RNA PCR Kit	Select the HIV RNA PCR testing kit that was used. If completing a paper form mark the kit from the response options provided. When completing the form within Rave, select the kit from the drop-down field.
HIV RNA PCR Kit Lower limit of detection	Select "20" or "40" as the lower limit of detection or record the viral copies/mL
CD4%	If automatically calculated, record the CD4+ percentage that was reported for the specimen in the item, "Absolute CD4". If the CD4+ percentage is not available (i.e., it was not reported and would have to be manually calculated), mark the "not available" box.
Final HIV Status	Once a participant's HIV status has been determined, record the final HIV status. If the participant's final HIV status is determined to be positive (according to the protocol testing algorithm), update the Clinical Product Hold/Discontinuation Log to reflect permanent discontinuation of study product. If the participant status is not clearly negative or clearly positive, mark the "pending" box and updated this item once the participant's final HIV status is known. When completing the paper form, mark the participant's final HIV status from the list of outcomes provided. When completing the form, select the participant's HIV status from the drop-down field.

HIV Test Results

Purpose:

This form is used to document HIV rapid test results from local lab confirmatory HIV testing.

General Instructions:

Record HIV test results on this form as they become available.

Item-specific Instructions:

Field	Instructions
Rapid HIV test 1 Kit	Select the kit name that was used from the drop-down field. If "Other" is selected, then specify the test kit in "If "Other, specify".
Rapid HIV test 1	If "Antibody positive", "Antigen positive", or "Antibody and antigen positive" is selected, complete a Clinical Product Hold and Product Discontinuation Log form, if applicable.
Rapid HIV test 2 Kit	Select the kit name that was used from the drop-down field. If "Other" is selected, then specify the test kit in "If "Other, specify".
Rapid HIV test 2	If the rapid HIV test 2 results is "Antibody positive", "Antigen positive", or "Antibody and antigen positive" complete a Clinical Product Hold and Product Discontinuation Log form, if applicable. If Rapid HIV test 1 and test 2 are both "Negative", end the form.

Interim Visit Summary

Purpose:

This form is used to summarize information at an interim visit and to record all procedures or assessments the participant received at any interim study visit (e.g., if a clinically indicated physical exam is performed) completed during the study.

General Information/Instructions:

This form is required for each interim visit completed for a participant.

Item-specific Instructions:

Field	Instructions
Visit Date	A complete date is required.
Interim Visit code	Enter the applicable interim visit code. Refer to the Data Collection SSP for more information on visit codes.
Was study product held at this visit?	Select 'Yes' or 'No'. If 'Yes', then complete a Product Hold form within the Ongoing Logs folder.
Was study product use permanently discontinued (scheduled or early) at this visit?	Select 'Yes' or 'No'. If 'Yes', then complete a Product Discontinuation form within the Discontinuations folder.
Did the participant exit/terminate the study at this visit?	Select 'Yes' or 'No'. If 'Yes', then complete a Study Discontinuation form within the Discontinuations folder.

Field	Instructions
Were any new adverse events (AEs) reported at this visit?	Select 'Yes' or 'No'. Select 'Yes' if at least one Adverse Event (AE) was newly completed for this visit. Navigate to the Ongoing Logs folder to complete an entry for the applicable AE(s).
Is the participant taking any concomitant medications that have not been previously reported?	Select 'Yes' or 'No'. Select 'Yes' if at least one concomitant medication was newly completed for this visit. Navigate to the Ongoing Logs folder to complete an entry for the applicable medication(s).
Have any protocol deviations been reported at this visit?	Select 'Yes' or 'No'. Select 'Yes' if at least one protocol deviation was newly completed for this visit. Navigate to the Ongoing Logs folder to complete an entry for the applicable protocol deviation(s).
Reason for interim visit	Select the applicable checkboxes if an AE report or follow-up was completed or if product was returned or provided. Select 'Yes' or 'No' for Completion of missed visit procedures.
What study procedures were completed at this visit:	Select the checkbox for each study procedure listed. Select the applicable procedures that were completed at the study visit. The applicable form(s) will then be added to the participant's visit folder. For example, if a physical exam was performed, select the checkbox for **Physical Exam**. As indicated procedures that were not completed at this visit may be left blank. **Note**: The Tablet Assessment and the Ring Assessment forms will **not** be added via the Interim Visit Form. These forms will be added via the Ring Insertion and Removal form or the PrEP provisions and return form.

Local Laboratory Results

Purpose:

This form is used to provide data on the participant's laboratory Hemogram and Serum Chemistries test results.

General Information/Instructions:

Use this form to report the hematology and differential test results obtained from specimens collected at Screening, Visit 9.0 – Week 24, Visit 16 – Week 48, Visit 23/PUEV, and as indicated during the study as they become available.

If any or all of the lab tests listed on this form are repeated (re-drawn) between the Screening and Enrollment Visit, document the repeated results on the same Local Laboratory Results form. If the participant enrolls, the updated results should be submitted into the study database.

At Screening, record any applicable diagnoses within the Baseline Medical History Log form, when applicable.

During follow-up, if a test result(s) recorded on this form indicates that the participant has a new (or increased severity) laboratory-confirmed infection or diagnosis, this infection/diagnosis must be recorded as an adverse event on an Adverse Event (AE) Log form.

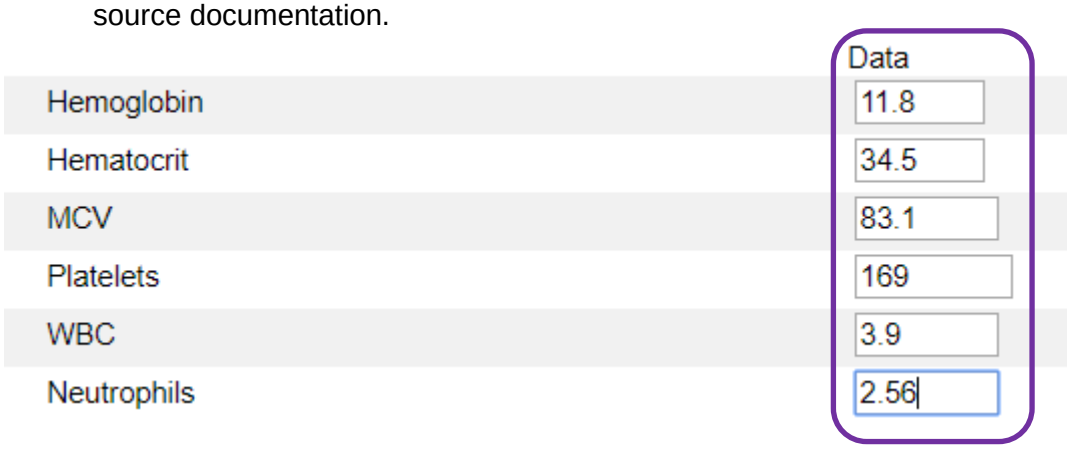
Entering Laboratory Results

- The lab that collected the specimens used for these tests will automatically be selected from the Lab dropdown list at the top of the form. The units and lab ranges for each result will be populated at the bottom of the form after selecting the appropriate lab. ***Note***: The Demographics form needs to be entered prior to entering data on the Local Laboratory Results form because the derived age from the Date of Birth on the Demographics form is used to populate the reference ranges.

- For each lab test, enter the specimen collection date at the top of the form for that specific test each time this form is completed unless it was not collected.

- For each lab analyte result (e.g. Hemoglobin, Hematocrit, MCV, Platelets, WBC, Neutrophils, Lymphocytes, Monocytes, Eosinophils, Basophils, Creatinine, Calculated Creatinine Clearance), record the numeric results in the appropriate field at the bottom of the form.

- For each lab analyte result, record the value with the same level of precision as the source documentation.



- Enter the severity grade at the top of the form for that specific result. The following results require entry of the severity grade (if applicable):

    - **HEMATOLOGY:** Hemoglobin, Platelets, WBC
    - **DIFFERENTIAL:** Neutrophils, Lymphocytes
    - **BLOOD CHEMISTRIES:** Creatinine, Calculated Creatinine Clearance

    See the *Severity Grade* section for further instructions on completing the severity grade.

Lab Result Units

- Results should be documented on the form using the following units:

  Note that the following units are equivalent:

  IU/L = U/L I/l x 100 = % 10^9/L = 10^3/mm^3 = 10^3/µL

  For creatinine, only record the result in the units listed on the source document.

  The following analytes should be recorded in the following format:

  - **Hemoglobin**: g/dL
  - **MCV:** fl
  - **Platelets**: cells/mm^3
  - **WBC:** cells/mm^3
  - **Neutrophils:** cells/mm^3
  - **Lymphocytes:** cells/mm^3
  - **Monocytes:** cells/mm^3
  - **Eosinophils:** cells/mm^3
  - **Basophils:** cells/mm^3
  - **Creatinine**: mg/dL
  - **Calculated Creatinine Clearance:** mL/min

Reporting Severity Grade

- Record the severity grade at the top of the form by selecting from the drop-down menu for each corresponding lab analyte when applicable. If the analyte does not meet criteria for severity grade 1 or greater per the DAIDS Toxicity table (Version 2.1), select the 'Not gradable' option.

- The severity grade options are as follows:
  - Grade 1 – Mild
  - Grade 2 – Moderate
  - Grade 3 – Severe
  - Grade 4 – Potentially life-threatening
  - Not gradable

- If any values meet the criteria for severity grade 1 or greater, according to the appropriate *DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events*, record the grade. If the value is below Grade 1, select the option 'not gradable'.

- Always compare the severity grade range to the value that was recorded on the form (not the lab-reported value).

- When working with calculated severity grade ranges (e.g., 1.1–1.5 times the site lab upper limit of normal), the calculated range may have more significant digits than the lab result.

  - Treat all missing digits in the lab value as zeros.

- If the lab value falls between two calculated severity grade ranges, assign it the higher grade.

- Record any Grade 1 or higher lab values on the "Baseline Medical History Log" or "Adverse Event Log" form(s) as applicable.

- If an abnormal lab finding meets AE reporting criteria, select the corresponding AE within the drop-down menu. Please note that the AE must be entered within the Ongoing Logs folder prior to completing this form in order to link the associated AE.

Missed Visit

Purpose:
Complete this form in the event that an enrolled participant misses a required visit according to the visit window outlined in the protocol or Study-specific Procedures (SSP) manual.

General Information/Instructions:
A missed visit form will be dynamically added to a visit folder if the response to "Was this visit completed?" on the Follow-up Visit Summary from is "No". Complete the Missed Visit form only for this visit.

Item-specific Instructions:

Field	Instructions
Target Visit Date	Record the target date of the visit. A complete date is required.
Reason visit was missed	Select the reason that the participant missed the visit from the drop-down list. If the reason that the participant missed the visit is not included in this list, select 'Other', and specify the reason that the reason was missed in the 'If "Other", specify' text field provided.
Steps taken to address the missed visit (Corrective action plan)	Record the corrective steps that have been taken or will be taken to address the missed visit and help prevent future missed visits.

Participant Identifier

Purpose:
The Participant Identifier page within Medidata Rave will generate each participant's PTID. This page is the first form completed within Medidata Rave for each participant.

General Instructions:
Complete this form for every MTN-034 participant once she has provided written informed consent for study screening and enrollment.

Item-specific Instructions:

<table>
<tr><th>Field</th><th>Instructions</th></tr>
<tr><td>Participant ID</td><td>To add a participant to the study database, select the “Add Subject” link on the MTN-034 site-specific home page. The Participant Identifier page will appear. This is the first page that should be completed for each participant.

No data entry is required by the site on this form. Click the “Save” button at the bottom of the form. A pop-up box will appear to indicate that a participant has been added to the database and the home page for the participant’s file will appear. The link to refer back to the Participant Identifier page is located at the top of each participant’s home page. The participant ID will appear on each form generated in Medidata Rave. The participant ID should be written at the top of each paper form completed for a participant.

The first three digits of each participant ID will comprise of the Rave site ID. Therefore, each participant ID will begin with the site ID. A list of Rave site IDs is provided in the table below:
<table>
<tr><th>CRS Name</th><th>DAIDS ID</th><th>Rave Site ID</th></tr>
<tr><td>Emavundleni, Cape Town</td><td>30346</td><td>779</td></tr>
<tr><td>MU-JHU, Uganda</td><td>30293</td><td>753</td></tr>
<tr><td>WRHI, Johannesburg</td><td>31639</td><td>805</td></tr>
<tr><td>Spilhaus, Zimbabwe</td><td>30314</td><td>771</td></tr>
</table>
</td></tr>
</table>

Participant Transfer

Purpose:
Complete this form when a participant is permanently transferring to another study clinic/site.

General Instructions:
The Participant Transfer form is completed by the transferring site (the site that the participant is leaving). This form should be added to the participant case book by selecting it from the list of optional study procedures within the **Additional Study Procedures** or **Interim Visit Summary** form. The Participant Transfer form should be added to the folder at which the participant is transferred to another site.

For more information on participant transfers, refer to the MTN-034 protocol, Study-specific Procedures (SSP) manual, and/or Manual of Operations (MOP).

Field	Instructions
Name of transferring study site	Select the transferring site from the drop-down field.
Name of receiving study site	Select the receiving site from the drop-down field.
Date participant records were sent to receiving study site	A complete date is required.

Participant Receipt

Purpose:
Complete this form when a transferred participant has provided informed consent at the receiving study clinic/site.

General Instructions:
The Participant Transfer form is completed by the receiving site (the site at which the participant will continue her study visits) when the participant's electronic case book has been transferred to the receiving site. This form should be added to the participant case book by selecting it from the list of optional study procedures within the **Additional Study Procedures** or **Interim Visit Summary** form within the last completed study visit at the transferring site (i.e., the Participant Transfer and Participant Receipt form should be completed within the same visit folder). The Participant Receipt form will then be added to the applicable study visit folder within Rave.

The participant will retain her original Participant ID (PTID) assigned by the original study site. Do not assign a new Participant ID.

For more information on Participant Transfer and Receipt, refer to the MTN-034 protocol, Study-specific Procedures (SSP) manual, and/or Manual of Operations (MOP).

Field	Instructions
Name of receiving study site	Select the transferring site from the drop-down field.
Name of transferring study site	Select the receiving site from the drop-down field.
Date informed consent signed at receiving site	A complete date is required.
Date informed consent for specimen storage was signed at receiving site	A complete date is required.

Pelvic Exam

Purpose:
This form is used to document the participant's pelvic exam assessment.

General Instructions:
Complete this form at Screening, Enrollment, Visit 6 – Week 12, Visit 9- Week 24, Visit 13 – Week 36, Visit 16 – Week 48, Visit 20 – Week 60Visit 23/PUEV, and when clinically indicated at all other study visits. Transcribe information from the **Pelvic Exam Diagrams** form or other local site-specific source document into this form for submission in Medidata Rave.

Item-specific Instructions:

Field	Instructions
Pelvic exam assessment	If 'not done' is selected, then this is the end of form and all remaining items should be left blank.

	Select 'abnormal findings' or 'no abnormal findings' to indicate any findings from the pelvic exam. If 'no abnormal findings' is selected, then skip the "Abnormal findings" section.
Exam Date	A complete date is required.
Abnormal findings	Select the box to the right of each abnormal finding observed and check all that apply. Specify additional details in the text field provided where applicable. If an observed abnormal finding is not listed, select "Other abnormal findings" and specify/describe the abnormal findings in the text field provided, including the anatomical location. Please record any baseline abnormalities on the Baseline Medical History Log form. Any post baseline abnormalities or baseline conditions that worsened post baseline should be reported on the Adverse Event form. In general, for abnormal findings reported as adverse events on an AE Log, use the abnormal finding text provided on this form as the AE descriptive text. Abnormal blood or bleeding, describe: Note "expected" bleeding due to menses or contraception is considered normal and therefore should not be documented on this form. Changes in "expected" genital bleeding will not be considered an abnormal finding and not considered an AE unless deemed to be an SAE.
Were any new pelvic finding AEs reported at this visit?	Record whether an AE was identified and reported at this visit as part of the pelvic exam assessment by selecting 'Yes' or 'No'. If an AE was reported at the study visit, select the corresponding AE log form within the dynamic searchlist function on the form. Up to 3 AEs can be selected. This item should be marked 'No' prior to participant enrollment in the study (i.e., prior to the AE reporting period).
Cervical Ectopy	Select the percentage of cervical ectopy observed during the pelvic exam assessment by selecting the appropriate drop-down option within the form. Select 'Not done if cervical ectopy was not assessed.

Pelvic Exam Diagrams Form (non Medidata Rave form)

Purpose:
This form is used to document all variants of normal and all abnormal findings observed during study pelvic exams (screening through termination/study exit).

General Information/Instructions:
This form is completed at Screening, Enrollment, Visits 6, 9, 13, 16, 20, Visit 23/PUEV, and when as clinically indicated at all other study visits. Transcribe information onto the appropriate Pelvic Exam form and store this form in the participant's chart notes. This form is available to

download and print on the MTN-034 Atlas webpage under the Case Report Forms section within the “Other Documents” section. Please refer to the back of the form for specific guidelines on completing this form.

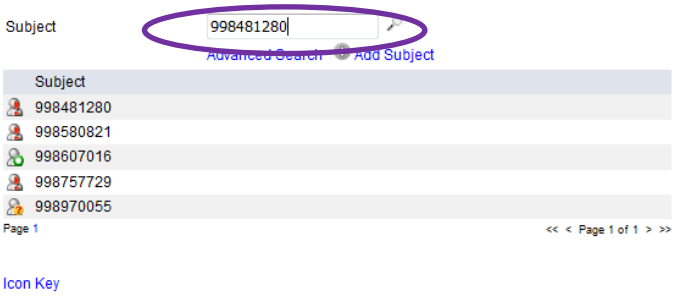
Pharmacy Dispensation Log

Purpose: This form is completed by the study pharmacists to collect tablet bottle and vaginal ring dispensation information.

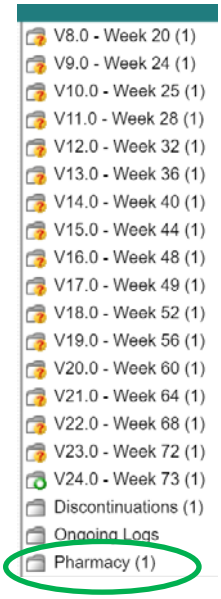
General Instructions:
Complete this form at every visit at which study product is dispensed. Complete a separate entry (e.g., log line) for each medication that is dispensed. Use the “Add a new Log line” button to add each dispensed medication in Medidata Rave.

This form is completed by pharmacy staff only and is not visible to site clinic staff. Only pharmacists who have been granted this role will be able to view and enter data on this form.

- Select the applicable PTID as documented on the prescription. The search list can be used to find the PTID.



- Navigate to the Pharmacy folder to complete the Pharmacy Dispensation form.



- Complete the Pharmacy Dispensation form and save the form.

Item-specific Instructions:

Field	Instructions
Study Product Sequence	Choose the Study Product Sequence from the dropdown menu for the sequence the participant is assigned to. This will only need to be chosen once at the Enrollment Visit, and will be present on the form anytime thereafter when completing the log items on this form.
Study Product Sequence (autopopulated from Medidata Balance)	The "Study Product Sequence field (auto-populated from Medidata Balance)" field will not appear on the Pharmacy Dispensation CRF **until the form is saved** as this field is a QC check to ensure that data entry of the study product sequence and study product is accurate on the CRF. Site staff should leave this field blank when completing the form. Once the form is saved, ensure that this field is the same as the "Study Product Sequence" selected by site staff.
Was a vaginal ring or tablet bottle dispensed at this visit?	Select whether a Truvada Bottle or a Vaginal Ring was dispensed at this visit based on the participant's randomization assignment.
Visit study product dispensed	Select the study visit at which study product was dispensed. If study product was dispensed at an interim visit, select "interim visit".
If interim visit, specify visit code	If 'interim visit' was selected for the item "Visit study product dispensed", provide the interim visit code in the following format: (X)X.X. A leading zero is not required.
Date study product dispensed	Record the exact day, month, and year study product was dispensed to the participant. A complete date is required.
How many vaginal rings or tablet bottles were dispensed?	Select the number of vaginal rings or Truvada bottles that were dispensed at this visit.
Tablet bottle Lot number #1:	Record the Truvada bottle lot number for the bottle dispensed to the participant. Up to nine (9) characters and letters are allowable.
Tablet bottle Lot number #2:	If one Truvada bottle was dispensed at a visit, this item should be left blank. Up to nine (9) characters and letters are allowable.
Vaginal Ring #1 Lot number	Record the manufacturing lot number for the vaginal ring dispensed to the participant. Up to six (6) characters and letters are allowable.
Vaginal Ring #2 Lot number	If one vaginal ring was dispensed at a visit, this item should be left blank. Up to six (6) characters and letters are allowable.

Physical Exam

Purpose:
This form is used to document the participant's physical exam findings.

General Instructions:
Complete this form at Screening, and Visits 4-9, 11-16, 18-22, Visit 23/PUEV, and when clinically indicated during follow-up. If abnormal findings are found for any of the assessments, enter the information on the **Baseline Medical History Log** or **Adverse Event Log** form(s) as applicable.

Item-specific Instructions:

Field	Instructions
Exam Date:	Enter the date the physical exam was performed. A complete date is required.
Organ Systems or Body Parts Evaluated:	For each organ system or body part evaluated, indicate whether the findings were normal or abnormal. If abnormal, describe the abnormality in the corresponding text field. For any baseline abnormal and clinically significant findings, record the associated condition(s) on the Baseline Medical History Log form. Any post baseline abnormalities or baseline conditions that worsened post baseline should be reported on the Adverse Events Log form. Normal findings may also be described in the text field/space, but it is not required. If not evaluated, select 'Not Done'. Additional information may also be provided in the text field for why 'Not done', but this is not required. Per protocol, lymph nodes, abdomen, neck, heart, lungs, extremities, skin, and neurological may be omitted after the Enrollment Visit.
Other:	If other systems were assessed not covered by the pre-defined assessments, then please specify whether findings were 'Abnormal' or 'Normal' under the "Other" section. If another body system was evaluated and the findings were normal, select 'Normal'. Specify the body system being referenced and describe the findings in the text field provided. The body system can be specified in the text field provided. If no other abnormal findings are identified, select 'Not Done'.

Pregnancy History

Purpose:
This form is used to document the participant's pregnancy history.

General Instructions:
A Pregnancy History form is required once for a participant who becomes pregnant during the study.

To complete a Pregnancy History form within Medidata Rave, navigate to the "Add Event" on the Participant's homepage. Click "Pregnancy History" then "Add" and a pregnancy history folder will appear for data entry.

Item-specific Instructions:

Field	Instructions
Has the participant ever been pregnant before?	If the participant has never been pregnant before, select "No" and end the form. If 'yes', an entry is required for each of the following: Number of full term live births (>=37 weeks), Number of premature live births (less than 37 weeks), Number of spontaneous fetal deaths and/or still births (>=20 weeks), Number of spontaneous abortions (less than 20 weeks), Number of therapeutic/elective abortions, Number of ectopic pregnancies. Enter '00' for any that do not apply.
Does the participant have a history of pregnancy complication or fetal/infant congenital anomalies?	If the participant does not have a history of pregnancy complications, select 'No' and end the form. If "Yes", then include information on pregnancy complications and fetal/infant congenital anomalies experienced prior to enrolling in the study as well as any conditions experienced/reported during the study in the corresponding text field provided.

Pregnancy Outcome Log

Purpose:
This form is used to report pregnancy outcome information for a pregnancy reported post-enrollment. A Pregnancy Outcome Log line must be completed for each pregnancy reported during the study.

General Instructions:
This form will dynamically be added to the Pregnancy folder when a positive Pregnancy test is recorded on the Pregnancy Test form. by study staff. For each pregnancy outcome, complete

one log line. To add another pregnancy outcome (if needed), use the "Add a new Log line" button to add each additional pregnancy outcomes.

Item-specific Instructions:

Field	Instructions
Is the outcome of this pregnancy obtainable?	If the outcome of the pregnancy is not able to be obtained, select "No" and end the form.
How many pregnancy outcomes resulted from this reported pregnancy?	If the pregnancy results in two or more outcomes, complete a Pregnancy Outcome Log form (new log line) for each outcome. If the item is completed as greater than "1", additional Pregnancy Outcome Log lines will be added to the Pregnancy Outcome Log form, as needed. Each Pregnancy Outcome form will have different outcome numbers.
Outcome Date	A complete date is required.
Place of delivery/outcome	Enter the place of delivery/outcome from the drop-down menu. If "Other", then specify relevant details in the "If, Other, specify" text field provided.
Specify Outcome	Specify the outcome from the drop-down menu. If the outcome is still birth/intrauterine fetal demise, spontaneous abortion, therapeutic/elective abortion, or ectopic pregnancy, the outcome itself is not an adverse event (AE). If a therapeutic/elective abortion is performed due to a pregnancy complication, the pregnancy complication should be reported on an Adverse Event (AE) Log, if prior to termination, with 'therapeutic procedure/surgery' checked for response option "Other action(s) taken" for the item "Action taken with study product". If there are any maternal complications as a result of the pregnancy outcome, refer to the protocol, Study-specific Procedures (SSP) manual, and *Manual for Expedited Reporting of Adverse Events to DAIDS, Version 2* for guidance on AE and expedited AE reporting requirements. If "Other", then specify relevant details in the "If, Other, specify" text field provided.
Method	Select the method from the drop-down menu only if the outcome is 'full term live birth (≥37 weeks)' or 'premature term live birth (< 37 weeks)'. "Operative Vaginal" delivery includes delivery with forceps and/or vacuum. If the outcome is 'full term live birth', skip to "Were there any complications related to the pregnancy outcome?"
Provide a brief narrative of the circumstances	Include information on medical conditions associated with the outcome, including early contractions, rupture of membranes, and cramping, along with actions taken as a result of these conditions. This item is only required if **not** a full term live birth.

Field	Instructions
Were there any complications related to the pregnancy outcome?	Select 'yes' or 'no' to indicate if there were any complications related to the pregnancy outcome. If 'no', then items "Delivery-related complications" and "Non-delivery related complications" are not required.
Delivery-related complications	Select 'None' or check all that apply. If "Other", then specify relevant details in the "If, Other, specify" text field provided.
Non-delivery related complications	Select 'None' or check all that apply. If "Other", then specify relevant details in the "If, Other, specify" text field provided.
Were any fetal/infant congenital anomalies identified?	Record if any fetal/infant congenital anomalies were identified. If "No" or "Unknown", go to statement "Complete the infant items below for live births only" above "Infant gender".
Congenital anomalies identified.	If there were fetal/infant congenital anomalies identified, then check all that apply. If a woman on study has a baby with a congenital anomaly, report the event on an Adverse Event (AE) Log form, if prior to study discontinuation. On the AE Log form, record "Congenital Anomaly in Offspring" in the AE description, record the Outcome Date as the Onset Date, and record the specific anomaly in the Comment Section. Submit an Expedited Adverse Event (EAE) Reporting form.
Specify congenital anomaly/defect AE	The corresponding AE log form must be completed to link the congenital anomaly/defect AE to the AE log form entered. Choose the applicable AE from the drop-down list.
Describe the congenital anomaly/defect	Describe the congenital anomaly/defect in the text field provided.
Infant items	Complete the infant items for live births only. Otherwise, end the form.
Infant Gender, Infant birth weight, Infant birth length, Infant birth head circumference, Infant birth abdominal circumference	Complete these items for live births only. Record the information as documented in medical records. If no medical record documentation of the information is available, complete this item based on participant report. Check the "unavailable" box if no medical record documentation is available and the participant does not know the information.
Infant Gestational age by examination in days and weeks	Record the infant's gestational age at birth. If the infant's gestational age is determined using the Ballard method, record "0" in the "days" box. Check the "unavailable" box if no medical record documentation of the infant's gestational age is available and end the form. If 'other' method is selected for "Method used to determine gestational age", specify in the corresponding "If other, specify" text field.

Pregnancy Report

Purpose:
Complete this form when reporting a pregnancy of a study participant post enrollment through study discontinuation.

General Instructions:
This form will dynamically be added to the Pregnancy folder when a positive Pregnancy test is recorded on the Pregnancy Test form by study staff.

Item-specific Instructions:

Field	Instructions
1a. First day of last menstrual period	A complete date is required. Record best estimate if date not known. If the participant is amenorrheic, select the checkbox for item 1b 'Amenorrheic for past 6 months' and leave the First day of last menstrual period date fields blank.
2. Estimated date of delivery	A complete date is required.
What information was used to estimate the date of delivery?	Select 'yes' or 'no' to indicate what information was used to estimate the date of delivery. If another method was used which are not covered by the currently listed methods, please select 'Yes' for "Other" and describe them in the 'If other, specify' text field provided.
3d. Physical Examination	A physical examination to determine estimated date of delivery includes fundal height, uterine size by pelvic exam, and/or fetal heart rate.
4. Has the participant ever been pregnant before?	If the participant has never been pregnant before, select "No" and end the form and leave remaining items blank.
4a. Is this the participant's first pregnancy since enrollment in this study?	If this pregnancy is not the first reported pregnancy since the participant's enrollment in the study, select 'No' and skip to item 5, "Does the participant have a history of pregnancy complications or fetal/infant congenital anomalies?" (Items 4b-4g are not required).
5. Does the participant have a history of pregnancy complications or fetal/infant congenital anomalies?	If the participant does not have a history of pregnancy complications, select 'No' and end the form. If "Yes", then include information on pregnancy complications and fetal/infant congenital anomalies experienced prior to enrolling in the study as well as any conditions experienced/reported during the study in the corresponding text field provided.

Pregnancy Test Result

Purpose:
This form is used to document the pregnancy test result as the result becomes available from the local lab.

General Instructions:
This form is required at Visit 04.0-09.0, 11.0-16.0, 18.0-23.0 and at other visits if indicated.

Item-specific Instructions:

Field	Instructions
Was a pregnancy test done?	Record if a pregnancy test was done by entering 'Yes' or 'No'. If 'No' is selected, then end of form and leave remaining items blank. • If a pregnancy test was not done, please do NOT complete the "Date of Pregnancy Test", or "Test result". • If the sample was collected, then complete "Date of Pregnancy Test" and "Test result".
Date of Pregnancy Test	Record the date that the pregnancy test was collected and NOT the date the results were reported or recorded within the form for this visit. A complete date is required.
Test Result	Record the result of the pregnancy test - positive (pregnant) or negative (NOT pregnant) by selecting the appropriate radio button. If the result is **"Positive"** at a follow-up visit, then complete a Product Hold form, and Pregnancy Report form, and Pregnancy History form.
First day of last menstrual period	Enter the first day of the last menstrual period (first day of bleeding). If the participant has been "amenorrheic for the past 6 months" OR has had "no menses since participant's last visit", select the applicable radio button or mark the applicable box on the paper form. If one of these options is selected, then a date does not need to be recorded. If either of these options is selected, then this is the end of form and the next item "last day of last menstrual period" does NOT need to be completed. The month and year are required.

Field	Instructions
Last day of last menstrual period	Enter the last day of the last menstrual period (last day of bleeding). However, if the participant is currently menstruating, then select the "ongoing" box and the date should be left blank. The month and year are required.

PrEP Provision and Returns

Purpose:
This form documents if tablet bottle(s) were provided and/or returned to the participant.

General Instructions:
Complete this form at the Study Product Initiation visit up through the participant's scheduled Product Use End Visit within the period in which the participant has been randomized to receive Truvada tablets. If the participant permanently discontinues from study product prior to her PUEV, this form is discontinued. Complete this form during Period 3 at each visit where a participant chooses to use the tablets.

Field	Instructions
No tablet bottle(s) returned	If a Truvada bottle was not provided at a study visit, skip the remaining questions within the Tablet Bottle Return section and go to Tablet Bottle Provision.
No tablet bottle(s) provided	If no tablet bottle(s) were provided at this visit, end of form.
Number of tablet bottles provided	If at least one tablet bottle is provided at this visit, the Tablet Assessment form will be added to the visit folder for completion.

Product Choice

Purpose:
This form documents the participant's choice for what study product she chooses to use during Period 3.

General Instructions:
This form should only be completed at Visit 16 – Week 48 (Period 3). This form is an interviewer-administered with questions provided in local language.

Field	Instructions
Now that you have tried out each product and used it for 6 months, you have the option to choose which prevention method you would like to use for the next study period.	This question should be read aloud word for word in the participant's preferred language. Select from the drop-down menu "Tablets", "Ring" or "Neither". If "Neither" is chosen, skip to item 4 on the form.
Would you say you chose this product mainly because you liked the product you chose, or because you disliked the other product?	This question and the response options should be read aloud word for word in the participant's preferred language.
Ask the participant to explain her response to the previous question.	Record the response exactly as stated by the participant.

Product Change

Purpose:
This form documents when the participant chooses to change study product during Period 3.

General Instructions:
Complete this form during Period 3 (Visits 17-22) if the participant chooses to switch study product or stop product use all together.

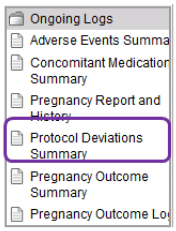
Item-specific Instructions:

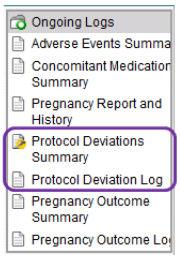
Field	Instructions
What product was the participant using prior to this visit?	Indicate whether the participant was using the "Ring", "Tablets" or "Neither" prior to this study visit. If the participant has been permanently discontinued from one study product during Period 1 or 2, select the product that the participant is eligible to use or neither.
What product does the participant want to start using at this visit?	Indicate whether the participant wishes to start using the Vaginal Ring, Truvada Tablets or Neither at this study visit. If "Neither", skip to item 5.
Would you say you wanted to change products mainly because you disliked the product you were using before, or because you preferred the other product?	This question and the response options should be read aloud word for word in the participant's preferred language.
Ask the participant to explain her responses to the previous questions.	Record the response exactly as stated by the participant.

Protocol Deviation Summary

Purpose:
This form documents if a protocol deviation has occurred.

Generation Instructions:
This form is present within the “Ongoing Logs” folder. Selecting ‘Yes’ in the “Protocol Deviations Summary” will add the “Protocol Deviation Log” form.





Item-specific Instructions:

Field	Instructions
Have any protocol deviations occurred?	Select ‘Yes’ or ‘No’. If ‘Yes’ is selected, then the “Protocol Deviation Log” form appears dynamically within the Ongoing Logs folder and can then be completed.

Protocol Deviation Log

Purpose:
This form documents and reports protocol deviations identified for study participants during the implementation of MTN-034.

General Information/Instructions:
Complete this form each time a protocol deviation is identified for a participant during study participation (including the screening period). Once the Protocol Deviation Log form has been created, complete one page per protocol deviation when entering in the study database. To add an additional deviation within Medidata Rave, clicking “Add a new Log line” will add an additional page for a new deviation to be completed. Consult the MTN Regulatory Team (mtnregulatory@mtnstopshiv.org) and the Study Management Team if you are unsure if an event requires reporting as a deviation.

Item-specific Instructions:

Field	Instructions
Site awareness date	Record the date the site became aware of the deviation. A complete date is required.

Field	Instructions
Deviation date	Record the date the deviation occurred (start date). A complete date is required.
Type of deviation	Record the applicable deviation by selecting from the drop-down menu. *Please see table below for the types of deviations.* When entering the type of deviation, the first few letters of the description can be entered within the drop-down search list to find the applicable deviation to be entered. Record "other" if none of the listed categories match.
Description of deviation	Use the text field to briefly describe the specific details of the deviation.
Plans and/or actions to address the deviation	Use the text field to provide a brief description of the plans to address the deviation.
Plans and/or actions to address for future deviations	Use the text field to provide a brief description of the plans to address future deviations.
Deviation reported by	Enter the staff code of the site staff person who completed the form. Sites will need to assign a **four-digit** staff code to each site staff person who will be completing this form. This list is created, maintained and kept at the study site.

PROTOCOL DEVIATION CODE LIST	
Description	**Description**
Inappropriate enrollment: The participant enrolled and not all eligibility requirements were met.	**Unreported AE**: Site staff become aware of an AE, but do not report it per protocol requirements.
Failure to follow randomization or blinding procedures: Include instances where randomization procedures were not followed by site staff, or product blinding procedures were not followed by pharmacy staff.	**Unreported EAE:** Site staff become aware of an EAE, but do not report it per protocol and DAIDS EAE Manual requirements.
Study product management deviation: The site staff did not instruct the participant to hold, permanently discontinue, or resume study product use per protocol requirements.	**Breach of confidentiality:** Include potential and actual cases where participant confidentiality is breached. For example, a staff member put a participant's name on a case report form.
Study Product dispensing error: The wrong study product was dispensed to a participant, or study product was dispensed to a participant who permanently discontinued study product use. Pharmacy staff must follow up with the MTN Pharmacist separately.	**Physical assessment deviation:** Include missed or incomplete physical/pelvic exam assessments.
Study Product use/non-use deviation: Only applicable when a participant does not have her first tablet dose directly observed per protocol (i.e. she takes her tablet dose prior to her clinic visit)	**Lab assessment deviation:** Include missed, or incomplete lab specimen collection
Study product sharing: Participant has shared study product with another person or study participant.	**Mishandled lab specimen:** Include errors in labeling, physical handling, processing, testing, storage, or shipment of collected lab specimens.
Study product not returned: Study product was not returned by the participant per protocol requirements.	**Staff performing duties that they are not qualified to perform:** use for any instance when any study procedure, including clinical and administrative procedures, is completed by a staff member who is not

	adequately qualified AND delegated to perform the procedure.
Conduct of non-protocol procedure: A clinical or administrative procedure was performed that was not specified in the protocol and was not covered under local standard of care practice.	**Questionnaire administration deviation:** A required questionnaire was not completed according to protocol requirements. Include instances where the wrong questionnaire was completed.
Improper AE/EAE follow-up: use when an AE or EAE is not followed per protocol. For example, a clinical finding/lab result is not re-assessed as outlined in the protocol.	**Counseling deviation:** Protocol-required counseling was not done and/or not documented correctly.
Use of non-IRB/EC-approved materials: Include use of ANY study-related material that requires IRB or EC approval for use per site requirements.	**Use of excluded concomitant medications, devices, or non-study products.**
Informed consent process deviation: Examples include failure to accurately execute and/or document any part of the informed consent process.	**Visit completed outside of window:** Use when visit procedures for a visit are done within the wrong window or not in a designated visit window. For example, if visit 3.0 procedures are done in the visit 4.0 window.
Other	

Product Preference and Acceptability

Purpose:
This form documents the preference and acceptability of the product from the participant.

General Instructions:
Complete this form at visits 09.0 – Week 24 and Visit 16.0 –Week 48 or when a participant terminates early.

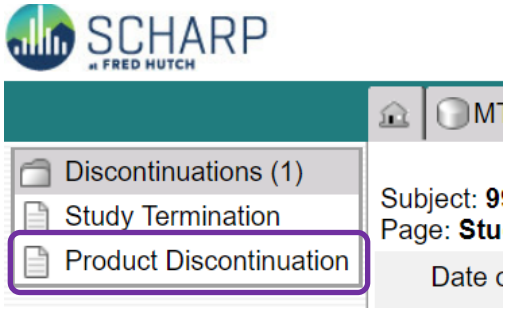
Item-specific Instructions:

Field	Instructions
What product did the participant use most recently?	Complete either Ring or Tablets. If 'Ring' is chosen, complete item 2 and skip Item 3. If 'Tablet' is chosen, skip item 2 and complete item 3.
Please rate how much you like using the ring for HIV prevention.	This question and the response options should be read aloud word for word in the participant's preferred language.
Please rate how much you like using the tablets for HIV prevention.	This question and the response options should be read aloud word for word in the participant's preferred language.
Would you prefer to use the ring or the tablets for HIV prevention?	Complete this item for visit 23 OR when a participant discontinues from study product early due to Pregnancy or Seroconversion. This question and the response options should be read aloud word for word in the participant's preferred language.

Product Discontinuation

Purpose:
This form documents a participant's permanent discontinuation of study product use.

General Instructions:
This form is present within the "Discontinuations" folder. Complete this form for each enrolled participant when study product use is permanently discontinued (early or scheduled at the end of each study product period).



Item-specific Instructions:

Field	Instructions
Date participant last used study product	A complete date is required. Record the date when the participant completed or was permanently discontinued from study product.
Primary reason for ending study product use:	Record the primary reason from the drop-down menu. If 'Adverse Event' is selected, specify the AE entry (in Medidata Rave, choose the AE from the AE dynamic drop-down list). **Note**: If study product is permanently discontinued due to an AE or allergic reaction to the vaginal ring or tablet, the AE log page must be entered into Rave prior to linking the AE on the Product Discontinuation form in order for the AE to be available to select with the drop-down field. If "Other", then specify relevant details in the "If, Other, specify" text field provided.

Product Hold Summary

Purpose:
This form documents if a clinician-initiated product hold was applied during the study.

General Instructions:
This form is present within the "Ongoing Logs" folder. Selecting 'Yes' to the "Does the participant have any clinical product holds to be applied?" prompt will add the "Clinical Product Hold" log to the "Ongoing Logs" folder.

Product Hold Log

Purpose:
This form is used to document temporary clinical holds of study product use as instructed by study site staff.

General Instructions:
This form is completed each time a participant is instructed by study staff to temporarily stop (hold) study product use. If, at the same visit, a product hold is initiated for more than one reason, complete one Product Hold log line for each reason. To add an additional Clinical Product Hold log line within Medidata Rave, click "Add a new Log line" to add an additional log line for a new product hold to be completed.

Complete this form for any clinical reason that warrants a product hold regardless of whether participants choose to use the ring or tablet or who choose to not use study product during the study. Do not complete this form in cases where a participant has decided herself to not use the study product.

Item-specific Instructions:

Field	Instructions
Date when study product hold was initiated	Record the date when the product hold was initiated or would have been initiated in instances where the participant has chosen not to use the ring. A complete date is required.
Visit when study product hold was initiated	If "Interim visit" is chosen, provide a response for "If Interim visit" is chosen, provide interim visit code" and record the interim visit code using the following format: (x)x.x.
Why is study product being held?	Record the reason that study product is being held. If study product is held for any reason not specified, mark "Other" and specify the reason in the If Other", specify. Note that participant decline, or refusal of study product is not documented as a product hold. Do not record this as a reason in 'If, Other, specify".
Adverse Event	If study product is being held due to "Adverse Event", select the applicable AE from the drop-down field provided. **Note**: If study product is being held due to an AE, the AE log page must be entered into Rave prior to completion of the Clinical Product Hold log form in order for the AE to be available to select with the drop-down field.

Concomitant Medication	If study product is being held due to "Reported use of PEP", specify the corresponding concomitant medications log form on which the medication was reported in from the drop-down field provided with Rave. At least one medication must be specified and up to four medications can be recorded. **Note**: If the product hold is due to report of medication use, the corresponding concomitant medications log page must be entered into Rave prior to completion of the Product Hold log form in order the medication be to be available within the drop-down field.
Date study product resumed	Record the date that the participant was instructed to resume study product.
Was the participant instructed to resume study product use?	If 'Yes', enter below the date that the participant was instructed to resume study product within the "Date study product resumed" field. Mark, "No – permanently discontinued" if the participant was permanently discontinued from study product due the reason indicated on this form. Mark, "No – early termination" if the product hold was ongoing at the visit at which the participant terminated early from the study. Complete the Product Discontinuation form. Mark, "No – hold continuing at scheduled PUEV" if the product hold was ongoing at time of the participant's scheduled Product Use End Visit. Complete the Product Discontinuation form. Mark, "No – hold continuing for another reason" if the participant would have been instructed to resume study product based on the resolution of the reason indicated on this form. If 'No – hold continuing for another reason', enter below the 'date study product hold continuing for another reason'.
Date study product hold continuing for another reason	Record the date that the participant would have been instructed to resume study product based on the resolution of the reason indicated on this form.

Randomization

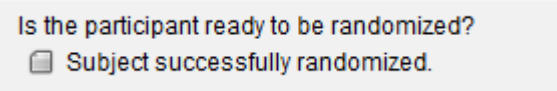
Purpose:

This form is used to officially randomize a participant for MTN-034. This form is completed at Enrollment for participants who have provided informed consent and who are eligible to participate in the study.

General Instructions:

Complete this form for each participant who will enroll in MTN-034 indicating the participant is ready to be randomized. The Randomization Date and Time will be auto-populated from Medidata Balance into Medidata Rave. Upon saving this form, the participant's treatment assignment will be generated in Medidata Balance. The item "Did the participant meet all eligibility criteria?" on the Eligibility Criteria form must be completed before the Randomization form in order for the randomization to be successful.

Item-specific Instructions:

Field	Instructions
Is the participant ready to be randomized?	Select 'Yes' and Save the form. If the participant is successfully randomized, a note will appear under this item as shown below:  If randomization was not successful, this message will not appear, and the Randomization Date and Time will not automatically populate. If successful, the participant will be assigned to a product sequence and to participation in Serial IDI in the Medidata Balance module.
Randomization Date and Time	Once "Is the participant ready to be randomized?" is saved as 'Yes', then the randomization Date and Time will automatically populate. The Randomization Time will be auto-populated in Coordinated Universal Time (UTC).
Randomization ID	Once "Is the participant ready to be randomized?" is saved as "Yes" and the form is saved, the Randomization ID will automatically populate. The Randomization ID should be used to identify those participants who are randomized to Serial IDI. Refer to the study SSP for instructions for Serial IDI randomization.

Ring Assessment

Purpose:
This form is used to document assessment of ring insertion.

General Instructions:
This form is dynamically added to the study visit folder when the Ring Insertion and Removal form is completed and "Was a ring inserted at this visit?" is equal to "Yes".

Item-specific Instructions:

Field	Instructions
Did the participant attempt to insert a ring herself?	If "No, inserted by study staff", provide a response in the "please describe the reason' in the text box provided. If "Yes", skip to item 3.

Field	Instructions
Based on your assessment and her feedback, how easy or difficult was it for the participant to insert the ring?	Use the following guidelines to categorize the level of ease or difficulty: - Very difficult: Required 3+ attempts and/or caused pain, severe discomfort - Difficult: Required 2 attempts and/or caused moderate discomfort - Easy: Required 1 attempt with some ring repositioning and/or caused mild discomfort - Very easy: Smooth insertion and positioning in one attempt with no discomfort If the number of attempts and the level of discomfort experienced match different response options, choose the response option that corresponds with the more difficult experience. For example, if a participant inserted the ring after two attempts but it caused pain, select "very difficult." If "Easy" of "Very easy" skip to item 5. If "Very difficult" or "Difficult" at least one item under "If Very difficult or Difficult", why? (4a-4f) should be marked. If "Other", then specify relevant details in the "If, Other, specify" text field provided.
Did the participant require any help from the clinician to insert the ring?	If "Yes" provide a response for If "Yes", specify. If "No", skip to item 6.
Did study staff verify that the ring was in place?	If "No" provide a response for If "No", specify and end the form. If "Yes", skip to Item 7
If "Yes", upon verifying, was the ring correctly inserted by the participant?	If "No" provide a response for If "No", specify. If "Yes", end of form.

Ring Insertion and Removal

Purpose:
This form documents if a vaginal ring was provided and/or returned to the participant.

General Instructions:
Complete this form starting at the Study Product Initiation visit up through the participant's scheduled Product Use End Visit within the period in which the participant has been randomized to receive the ring. If the participant permanently discontinues from study product prior to her PUEV, this form is discontinued. Complete this form during Period 3 at each visit where a participant chooses to use the ring.

Field	Instructions
No ring provided	If a vaginal ring was not provided at a study visit, skip the remaining questions within the RING PROVISION section and go to “RING RETURN”.
Was a ring inserted at this visit?	If “Yes’, the Ring Assessment form will be added to the visit folder for completion. If “No”, specify the reason(s) why the ring was not inserted.
Did the participant have a ring in place at the start of the visit?	This item is required even if it is the Enrollment visit or a product switch visit.
Ring not returned	This item is required even if it is the Enrollment visit or a product switch visit. If a vaginal ring was not returned at a study visit, end the form. If a vaginal ring was returned, provide the date the ring was returned in the specified field.
Date returned ring #1 was provided	This should be the date the Ring #1 was **provided** to the participant.
Date returned ring #1 was inserted	This should be the date the Ring #1 was **inserted**. If this date is Unknown, mark the “Unknown’ box.
Date returned ring #1 was removed	This should be the date the Ring #1 was **removed**. If this date is Unknown, mark the “Unknown’ box.
Date returned ring #2 was Provided/Inserted and Removed	Enter the ‘Provided’ date, ‘Inserted’ and ‘Removed dates’, OR mark the “Unknown” if the Inserted or Removed dates are unknown. These dates or the “Unknown” should only be provided if there are **2** rings returned. If only 1 ring was returned, skip to “Was the ring(s) stored.
Was the ring(s) stored?	Select “Stored” if the ring was collected and stored at this visit and end the form. If the ring was not collected or was not stored at this visit, specify the reason why the ring was either not collected and/or stored.

Screening Date of Visit

Purpose:

This form is used to document the date of the participant’s Screening Visit.

General Instructions:

If screening procedures conducted across multiple days, this date should correspondent to the first day where screening procedures are done. If a participant has a second screening attempt, update this form with the date from the second screening attempt (do not complete a new form).

Screening Menstrual History

Purpose:
This form is used to document information on the participant's menstrual history, including menstrual-related symptoms and abnormal bleeding patterns.

General Instructions:
Complete this form at the V1.0 - Screening Visit. Please record any baseline abnormalities (e.g. abnormal bleeding patterns such as amenorrhea, menorrhagia, metrorrhagia or menstrual symptoms which contribute to a medical condition (e.g. dysmenorrhea, pre-menstrual syndrome) on the Baseline Medical History Log form.

Item-specific Instructions:

Field	Instructions
Date of assessment	Record the date the medical history condition/event was reported by the participant. A complete date is required.
First day of last menstrual period	Record the first day of the participant's most recent menstrual period. At a minimum, the month and year are required. If the participant has been amenorrheic for the past 6 months, mark "Amenorrheic for past 6 months" and leave the "First day of last menstrual period" blank.
Last day of menstrual period	Enter the last day of the last menstrual period (last day of bleeding). At a minimum, the month and year are required. If the participant is currently on her menses, check "Ongoing" and leave the last day of last menstrual period blank.
Provide additional details as needed to describe the participant's baseline menstrual bleeding pattern.	During follow-up, occurrences of genital bleeding will be compared to the participant's baseline bleeding pattern, as documented on this form. With this in mind, use the text field to describe, as best as possible, any additional details on the participant's usual genital bleeding pattern. Include details such as the number of sanitary pads typically used, any spotting that is experienced, and any additional details on amount/heaviness of flow. Note that up to 400 characters are allowed in this field.

Seroconverter Laboratory Results

Purpose:
This form is used to document HIV confirmatory results from local lab confirmatory HIV testing.

General Instructions:
Record HIV test results on this form as they become available.

Item-specific Instructions:

Field	Instructions
Were T Cell Subsets collected for testing?	If "Yes", a collection date and result is required. If "No", skip to "Were Absolute CD4+ collected for testing?"
T Cell SUBSETs collection date	A complete date is required if T Cell Subsets were collected.
Absolute CD4 collection date	A complete date is required if "Absolute CD4+ were collected
Were Absolute CD4+ collected for testing?	If "Yes", a collection date and result is required. If "No", skip to "Was HIV RNA PCR testing completed?"
CD4%	If automatically calculated, record the CD4 percentage that was reported for the specimen in the item, "Absolute CD4%". If the CD4 percentage is not available (i.e., it was not reported and would have to be manually calculated), mark the "not available" box.
Was HIV RNA PCR testing completed?	If "Yes", a collection date and result is required. If "No", skip to "Was seroconverter plasma collected for storage?"
HIV RNA PCR collection date	A complete date is required if HIV RNA PCR were collected.
	Note that the ">" symbol is "greater than", the "<" symbol is "less than" and the "=" is "equal to" the result provided. When completing this item on the form within Rave, select the "greater than", "equal to", or "less than" from the drop-down menu.
HIV RNA PCR	Record the participant's HIV RNA PCR result exactly as it appears on the lab report source documentation, regardless of whether the result is more or less than the limit of detection for the assay. If the HIV RNA PCR target is not detected, mark the "target not detected" box and leave the HIV RNA PCR field blank. If the HIV RNA PCR result is below the limit of detection, indicate that the results is "less than" the value provided. If HIV RNA PCR testing is not done/not collected, skip to the Seroconverter Plasma Storage items.
HIV RNA PCR Kit	Select the HIV RNA PCR testing kit that was used. If completing a paper form, mark the kit from the response options provided. When completing the form within Rave, select the kit from the drop-down field.
HIV RNA PCR Kit Lower limit of detection	Select "20" or "40" as the lower limit of detection or record the viral copies/mL
Seroconverter Plasma storage collection date	A complete date is required if Seroconverter plasma for storage was collected.
Seroconverter Plasma storage	Mark "Stored" or "Not stored", if not stored, provide a reason it was not stored in the "Seroconverter Plasma storage reason not stored" field.

Social Benefits and Impacts

Purpose:

This form documents if a social benefit and/or impact has been reported by the participant during the study. **General Instructions:**
This form is completed quarterly during follow-up and is a participant administrated form. The questions should be read aloud in the participant's preferred language. If a social harm or a social benefit is reported on this form, complete a Social Benefit log form or a Social Impact log form, as applicable.

Field	Instructions
At any time during the past 3 months, have you experienced a positive change in your life related to your study participation?	Select 'Yes' or 'No'. If 'Yes' is selected, then the "Social Benefit" form appears in the visit folder and can then be completed
At any time during the past 3 months, have you experienced a negative change, event, or experience in your life related to your study participation?	Select 'Yes' or 'No'. If 'Yes' is selected, then the "Social Impact" form appears in the visit folder and can then be completed

Social Benefit Summary

Purpose:
This form documents if a social benefit has been reported by the participant during the study.

General Instructions:
This form is present within the "Ongoing Logs" folder. Selecting 'Yes' in the "Social Benefit Yes/No" prompt will add the "Social Benefit" form.

Field	Instructions
Did a social benefit occur?	Select 'Yes' or 'No'. If 'Yes' is selected, then the "Social Impact" form appears dynamically and can then be completed.

Social Benefits Log

Purpose:
This form records the occurrence and update of social benefits reported by participants at any time during the study.

General Instructions:
This form should be completed only when a participant has a positive experience associated with study participation. A new form should be completed whenever a new social impact is recorded. This form can also be updated, as applicable. Once the Social Benefit Log form has been created, complete one page per social benefit when entering in the study database. To add an additional social benefit within Medidata Rave, clicking "Add a new Log line" will add an additional page for a new social benefit to be completed. If completing social benefits on paper, print and complete one form for each social benefit.

Field	Instructions
Reported at Visit	Select the visit at which the social harm was reported. If the social harm was reported at an interim visit, select "interim visit" and record the interim visit code using the following format: (x)x.x.
The social benefit was related to:	Record the applicable social benefit by selecting from the drop-down menu if completing electronically. If completing this form on a paper form, mark the applicable social impact type from the list.
What impact did this situation have on the participant's quality of life?	Assess the impact of the social benefit on the participant's quality of life based on participant self-report.
Person 1, Person 2, Person 3	For each person the social benefit involved, select the type of relationship. If the relationship is "other", please specify in the text field provided. Mark 'child' if the person the social benefit involved is biologically the child of the participant, etc.

Social Impact Summary

Purpose:
This form documents if a social impact has been reported by the participant during the study.

General Instructions:
This form is present within the "Ongoing Logs" folder. Selecting 'Yes' in the "Social Impact Yes/No" prompt will add the "Social Impact" form.

Field	Instructions
Did a social impact occur?	Select 'Yes' or 'No'. If 'Yes' is selected, then the "Social Impact" form appears dynamically and can then be completed.

Social Impact Log

Purpose:
This form records the occurrence, update, and resolution of adverse social harms reported by participants at any time during the study.

General Instructions:
This form should be completed only when a participant has a negative experience associated with study participation. A new form should be completed whenever a new social impact is reported. This form should also be updated, as applicable.

To add an additional social impact within Medidata Rave, clicking "Add a new Log line" will add an additional page for a new social impact to be completed.

Field	Instructions
Onset date	Record the date the negative experience first started. At a minimum, a month and year are required.
Reported at Visit	Select the visit at which the social harm was reported. If the social harm was reported at an interim visit, select "interim visit" and record the interim visit code using the following format: (x)x.x.
Social Impact Type	Record the applicable social impact type by selecting from the drop-down menu if completing electronically. If completing this form on a paper form, mark the applicable social impact type from the list.
What impact did this situation have on the participant's quality of life?	Assess the impact of the social harm on the participant's quality of life based on participant self-report.
Record current status	This item may be updated at subsequent visits.
Closure Date	Record the closure date if the current status is selected as "unable to resolve; no further action taken", or "resolved". Leave this item blank if the current status is selected as "Unresolved" or "Unresolved at end of study".

Specimen Storage

Purpose:
This form is used to document collection and storage of gram stain, and plasma, vaginal swab for biomarkers and qPCR (microbiota), cervical swab for biomarkers, CVL for biomarkers, Cervical Cytobrush, HSV-2, and Dried Blood Spot for PK specimens by the local site laboratory during follow-up.

General Instructions:
Complete this form at Enrollment, Visits 4-9, 11-16, 18-22, and Visit 23/PUEV, as indicated at other visits during follow-up.

Item-specific Instructions:

Field	Instructions
Was [specimen] sample collected?	Select 'Yes' or 'No'. If 'No', then do not complete the date of collection and storage item(s). Spilhaus CRS only: Cervical Cytobrush is only required to be collected at the Spilhaus site. For all other sites, mark "No" for "Was sample collected?" and leave the remaining entries blank.
Date of Collection	Record the date that the first specimen(s) was collected, NOT the date the results were reported or recorded on the form for this visit. A complete date is required.

Field	Instructions
Stored/Not Stored	Enter 'Stored' for specimens that are collected and sent to the lab for processing. If the specimen is required to be stored, but for some reason it is not stored, select 'Not stored' and record the reason in the corresponding "If not stored, specify reason" text field provided.

STI Test Results

Purpose:
This form is used to document STI test results performed by the local site laboratory.

General Instructions:
Complete this form at the Screening Visit, Enrollment Visit, Visits 6, 9, 13, 16, 20, Visit 23/PUEV, and as indicated during the study.

If any or all of the lab tests listed on this form are repeated (re-drawn) between the Screening and Enrollment Visit, document the repeated results on the same STI Results form. If the participant enrolls, the updated results should be submitted into the study database.

At Screening, record STI diagnoses in Baseline Medical Conditions Log form, when applicable.

Item-specific Instructions:

Field	Instructions
Date of collection	Record the date that the first specimen(s) was collected, NOT the date the results were reported or recorded on the form for this visit. A complete date is required.
Was a sample done/collected?	Select 'Yes' or 'No' for each test. If 'No', then the remaining items for that specific test do not need to be completed.
Not reported/Not done	Select 'not reported' or 'not done' in the event that a specimen was not collected, or if the specimen was collected, but a result is not available due to specimen loss or damage.
Results Reporting	During follow-up, if a test result(s) recorded within this form indicates that the participant has a new (or increased severity) laboratory-confirmed infection or diagnosis, this infection/diagnosis must be recorded as an adverse event in the Adverse Event Log form.
Was a vaginal pH done?	If a vaginal pH was not done, then do not complete the "Date of Collection" or "Vaginal pH" item.
Vaginal pH	Record the vaginal pH (e.g. 4.1).
Vaginal wet prep	If "Vaginal wet prep" was not done or not collected, select the 'No' option for "Was a vaginal wet prep sample collected?", and do not complete the "Date of collection" or corresponding test results. If a vaginal wet prep was performed but not all assays were completed, select "Not done" for each uncompleted wet prep assay.
Homogenous vaginal discharge	Select 'Positive' if homogeneous vaginal discharge was observed.

Field	Instructions
Whiff test	Select 'Positive' if whiff test were observed.
Clue Cells ≥20%	Select 'Positive' if 20% or more of the cells were clue cells.
Trichomonas vaginalis	Select 'Positive' if trichomonads were observed.
Buds and/or hyphae (yeast)	Select 'Positive' if yeast buds and/or hyphae were observed
Syphilis Serology	If "Syphilis serology" was not done or not collected, select the 'No' option for "Was a sample collected for Syphilis testing?", and do not complete the "Date of collection" or corresponding test results. If the syphilis screening test was done, complete the "Date of Collection" and the test result (either 'Non-reactive' or 'Reactive' or 'Not reported' in the event that a specimen was collected, but the result is not available due to specimen loss or damage). If the test result is 'Reactive', then complete the remaining Syphilis items. If 'non-reactive', then proceed to the Trichomonas items.
Syphilis titer	Record the titer in the format 1: XXXX. When completing this form in Medidata Rave, please include the "1:" in the same field for the syphilis titer.
Syphilis confirmatory test	If the result of the Syphilis screening test is 'Reactive,' complete the Syphilis confirmatory test results.
Trichomonas Testing	If Trichomonas testing was not done or not collected, select 'No' for "Was a sample collected for Trichomonas testing?" and do not complete the 'Collection date' or corresponding test result. If the specimen was collected, complete the 'Collection date' and the test result.
NAAT for GC/CT	If "NAAT for GC/CT" was not done or not collected, select the 'No' option for "Was a vaginal sample collected for NAAT for GC/CT?" and do not complete the "Date of collection" or corresponding test result.
N. gonorrhea	If "N. gonorrhea" was not done or not collected, select the 'Not done' option. If the specimen was collected, complete the "Date of collection" and the test result.
C. trachomatis	If "C. trachamotis" was not done or not collected, select the 'Not done' option. If the specimen was collected, complete the "Date of collection" and the test result (either 'Positive' or 'Negative').
Hepatitis B Surface Antigen (HbsAG)	If "Hepatitis B Surface Antigen (HbsAG)" was not done or not collected, select the 'No' option for "Hepatitis B Surface Antigen (HbsAG)" and do not complete the "Date of collection" or corresponding test result.

Study Termination

Purpose:
This form is used to document a participant's exit from the study (i.e., scheduled or early study termination).

General Instructions:
This form is present within the Discontinuations folder. Complete this form for each enrolled participant at either the scheduled exit/end of study visit or when the participant is no longer participating in the study.

Item-specific Instructions:

Field	Instructions
Date of Study Exit	A complete date is required.
Did the participant complete the study?	Select 'Yes' or 'No'. Select 'Yes' if the participant completed her Visit 24 Visit/Phone Contact – Week 73 Visit. Select 'No' if the participant terminated the study early.
Primary reason for non-completion	Select one reason from the drop-down menu if the participant did not complete the study.
If withdrawal of consent by participant, investigator decision, or other, specify	If the primary reason is 'Withdrawal of consent by participant', 'Investigator decision', or 'Other', then provide additional details in the text field provided.
If death, enter date of death	If the primary reason for study non-completion is 'death', provide the date of death. A complete date is required.
Was termination associated with an adverse experience?	Select 'Yes', 'No', or 'Don't know'. If 'No' or 'Don't Know', then this is the end of form.
If yes, select applicable Adverse Event	Select the applicable Adverse Event from the list of AEs in the drop-down menu. In situations where more than one AE are associated with termination, record the AE that most strongly influenced the decision to terminate.

Tablet Assessment

Purpose:
This form is used to document whether the participant's first tablet dose was observed at the clinic.

General Instructions:

This form is dynamically added to the study visit folder when the PrEP Provisions and Returns form is completed and “Number of tablet bottles provided” has a response of either 1 or 2.

Item-specific Instructions:

Field	Instructions
2a. If "No", specify reason	Select the most appropriate reason from the dropdown list.
3. Explain the response for the reason provided why the participant's first tablet dose was not directly observed at the clinic.	If Item 2 is “No”, provide further information about why the participant’s first dose was not observed in this text field.
5. Based on your assessment and her feedback, how easy or difficult was it for the participant to swallow the tablet?	Use the following guidelines to categorize the level of ease or difficulty: - Very difficult: Required 3+ attempts and/or caused pain, severe discomfort - Difficult: Required 2 attempts and/or caused moderate discomfort - Easy: Required 1 attempt and/or caused mild discomfort - Very easy: Smooth swallowing in one attempt with no discomfort If the number of attempts and the level of discomfort experienced match different response options, choose the response option that corresponds with the more difficult experience. For example, if a participant swallowed the pill after two attempts but it caused pain, select “very difficult.”

Vital Signs

Purpose:
This form is used to document the participant’s vital signs.

General Instructions:
Complete this form at Screening, and Visits 4-9, 11-16, 18-22, Visit 23/PUEV and when clinically indicated during follow-up.

Item-specific Instructions:

Field	Instructions
Date of Assessment	Enter the date the participant’s vital signs were measured. A complete date is required.

Field	Instructions
Height	Enter the participant's height in centimeters. Per protocol, height is required only at the Screening Visit, and whenever calculated creatinine clearance is performed. At follow-up, height measured at the screening visit may be used to calculate calculated creatinine clearance. Refer to MTN-034 SSP section 7 for additional guidance. If height is not assessed, mark the "not done" checkbox.
Weight	Enter the participant's weight in kilograms. Weight is required at Screening, Visit 23- PUEV If weight is not assessed, mark the "not done" checkbox.
Body Temperature	Enter the participant's temperature and associated units (Celsius or Fahrenheit). The value can be reported up to one decimal (e.g. 37.2˚ C).
Systolic BP*	Enter the participant's systolic blood pressure in mmHg (e.g. 120 mmHg).
Diastolic BP*	Enter the participant's diastolic blood pressure in mmHg (e.g. 60 mmHg).
Blood Pressure Severity Grade	Record the severity grade by selecting from the drop-down menu, when applicable. See below for more information on grading.
Blood Pressure adverse event, if applicable	If the lab value meets AE reporting criteria, select the corresponding AE within the drop-down menu. Please note that the AE must be entered within the Ongoing Logs folder prior to completing this form in order to link the associated AE. If the AE is not reportable, mark the "Not reportable as an adverse event" box.
Pulse	Enter the participant's pulse in beats per minute (e.g. 60 beats/min).
Respirations	Enter the participant's respiratory rate in breaths per minute (e.g. 14 breaths/min).

* The most recent BP reading that is used for clinical management should be recorded on the Vital Signs form. In instances where the BP has already been entered within Medidata Rave, these fields (Systolic BP and Diastolic BP) can be updated within the form and re-saved.

Reporting Severity Grade for Blood Pressure

- Record the severity grade on the form by selecting from the drop-down menu for Blood pressure. If the BP does not meet criteria for severity grade 1 or greater per the DAIDS Toxicity table (Version 2.1), select the 'Not gradable' option.

- The severity grade options are as follows:
    - Not gradable
    - Grade 1 – Mild
    - Grade 2 – Moderate

  - Grade 3 – Severe
  - Grade 4 – Potentially life-threatening

- If the lab value falls between two calculated severity grade ranges, assign it the higher grade. Example: If systolic is grade 2 and diastolic is grade 1, assign BP grade 2.

- Record any Grade 1 or higher BP values on the “Baseline Medical History Log” or “Adverse Event Log” form(s) as applicable.