CRF Completion Guidelines

MTN-043

Version 1.0 (06-JUL-2020)

CRF Completion Guidelines

Protocol Name:	Phase 3B, Randomized, Open-Label, Safety, and Drug Detection Study of Dapivirine Vaginal Ring and Oral TRUVADA® in Breastfeeding Mother-Infant Pairs
Protocol Number:	MTN-043
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CRF Summary Table

CRF Name	Log form	Translated	Participant type:
Additional Study Procedures	NO	NO	Mom
Adverse Event Log	YES	NO	Mom & Infant
Adverse Event Y/N	NO	NO	Mom & Infant
Baseline Behavioral Assessment	NO	**YES**	Mom
Baseline Medical History Log	YES	NO	Mom & Infant
Baseline Medical History Y/N	NO	NO	Mom & Infant
Behavioral Assessment - Follow Up	NO	**YES**	Mom
Behavioral Assessment - Month 3 Follow Up	NO	**YES**	Mom
Chemistry Panel	NO	NO	Mom
Concomitant Medications Log	YES	NO	Mom & Infant
Concomitant Medications Y/N	NO	NO	Mom & Infant
COVID-19 Behavioral Assessment	NO	YES	MOM
Demographics	NO	**YES**	Mom
Discontinuation of Study Product	NO	NO	Mom
Edinburgh Postnatal Depression Scale	NO	**YES**	Mom
Enrollment	NO	NO	Mom & Infant
Feeding Assessment - Follow Up	NO	**YES**	Mom
Feeding Assessment - Screening and Enrollment	NO	**YES**	Mom
Feeding Inventory	NO	**YES**	Mom
Follow-up Visit Summary	NO	NO	Mom
Follow-up Visit Y/N	NO	NO	Mom & Infant
Hematology	NO	NO	Mom

HIV Confirmatory Results	NO	NO	Mom
HIV Test Results	NO	NO	Mom
IDI Tracking	NO	NO	Mom
Inclusion/Exclusion Criteria	NO	NO	Mom
Infant Additional Study Procedures	NO	NO	Infant
Infant Ages and Stages Assessment	NO	NO	Infant
Infant Demographics	NO	NO	Infant
Infant Follow-up Visit Summary	NO	NO	Infant
Infant HIV Confirmatory Results	NO	NO	Infant
Infant Inclusion/Exclusion Criteria	NO	NO	Infant
Infant Interim Visit Summary	NO	NO	Infant
Infant Specimen Storage	YES	NO	Infant
Infant Vital Signs	NO	NO	Infant
Informed Consent	NO	NO	Mom & Infant
Interim Visit Summary	NO	NO	Mom
Missed Visit	NO	NO	Mom & Infant
Participant Identifier	NO	NO	Mom & Infant
Participant Type	NO	NO	Mom & Infant
Pelvic Exam	NO	NO	Mom
Pharmacy Dispensation	NO	NO	Mom
Physical Examination	NO	NO	Mom & Infant
Pregnancy History	NO	NO	Mom
Pregnancy Outcome Log	NO	NO	Mom
Pregnancy Report	NO	NO	Mom
Pregnancy Test Results	NO	NO	Mom
PrEP Provision and Returns	NO	NO	Mom

Product Hold Log	YES	NO	Mom
Product Hold Y/N	NO	NO	Mom
Protocol Deviations Log	YES	NO	Mom & Infant
Protocol Deviations Y/N	NO	NO	Mom & Infant
Randomization	NO	NO	Mom
Ring Adherence	NO	NO	Mom
Ring Adherence Y/N	NO	NO	Mom
Ring Assessment	NO	NO	Mom
Ring Insertion and Removal	NO	NO	Mom
Screening Date of Visit	NO	NO	Mom & Infant
Seroconverter Results	NO	NO	Mom & Infant
Social Impact	NO	**YES**	Mom
Social Impact Log	YES	NO	Mom
Social Impact Y/N	NO	NO	Mom
Specimen Storage	YES	NO	Mom
STI Test Results	NO	NO	Mom
Study Termination	NO	NO	Mom & Infant
Tablet Adherence	NO	NO	Mom
Tablet Adherence Y/N	NO	NO	Mom
Tablet Assessment	NO	NO	Mom
Urine Test Results	NO	NO	Mom
Vaginal Practices	NO	NO	Mom
Vital Signs	NO	NO	Mom

CRF Completion Guidelines

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-043. 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-043 Atlas web page: https://atlas.scharp.org/cpas/project/MTN/043/begin.view?

General Guidelines

- 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, Baseline Medical History, Inclusion/Exclusion Criteria and Product Hold

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).
    - Interim Visits - Infant (see section on "Infant Interim Visits" on how to add interim visits to a participant's casebook).
    - Pregnancy
    - Seroconversion folders
- The following CRFs can be added, if needed, to a participant's Screening and/or Enrollment folder:
    - STI Test Results – Enrollment Visit
    - Urine Test Results – Enrollment Visit
    - Urine Test Results – Screening Visit
    - Vaginal Practices – Enrollment Visit

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" to add a mother's interim visit or "Interim Visit - Infant" to add an infant's interim visit. An "Interim Visit" or "Interim Visit – Infant" folder will appear in the participant's casebook.
- Open the Interim Visit or Interim Visit - Infant folder to access the "Interim Visit Summary" or "Infant Interim Visit Summary" form. On the Interim Visit Summary or Infant 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 or Infant Interim Visit Summary form, enter the visit date as the earliest date visit procedures performed at the visit began.

Loading of Forms in Visit Folder

- Medidata Rave will add forms to a visit folder in a participant's casebook based on specified responses on forms. Below are a few key examples.
  - **Example 1**: Follow-up Visit Y/N
    - If item "Did the participant complete this visit?" is marked 'Yes', the Follow-up Visit Summary form and any other required forms will be added to the visit folder.
    - If item "Did the participant complete this visit?" 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.
    - If item "Did the participant complete this visit?" is marked 'No', no other forms will appear in the visit folder.
  - **Example 2**: Interim Visit form
    - Forms under " What study procedures were completed at this visit? Select all that apply." on the Interim Visit form that are checked will be added to the Interim Visit folder.

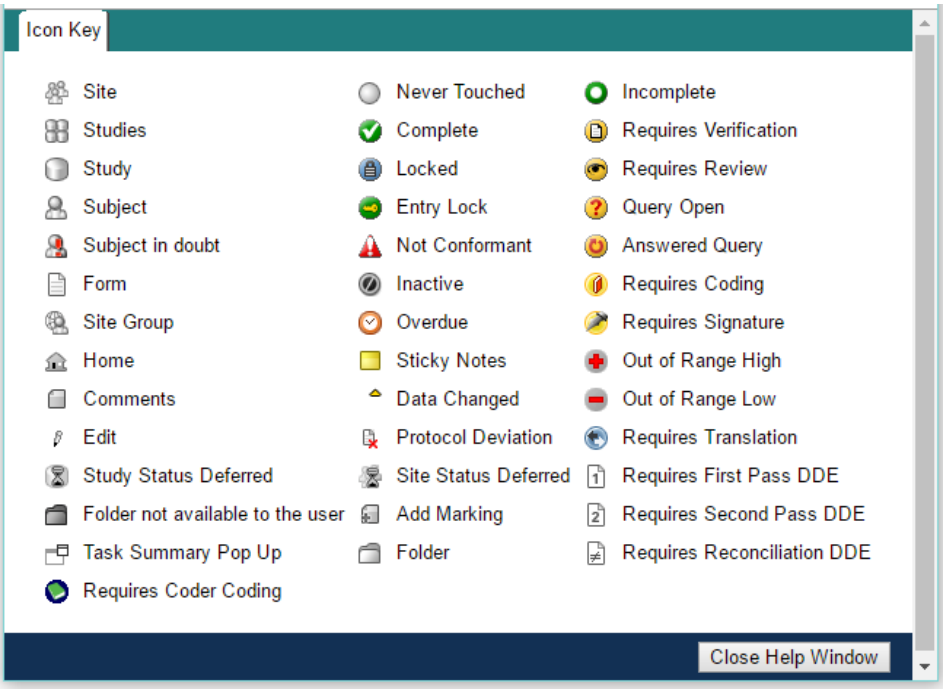
Dynamic Search Lists

- Dynamic searchlist functionality is used to look up Adverse Events data *(AE log line, start date, and term, e.g. "05JAN2020-FEVER")*.
- Dynamic searchlist functionality is present on the following forms: Concomitant Medications, Chemistry Panel, Discontinuation of Study Product, Hematology, Pelvic Exam, Product Hold Log, Study Termination, and Urine Test Results
- For Example:
  - An AE of '*FEVER*' started on 05JAN2020 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

A link to an Icon Key is available on the PTID (Subject)-level page. The key contains pictures and descriptions of the icons used in Rave. Below is a screen shot of the Icon Key.

Figure 1. Icon Key

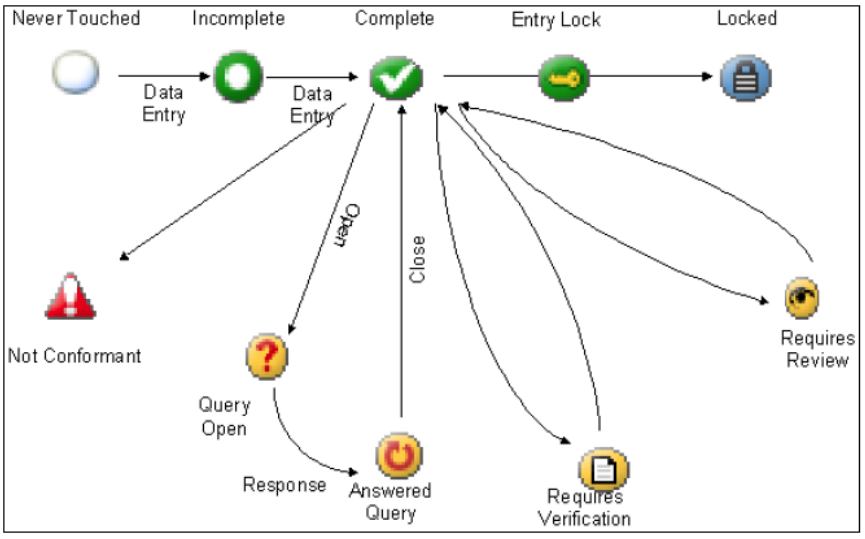


Icon Progression

The life cycle of participants, folders, forms, and fields follows a logical progression starting with “never touched” and moving toward “complete” and “locked”. Graphical icons are used throughout Rave to show 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 displays all pending tasks for the study. At the site level it displays the number of participants with outstanding tasks that need site review (see Figure 3); for example, open queries. Clicking on the arrow next to the task expands it to show the specific participants with open queries (see Figure 4). Clicking on a PTID will open the participant's casebook.

Figure 3. Site-Level Task Summary

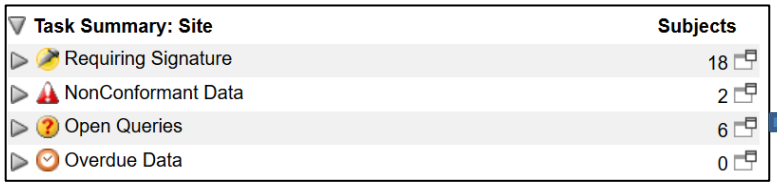
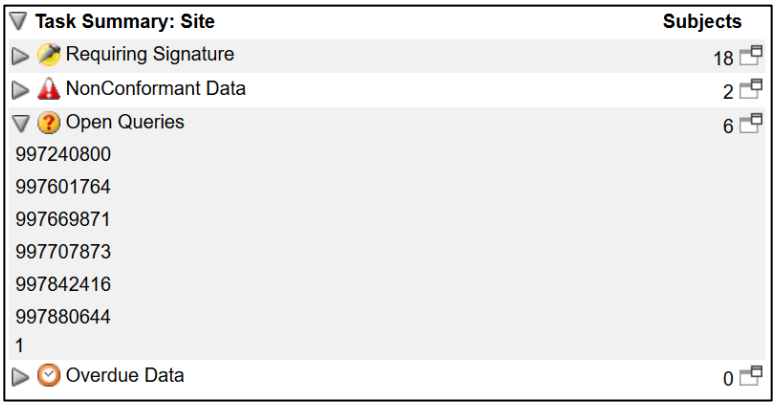
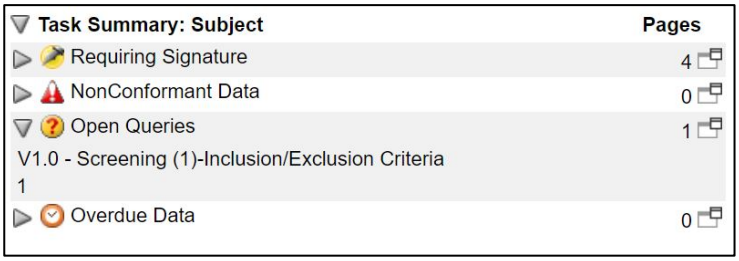


Figure 4. Site-Level Task Summary



At the Subject level the Task Summary displays the number of pages for that participant that need site review. In Figure 5 below, there is one open query on the Inclusion/Exclusion Criteria form at V1.0 – Screening. In the expanded task summary view, clicking on this form link will open the form.

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.

Recording Dates – Rave Form and/or Paper CRF

- 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.
- Month abbreviations are shown below. In Rave EDC, these abbreviations are in a drop-down list in the month field.

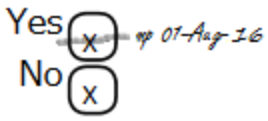
Month	Abbreviation	Month	Abbreviation
January	**JAN**	July	**JUL**
February	**FEB**	August	**AUG**
March	**MAR**	September	**SEP**
April	**APR**	October	**OCT**
May	**MAY**	November	**NOV**
June	**JUN**	December	**DEC**
Unknown	**UNK**		

For example, record September 20, 2016 as: 

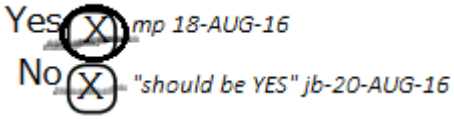
Data Corrections and Additions - Rave Form and/or Paper CRF

- Data fields may need to be updated or corrected, such as in response to a query or after site review.
- If the source document is non-CRF in nature (i.e., lab report), it is sufficient to make data updates in the study database itself. If a paper CRF was completed, make changes to the paper CRF first and then enter the updated data into Rave.
- Use the standards below when changing, clarifying, or amending data:
  - Draw a single horizontal line through the incorrect entry. Do not obscure the entry or make it unreadable with multiple cross-outs.

- Place the correct or clarified answer near the previous response.
- 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:



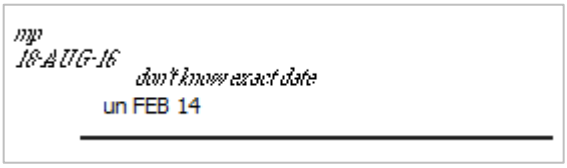
- If the correct answer has previously been crossed out, do the following:
  - circle the correct response,
  - write an explanation in the white space near the response, and
  - initial and date all corrections as shown below:



Missing and Unknown Data - Rave Form and/or Paper CRF

On paper CRF, if the answer to a required question is unknown, unavailable, or if the participant refuses to answer, draw a single horizontal line through the applicable question and initial and date. 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 that are refused, missing, unknown, or not applicable, regardless of whether they are marked as such during the initial 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.

Form-Specific Instructions

Additional Study Procedures

Participant Type: Mother

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.

Adverse Event Y/N

Participant Type: Mother and Infant

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

General Instructions:
This form is present within the "Ongoing Logs" folder. Selecting 'Yes' to the "Has the participant experienced an adverse event during the study?" prompt will add the "Adverse Event Log" to the "Ongoing Logs" folder.

Adverse Event Log

Participant Type: Mother and Infant

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 AE 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).
At which visit was this AE first reported?	Select a visit from the dropdown list. If "Interim visit" was selected for "At which visit was this AE first reported?", an interim visit code is required.
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.
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) or protocol-specific grading scales.
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" to the DPV vaginal ring, is the AE related to the drug (dapivirine) or device (ring itself or ring insertion)?	A response is required if the mother participant is randomized to the DPV vaginal ring and the AE is deemed "related" to study product. If the participant is randomized to oral Truvada, this item should be skipped. 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.
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-043. ***Dose increased:*** This option does not apply and should not be selected in MTN-043. ***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 Discontinuation of Study Product 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. Ensure Product Hold Y/N and Product Hold Log are completed. ***Not applicable*****:** Select if the AE's onset date is on or after the date the participant permanently discontinues study product use. Select for all infant AEs.
Other actions	Select 'None' or check all that apply. *Medication(s)*: Select 'Medication(s)' 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 "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.

Field	Instructions
Status/Outcome	***Recovered/resolved:*** AE is no longer present or has returned to baseline 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. ***Recovered/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?".
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.
SAE/EAE Onset Date	Provide the date the adverse event first meets ICH criteria for seriousness. A month and year are required.
Was this AE a worsening of a baseline medical condition?	Select "Yes" or "No", depending on if this AE was a worsening of a baseline medical condition?
Comments	This is a required field and is used to document the relationship to study product.

Baseline Medical History Y/N

Participant Type: Mother and Infant

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 Screening folder and is completed at the Screening Visit and updated at the Enrollment 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 Screening Visit 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

Participant Type: Mother and Infant

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 Screening folder after the "Baseline Medical History Y/N" 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 history or pregnancy history as well as any conditions identified during the pelvic exam, physical exam, or laboratory testing, and any congenital anomalies identified at birth for the infant.
- 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.
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 severity grade reported in Baseline Medical History should reflect the status at baseline. • If the severity grade has increased in severity or frequency during the study AE reporting period, then this should be reported as an AE and the Severity 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 protocol-specific grading tables or the current version of the *Division of AIDS (DAIDS) Table for Grading the Severity of Adult and Pediatric Adverse Events* (including relevant appendices/addendums).

Field	Instructions
Start date of medical history condition/event	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.
Date medical condition/event ended/resolved	A date is 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.

Baseline Behavioral Assessment

Participant Type: Mother

Purpose:
This form is used to provide data on the participant behavior.

General Instructions:
Use this form to report participant behavior at Enrollment. Do not go back and alter responses after the participant has been enrolled.

Read each question and all response options aloud to the participant.

Field	Instructions
1. .In general, how worried are you about the effect of [product] on your own health?	Select an option.
2. .In general, how worried are you about the effect of using [product] on your baby's health?	Select an option.
3 .Have you received breastfeeding or feeding-related advice or care from any of the following people? *Check all that apply*	Read each response option out loud, and select a response for each item.
4. .Besides yourself, who has the most influence on your decisions about feeding the baby?	Select an option from the dropdown menu. **If "**a..If another family member, specify" or "b..If Other, specify", provide details in the applicable text box.
5. .Now I will ask you whether important people in your life support your product use. Are the following people supportive, not supportive or don't know about your use of [product]?	Read each response option out loud, and select a response for each item using the dropdown menus. If "h..Is there another important person in your life?" is "Yes", specify, and provide an answer for "If yes, is this person…?" using the dropdown menu.
6. .I am now going to read you some statements about how often you receive support from people around you. By "support" I mean financial, social, emotional or other forms of help. Please tell me whether you experience or feel these things always, most of the time, some of the time, rarely or never.	Read each response option out loud, and select a response for each item using the dropdown menus.
7. .Has a doctor, nurse, or other professional ever talked with you about depression (or problems with emotions, nerves or mental health)?	Select 'Yes' or 'No'. ***If no, skip to item 9.***

8. .When did the health professional talk to you about depression (or problems with emotions, nerves or mental health)?	Mark all that apply.
9. .Have you ever wanted help for depression (or problems with emotions, nerves or mental health) from a doctor, nurse, or other professional?	Select 'Yes' or 'No'.
10. .Has a doctor, nurse, or other professional told you that you had depression (or problems with emotions, nerves or mental health)?	Select 'Yes' or 'No'. If "No", end of form
11. .When did the health professional tell you that you had depression (or problems with emotions, nerves or mental health)?	Mark all that apply
12. .Did you get counseling or any other treatment for your depression (or problems with emotions, nerves or mental health)?	Select 'Yes' or 'No'.

Behavioral Assessment – Follow Up

Participant Type: Mother

Purpose:
This form is used to provide data on the participant behavior.

General Instructions:
Use this form to report participant behavior at during follow-up visit 5 and 6.

Read each question and all response options aloud to the participant.

Field	Instructions
1. .Let's talk about your current comfort wearing the vaginal ring every day/ taking a pill every day….	Read each response option out loud, and select a response for each item.
2. .How easy or difficult is it for you to insert the vaginal ring?	Select an option from the dropdown menu.
3. .How easy or difficult is it for you to remove the vaginal ring?	Select an option from the dropdown menu.
4. .How easy or difficult is it for you to remember to take the pill?	Select an option from the dropdown menu.
5. .How easy or difficult is it for you to swallow the pill?	Select an option from the dropdown menu.
6. .In the last 30 days, how often did you experience nausea or gagging after swallowing the pill?	Select an option.
7. .In the last 30 days, how many times have you had vaginal sex? By vaginal sex, I mean when a man puts his penis inside your vagina.	Select an option from the dropdown menu.
8. .In the last 30 days, have you had anal sex? By anal sex, I mean when a man puts his penis inside your anus.	Select 'Yes' or 'No'. If "No", skip to item 10.
9. .During the last act of anal sex that you had, was a male condom used?	Select 'Yes' or 'No'.
10. .In the last 30 days, how often did you have a drink containing alcohol? By alcohol, we mean beer, wine, liquor, and home or local brews.	Select an option from the dropdown menu. *If "Never", skip to item 13.*

11. .How many drinks containing alcohol do you have on a typical day when you are drinking?	Select an option from the dropdown menu.
12. .How often do you have six or more drinks on one occasion?	Select an option from the dropdown menu.
13. .I am now going to read you some statements about how often you receive support from people around you. By "support" I mean financial, social, emotional or other forms of help. Please tell me whether you experience or feel these things always, most of the time, some of the time, rarely or never.	Read each response option out loud, and select a response for each item using the dropdown menu.
14. .I am now going to ask you some questions regarding mental health. Please answer "Yes" or "No" to the following.	Read each response option out loud, and select "Yes" or "No" for each item.

Behavioral Assessment – Month 3 Follow Up

Participant Type: Mother

Purpose:
This form is used to provide data on the participant behavior.

General Instructions:
Use this form to report participant behavior at Visit 7 – PUEV – Month 3 Follow Up.

Read each question and all response options aloud to the participant.

Field	Instructions
1. .Overall, how much do you like using the pill?	If the participant is using the vaginal ring skip this item. Select an option from the dropdown menu.

Field	Instructions
2. .Overall, how much do you like using the vaginal ring?	If the participant is using the Truvada oral tablet, skip this item. Select an option from the dropdown menu.
3. .Overall, how satisfied have you been with this method for preventing HIV?	Select an option from the dropdown menu.
4. .Let's talk about your current comfort wearing the vaginal ring every day/ taking a pill every day….	Select the best response for each item listed. If "e. .Does it cause any other issue?" is "Yes", specify in the text box provided. If "6. .Which method would you prefer to use for HIV prevention if breastfeeding?" is "other", specify in the text box provided. If "8. .Which method would you prefer to use for HIV prevention when you are not breastfeeding?" is "other", specify in the text box provided.
5. .Would you be willing to use [product] for HIV prevention when breastfeeding in the future?	Select an option
6. .If the vaginal ring or oral PrEP were available to you, which product would you prefer to use for HIV prevention?	Select an option from the dropdown menu.
7. .If the [study product] were available to you, would you prefer to use [study product] or male condoms for HIV prevention?	Select an option from the dropdown menu.
8. When you're not breastfeeding, would you be willing to use [product] for HIV prevention?	Select an option from the dropdown menu.
9. .In general, how worried are you about the effect of [product] on your own health?	Select an option.

Field	Instructions
10..Some women may have worries about the effect of [product] on their own health or wellbeing. Are you worried [product] could…?	Read each response option out loud, and answer "Yes" or "No" for each option. If "h. .Anything else related to [product]?" is "Yes", use the text box provided to specify.
11..In general, how worried are you about the effect of using [product] on your baby's health?	Select an option.
12..Some women may have worries about the effect of [product] on their baby's health. Are you worried [product] could…?	Read each response option out loud, and answer "Yes" or "No" for each option. If "f. .Anything else related to [assigned product]?" is "Other", specify in the text box provided. If using the pill, skip to 16.
RING	
13..How easy or difficult is it for you to insert the vaginal ring?	If the participant is using the Truvada oral tablet, skip this item. Select an option from the dropdown menu.
14..How easy or difficult is it for you to remove the vaginal ring?	If the participant is using the Truvada oral tablet, skip this item. Select an option from the dropdown menu.
15..Did you mind wearing the vaginal ring…	If the participant is using the Truvada oral tablet, skip this item. Read each response option out loud, and answer "Yes" or "No" for each option. If using the vaginal ring, skip to question 20.
PILL	
16..Did you mind swallowing the pills daily…	If the participant is using the vaginal ring skip this item. Read each response option out loud, and answer "Yes" or "No" for each option.
17..How easy or difficult is it for you to remember to take the pill?	If the participant is using the vaginal ring skip this item. Select an option from the dropdown menu.
18..How easy or difficult is it for you to swallow the pill?	If the participant is using the vaginal ring skip this item. Select an option from the dropdown menu.

Field	Instructions
19..In the last 30 days, how often did you experience nausea or gagging after swallowing the pill?	If the participant is using the vaginal ring skip this item. Select an option.
20..Have you received breastfeeding or feeding-related advice or care from any of the following people? Check all that apply.	Read each response option out loud, and check all applicable option. If “d. Another family member” or “k. Other”, specify in the text box(s) specified.
21..Besides yourself, who has the most influence on your decisions about feeding the baby?	Select an option from the dropdown menu. If “Another family member” or “Other”, specify in the text box(s) specified.
22..Now I will ask you whether important people in your life support your product use. Are the following people supportive, not supportive or don’t know about your use of [product]?	Read each response option out loud, and select a response for each item using the dropdown menus. If “h. .Is there another important person in your life?” is “Yes”, complete both “ .If yes, specify who” and “.If yes, is this person…?”
23..In the last 30 days how many times have you had vaginal sex? By vaginal sex, I mean when a man puts his penis inside your vagina.	Select an option from the dropdown menu.
24..How many male sex partners have you had since joining the study, in total? Please include ALL male sex partners with whom you had vaginal, anal or oral sex.	Numeric entries only permitted.
25..In the last 30 days, have you had anal sex? By anal sex, I mean when a man puts his penis inside your anus.	Select “Yes” or “No”. If "No", skip to 27.
26..During the last act of anal sex that you had, was a male condom used?	Select “Yes” or “No”.

Field	Instructions
27..In the last 30 days, how often did you have a drink containing alcohol? By alcohol, we mean beer, wine, liquor, and home or local brews.	Select an option from the dropdown menu. If "Never", skip to 30.
28..How many drinks containing alcohol do you have on a typical day when you are drinking?	Select an option from the dropdown menu.
29..How often do you have six or more drinks on one occasion?	Select an option from the dropdown menu.
30..I am now going to read you some statements about how often you receive support from people around you. By “support” I mean financial, social, emotional or other forms of help. Please tell me whether you experience or feel these things always, most of the time, some of the time, rarely or never.	Read each response option out loud, and select a response for each item using the dropdown menus.
31..I am now going to ask you some questions regarding mental health. Please answer "Yes" or "No" to the following.	Read each response option out loud, and select a response for each item.
32..Would any of the following keep you from asking for help with depression (or problems with emotions, nerves or mental health) if you thought you needed it?	Read each response option out loud, and select a response for each item. If “f. Other” is “Yes”, specify using the text box provided.
33. .We are interested in learning more about women’s wellbeing in their relationships. …..The next questions are about your relationship with your primary sex partner or any other partners. …Has your primary sex partner or ANY other current or previous partner:	Answer “Yes” or “No” for each of the scenarios listed.

Field	Instructions
34. .Since joining this study, has your primary sex partner or ANY other current or previous partner ever forced you to have sex by holding you down or hurting you?	Answer “Yes” or “No”.
35. .Since joining this study, has anyone else (not including current or past sexual partners) ever forced you to have sex by holding you down or hurting you?	Answer “Yes” or “No”.

Chemistry Panel

Participant Type: Mother

Purpose:
This form is used to provide data on the participant’s ALT, AST and Creatinine laboratory test results.

General Instructions:
Use this form to report the serum chemistries from specimens collected for mothers. Complete at Screening, and Visit 7 - PUEV (3-month visit) and as indicated during the study. Record results on this form as they become available.

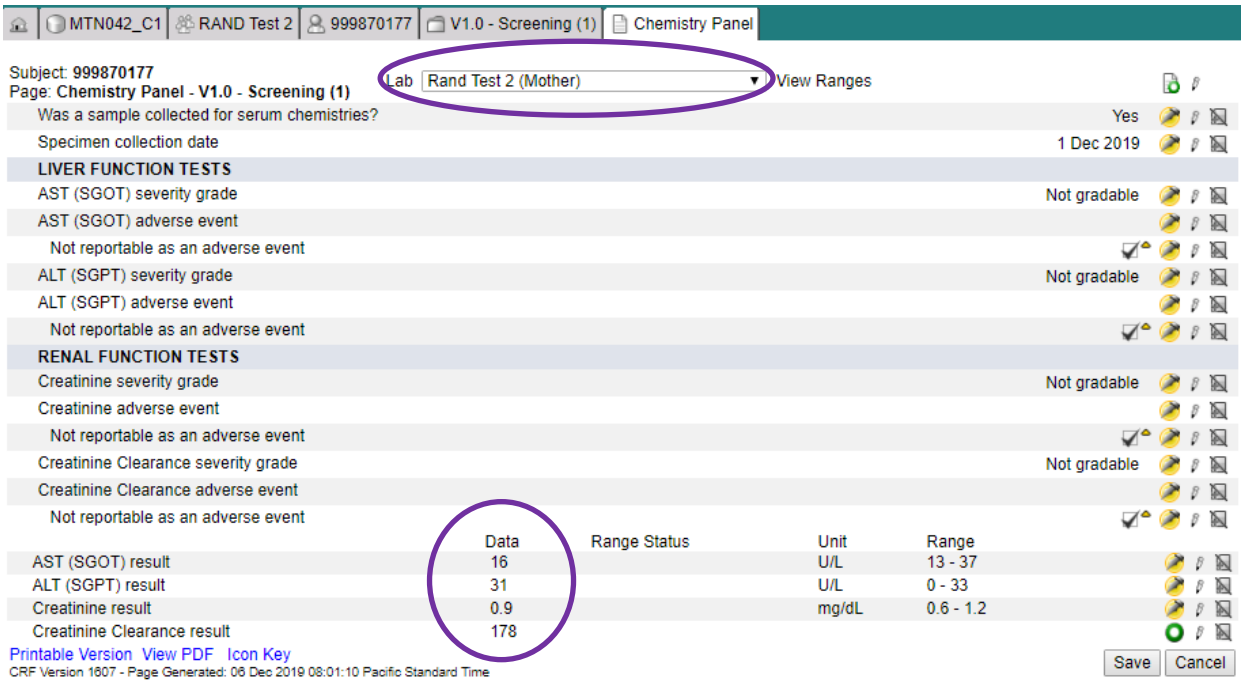
If any or all of the lab tests listed on this form are repeated (re-drawn) between the Screening and the participant’s Enrollment Visit, document the repeated results on the Screening Chemistry Panel form. If the participant enrolls, the updated results should be submitted into the study database.

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 should 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 and Follow-up Visit Summary needs to be entered prior to entering data on the Chemistry Panel eCRF because the derived age is used to populate the reference ranges.
- For each lab test (e.g., Serum Chemistries), 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 individual lab result (e.g. AST, ALT, Creatinine, Creatinine Clearance), record the numeric results in the appropriate field at the bottom of the form.



- 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):

    - **SERUM CHEMISTRIES:** AST (SGOT), ALT (SGPT), Creatinine, Creatinine Clearance

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

- The field “Not reportable as an adverse event” should be used when a participant enters the study with a lab value outside of the normal range, but acceptable for enrollment in the study; participating in the study with a sustained abnormal lab value throughout the study.
- Select “Not gradable” for value that does not meet grading criteria. If severity grade for a given lab value is “Not gradable”, “Not reportable as an adverse event” should be left blank.

Lab Result Units and Rounding

- Results should be documented on the form using the units used in the current version of the DAIDS AE Grading Table. If the units present on your source results report do not match the units on the form and in the DAIDS Toxicity Table, results must be converted before entry into the eCRF. An optional lab units conversion tool is available on Atlas: https://atlas.scharp.org/cpas/project/Collaborators/Lab%20Unit%20Conversion%20Tool/begin.view

- 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

  The following analytes should be recorded in the following format:

  - **AST/SGOT**: U/L, report as a whole number

- **ALT/SGPT**: U/L, report as a whole number
- **Creatinine**: mg/dL, report up to 5 decimal places
- **Calculated Creatinine Clearance:** mL/min, report up to 2 decimal places

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 current version of the DAIDS Toxicity table, 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 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.

Concomitant Medications Y/N

Participant Type: Mother and Infant

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

General Instructions:
This form is present within the "Ongoing Logs" folder. Selecting 'Yes' to the "Were any concomitant medications taken?" prompt will add the "Concomitant Medications Log" to the "Ongoing Logs" folder.

Concomitant Medications Log

Participant Type: Mother and Infant

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 using the generic name. If a combination medication does not have a generic name or the generic name is unknown, each active ingredient must be reported as a separate 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.

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. 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.
Frequency	Select the frequency from options provided in the drop-down list. Below is a list of common frequency abbreviations: • As needed • Every day • Twice daily • Three times daily • Four times daily • Once a month • Each hour • One time • 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.

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 3 AEs can be selected. If the medication was not administered to treat an AE, select 'No', and end the form.

COVID-19 Behavioral Assessment

Participant Type: Mother

Purpose:
This form is used to document behavioral data relating to COVID-19.

General Instructions:
This form is completed at the Enrollment and Visit 7 – PUEV – Month 3 Visit. This form is translated and questions should be read aloud word for word to the participant.

Item-specific Instructions:

Field	Instructions
1. Date of assessment	Please provide the date of birth. At a minimum, the year is required.
2 .How many people do you know personally who are (or have been) infected with COVID-19? Please include both suspected and confirmed infections, do not count yourself, and give your best estimate if you do not know the exact number. If completing at follow-up, only count those people who have been infected since you joined the study.	Enter a number. Only numeric characters are allowed.
3 .Were you infected (or suspected to be infected) with COVID-19? (If completing at follow-up, indicate if you've been infected since you joined the study)	Select an option

Field	Instructions
4 .Did you ever self-isolate or quarantine to prevent yourself from getting or transmitting COVID-19?	Select 'Yes' or 'No'.
5 .Now I'm going to ask you about some worries you might currently have. Please indicate how worried or concerned you are about the following things:	Read each response option out loud, and select a response for each item.
6 .Which of these concerns worries you the most? (pick one)	Select an option.
7 .Between getting COVID-19 and getting HIV, which is more concerning to you right now?	Select an option.
8 .How has COVID-19 influenced your interest in preventing HIV?	Select an option.
9 .How has COVID-19 influenced your interest in using [pills/ring]?	Select an option. .If Enrollment, skip to item 11.
10 .Did you experience any of the following situations because of COVID-19 and the plans used to manage the outbreak?	Read each response option out loud, and select "Yes" or "No" for each item.
11 .Do you think other people would judge you or treat you badly if you had COVID-19?	Select 'Yes' or 'No'. If Visit 7 - PUEV - Month 3, end of form

Field	Instructions
12 .I'm going to ask you about several different aspects of your life that might have changed because of COVID-19 (and the plans used to manage it). For each one, please tell me if the following has decreased, increased, or not changed because of COVID-19.	Read each response option out loud, and select a response for each item. If "m .Your feeling of connection to your primary partner" is "N/A: No primary partner", skip to item 13.
13 .Were you given any specific information about COVID-19 and pregnancy?	Select 'Yes' or 'No'.
14 .Were you given any specific information about COVID-19 and breastfeeding?	Select Yes or No. If "Yes", answer "b .Has this information impacted your feeding decisions at all?"
15 .We are curious to hear about how the coronavirus impacted you and your baby, if at all. Since the coronavirus pandemic started, please consider how you or your baby may have been impacted.	Read each response option out loud, and select a response for each item. If "f .Did you deliver your baby somewhere other than a health facility because of COVID-19?" is Yes, specify.

Demographics

Participant Type: Mother

Purpose:
This form is used to document a mother participant's demographics.

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 5 through 17 are translated and should be read aloud word for word to the participant.

Item-specific Instructions:

<table>
<tr><th>Field</th><th>Instructions</th></tr>
<tr><td>Date of birth</td><td>Please provide the date of birth. At a minimum, the year is required.</td></tr>
<tr><td>Age</td><td>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.</td></tr>
<tr><td>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><th>Malawi</th></tr>
<tr><td>Colored</td><td>Acholi</td><td>Ndebele</td><td>Chewa</td></tr>
<tr><td>Indian</td><td>Baganda</td><td>Shona</td><td>Lomwe</td></tr>
<tr><td>Sotho</td><td>Bagisu</td><td>White</td><td>Tumbuka</td></tr>
<tr><td>Xhosa</td><td>Bakiga</td><td>Other African Tribe</td><td>White</td></tr>
<tr><td>White</td><td>Banyankore</td><td>Other</td><td>Yao</td></tr>
<tr><td>Zulu</td><td>Banyaruanda</td><td></td><td>Other African Tribe</td></tr>
<tr><td>Other African Tribe</td><td>Banyoro</td><td></td><td>Other</td></tr>
<tr><td>Other</td><td>Basoga</td><td></td><td></td></tr>
<tr><td></td><td>Batoro</td><td></td><td></td></tr>
<tr><td></td><td>Iteso</td><td></td><td></td></tr>
<tr><td></td><td>Karamojong</td><td></td><td></td></tr>
<tr><td></td><td>Lango</td><td></td><td></td></tr>
<tr><td></td><td>Lugbara</td><td></td><td></td></tr>
<tr><td></td><td>Other African Tribe</td><td></td><td></td></tr>
<tr><td></td><td>Other</td><td></td><td></td></tr>
</table>
</td></tr>
<tr><td>5. Do you have a primary partner? By this I mean a husband, boyfriend, or steady partner with whom you regularly have sex.</td><td>Select 'Yes' or 'No'.

If 'No', skip to question 11.</td></tr>
</table>

Field	Instructions
6-8	Enter “Yes”, “No” or “Don’t know” for each question.
9. Do you believe your primary partner has sexual partners other than you?	Use the dropdown menu to select ‘Yes, I know’, ‘Yes, I suspect’, ‘No’, or ‘Don’t know’.
10. How many sex partners have you had in your lifetime?	Enter a number. Only numeric characters are allowed.
11. Since you started breastfeeding this baby how many times have you had vaginal sex? By vaginal sex, I mean when a man puts his penis inside your vagina.	Select an option from the dropdown menu.
12..Since you started breastfeeding this baby how many sex partners have you had in total? Please include ALL male sex partners with whom you had vaginal, anal or oral sex.	Enter a number. Only numeric characters are allowed. If "0", skip to item 15.
13-14	Select ‘Yes’ or ‘No’.
15. What methods have you ever used to prevent HIV?	Mark all that apply. If "Vaginal ring", specify which study. If "Other", specify
16. How satisfied were you with this method for preventing HIV?	Select ‘Very satisfied’, ‘Satisfied’, ‘Neutral’, ‘Dissatisfied’, ‘Very dissatisfied’ or ‘N/A’ for each of the methods listed. Select ‘N/A’ for methods NEVER used.
17. Since you started breastfeeding, how often did you have a drink containing alcohol? By alcohol, we mean beer, wine, liquor, and home or local brews.	Use the dropdown menu to select the most appropriate answer. If "Never", skip to item 20.

Field	Instructions
18..How many drinks containing alcohol do you have on a typical day when you are drinking?	Use the dropdown menu to select the most appropriate answer.
19..How often do you have six or more drinks on one occasion?	Use the dropdown menu to select the most appropriate answer.
20.How many cigarettes do you smoke per day?	Enter a number. Only numeric characters are allowed.

Discontinuation of Study Product

Participant Type: Mother

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 study product use end).

Item-specific Instructions:

Field	Instructions
Date that study product use ended	A complete date is required. Record the date when the participant was permanently discontinued from study product.
Visit that the study product use ended	Use the dropdown menu to select the visit that the study product use ended. If "Interim Visit", specify Interim Visit code.
Primary reason for ending study product use	Record the primary reason from the drop-down menu. If 'Adverse Event' or 'Death' is selected, specify the AE entry (in Medidata Rave, choose the AE from the AE dynamic drop-down list). If "Infant adverse event", record infant adverse event number. **Note**: If study product is permanently discontinued due to an AE, 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.

Edinburgh Postnatal Depression Scale

Participant Type: Mother

Purpose:
This form is used to administer and document a participant's Edinburgh Postnatal Depression assessment.

General Instructions:
Complete this form at Enrollment, visits 5, 6 and 7.

The form has been translated into site's local languages. Read the introductory statement at the beginning of the questionnaire aloud to the participant. Read each numbered statement (1 – 10) to the participant word-for-word; after reading each statement, read each response option word-for-word.

Item-specific Instructions:

Field	Instructions
Numbered items 1 – 10	Read each question and all response options aloud to the participant. Select the participant's response.
Following completion of this questionnaire, was the mother subsequently referred for further evaluation and/or management?	Do not read to the participant. Select 'yes' or 'no' based on whether referrals to additional support, evaluations, or treatments were subsequently made. If 'no', specify why this participant was not referred.
EPDS Score	The EPDS score will be calculated and populated here.

Enrollment

Participant Type: Mother and Infant

Purpose:
This form is used to document a participant's study enrollment. This form is completed at Enrollment for all participants who have provided informed consent and who are eligible to participate in the study. This form is used for TSDV purposes; only the infant section should be filled out for infants, and only the mother section should be filled out for mothers.

General Instructions:
Complete this form for each participant who is enrolled into MTN-043. Fill out the mother's Enrollment form first so that you can answer questions relating to mother's randomization on the Infant's form.

Item-specific Instructions:

Participant Type	Field	Instructions
FOR INFANT ONLY	If infant, has this participant enrolled in the study?	Select 'Yes' or 'No'. DO NOT complete this field if participant is a mother.

Participant Type	Field	Instructions
	Date of infant enrollment:	Record the infant's enrollment date (full date required). DO NOT complete this field if participant is a mother. **If Infant, end of form.**
FOR MOTHER MOTHER	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.
	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.
	Was the participant randomized to participate in IDI (In Depth Interview)?	Refer to the SSP procedures to determine whether the participant has been randomized to participate in the IDI.
	Was the participant invited to participate in IDI?	Indicate whether the participant was invited to participate in the IDI if randomized. Refer to the MTN-043 SSP for guidance.
	Will this participant participate in IDI?	Indicate whether the participant will participate in the IDI.

Feeding Assessment – Follow Up

Participant type: Mother

Purpose:
This form is used to document if the infant has been exclusively breastfed since their last visit or not, and how frequently the baby is breastfed.

General Instructions:
This form is completed for each follow-up visit (Visit 3 through Visit 7).

Field	Instructions
1. .What have you fed your baby since your last visit? *Do not read response options out loud.*	If the baby has been fed ANYTHING other than breastmilk (including water, porridge, solid foods, etc), select “Other”. A Feeding Inventory will need to be completed to document what foods the infant was given and how frequently. If "Other", has your baby completely weaned from breast milk? (Defined as at least one week without breast milk and no intention of restarting)
2. .Since your last visit, how many times per day on average were you breastfeeding (or providing breast milk to) your baby?	Enter a numeric entry (1-2 digits allowed)
3. .In the last 24 hours, how many times did you breastfeed (or provide your breast milk to) your baby?	Enter a numeric entry (1-2 digits allowed). Enter the date the infant last received breastmilk.

Feeding Assessment – Screening and Enrollment

Participant type: Mother

Purpose:
This form is documents what foods the infant has received in the week leading up to Screening and Enrollment.

General Instructions:
This form is completed at Screening and Enrollment.

Field	Instructions
1. .In the past seven days, what has your baby been fed...? (select all the apply)	Select each option which the infant has been fed in the last 7 days. If “other”, specify in the text box provided.
2. .In how many months will you introduce solid foods, baby formula, water, or other foods into your baby's diet?	Use the drop down menu to select the appropriate answer.
3. .How many times per day do you breastfeed (or provide breast milk to) your baby?	Enter a numeric entry (1-2 digits allowed)

Feeding Inventory

Participant type: Mother

Purpose:
This form is documents what foods the infant has received and how frequently since their last study visit.

General Instructions:
This form is completed as indicated throughout the study, for each visit in which it is reported that the infant has been fed anything other than breastmilk (specifically from their mother participating in the study) since the previous study visit.

Field	Instructions
Since last visit, which of the following has the baby been fed?	Use the dropdown menu to select each item the infant has been fed since their last study visit. If “other”, specify in the text box provided. If an infant has been fed more than one thing, record each item on a new log line.
Date infant first received since last visit:	A partial date is required (month and year).
On average, since your last visit, how often does baby receive?	Enter a numeric entry (1-2 digits allowed)
Main reason for introduction:	Use the dropdown menu to select the main reason for introduction. If “other”, specify in the text box provided.
Did any of the following people advise or encourage introducing this to the baby?	Use the dropdown menu to select the main person who has influenced introducing this item to the infant. If “other”, specify in the text box provided.

Follow-up Visit Y/N

Participant type: Mother and Infant

Purpose:
This form is documents whether 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 V3.0 – 1 week visit through V 8 – SEV.

Item-specific Instructions:

Field	Instructions
Did the participant complete this visit?	Select 'Yes' if any part of the visit was completed within the visit window. The Follow-up Visit Summary and any other required forms will be automatically added to the visit folder. Select 'No – Missed Visit' if the visit was not completed (i.e., no part of the visit occurred during the visit window). A Missed Visit form will automatically add to the visit folder to be completed.

Follow-up Visit Summary

Participant Type: Mother

Purpose:
These forms are used to summarize information from each participant follow-up study visit.

General Instructions:
This form is completed for each scheduled follow-up visit and is present in each follow-up visit folder, starting at V3.0 - Week 1 through V8.0 - SEV.

Item-specific Instructions:

Field	Instructions
Visit Date	A complete date is required.
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.
Was study product held at this visit?	Select 'Yes' or 'No'. If 'Yes', then complete a Product Hold form within the Ongoing 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.
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).
Were any protocol deviations 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).
Since her last visit, has the participant inserted anything in her vagina?	Select 'Yes' or 'No'. Select 'Yes' if she has inserted any non-medicated products (including non-medicated gels, water, soap, dry materials (such as paper, ashes, or powders)) vaginally. Complete the Vaginal Practices CRF. This field does not refer to vaginal sex (when a man puts his penis inside the vagina) Note: all medicated vaginal products (including prescription medications, over-the-counter preparations, vitamins and nutritional supplements, and herbal preparations) should be recorded as concomitant medications.
Were any additional study procedures or forms completed outside of the scheduled study visit per protocol?	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.

Hematology

Participant Type: Mother

Purpose:
This form is used to provide data on the participant's laboratory test results.

General Information/Instructions:
Use this form to report the hematology and differential test results. For mothers, complete at Screening, and Visit 7 – PUEV.

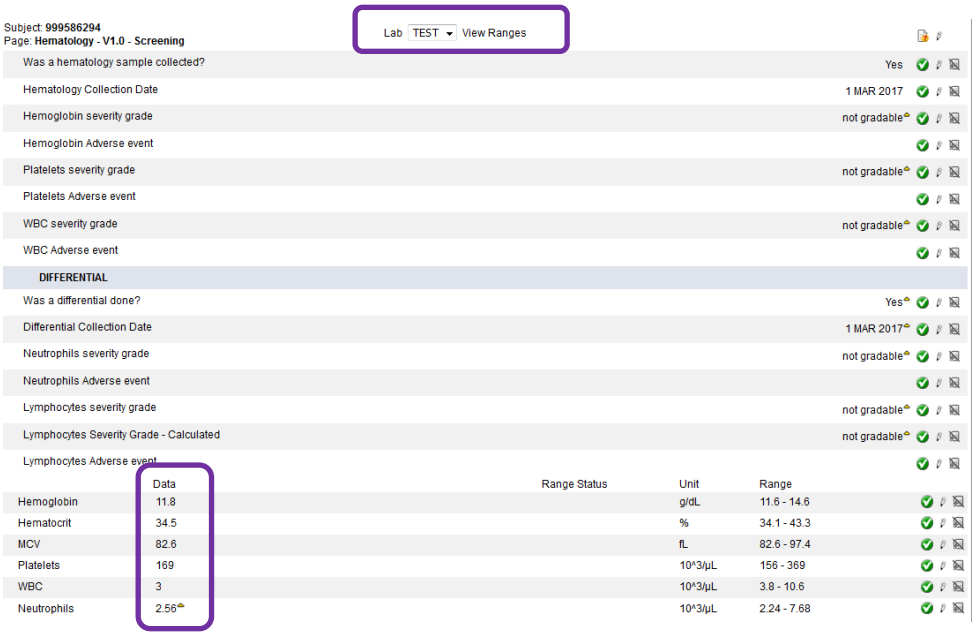
If any or all of the lab tests listed on this form are repeated (re-drawn) between the Screening and Enrollment Visit, document the repeated results on the same Hematology form. If the participant enrolls, the updated results should be submitted into the study database.

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

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 should 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 and Follow-up Visit Summary or eCRFs needs to be entered prior to entering data on the Hematology eCRF because the derived age is used to populate the reference ranges.
- For each lab test (Hematology and Differential), 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 individual lab result (Hemoglobin, Hematocrit, MCV, Platelets, WBC, Neutrophils, Lymphocytes, Monocytes, Eosinophils, Basophils), record the numeric results in the appropriate field at the bottom of the form.



- 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

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

- The field “Not reportable as an adverse event” should be used when a participant enters the study with a lab value outside of the normal range, but acceptable for enrollment in the study; participating in the study with a sustained abnormal lab value throughout the study.
- Select “Not gradable” for value that does not meet grading criteria. If severity grade for a given lab value is “Not gradable”, “Not reportable as an adverse event” should be left blank.

Lab Result Units and Rounding

- Results should be documented on the form using the units used in the current version of the DAIDS AE Grading Table. If the units present on your source results report do not match the units on the form and in the DAIDS Toxicity Table, results must be converted before entry into the eCRF. An optional lab units conversion tool is available on the MTN-043 site, under Study Implementation Materials: https://mtnstopshiv.org/research/studies/mtn-043/mtn-043-study-implementation-materials

- Note that the following units are equivalent:

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

  The following analytes should be recorded in the following format:

  - **Hemoglobin**: g/dL, report up to 5 decimals
  - **MCV:** fL, report up to 5 decimals
  - **Platelets**: cells/mm^3, report as a whole number
  - **WBC:** cells/mm^3, report as a whole number
  - **Neutrophils:** cells/mm^3, report as a whole number
  - **Lymphocytes:** cells/mm^3, report as a whole number
  - **Monocytes:** cells/mm^3, report as a whole number
  - **Eosinophils:** cells/mm^3, report as a whole number
  - **Basophils:** cells/mm^3, report as a whole number

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" eCRF(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.

HIV Confirmatory Results

Participant Type: Mother

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.
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 result is "less than" the value provided.
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.
Was plasma stored for HIV confirmatory testing?	If plasma was stored for confirmatory testing, complete the Specimen Storage CRF to document that "Plasma for archive" was collected and stored.

Field	Instructions
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 Product Hold Log/Discontinuation of Study Product form 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.
Plasma for HIV confirmatory testing collection date:	A complete date is required if plasma for HIV confirmatory testing was stored.

HIV Test Results

Participant Type: Mother

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
Was Rapid HIV test sample 1 collected for testing?	Select "Yes" or "No", as appropriate.
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 Product Hold Log and Discontinuation of Study Product 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".

Field	Instructions
Rapid HIV test 2	If the rapid HIV test 2 results is “Antibody positive”, “Antigen positive”, or “Antibody and antigen positive” complete a Product Hold Log and Discontinuation of Study Product form, if applicable. If Rapid HIV test 1 and test 2 are both “Negative”, end the form. **If at least one Rapid HIV tests is positive, complete the HIV Confirmatory Result form.**

IDI Tracking

Participant Type: Mother

Purpose:
This form is used to document completion of the in-depth-interview (IDI).

General Instructions:
Complete this form at the visit when the IDI is performed. The form can be added to a scheduled study visit using the Additional Study Procedures form or added to an interim visit using the Interim Visit Summary form.

Inclusion/Exclusion Criteria

Participant Type: Mother

Purpose:
This form is used to document participant eligibility for enrollment in MTN-043, and if applicable, type of ineligibility.

General Instructions:
Complete this form for each mother screened in MTN-043. 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
Did the participant meet all eligibility criteria?	Select “Yes” or “No”, as appropriate.
Eligibility Status	If the participant is eligible, but did not enroll in the study, select “Eligible/Not enrolled” and specify the reason in the text field provided. Select “Incomplete Screening” if the participant did not complete all screening procedures.
Was the participant enrolled into MTN-043?	Select “Yes” or “No”, as appropriate.

Field	Instructions
Select reason(s) 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 "E9. Has a condition that, per IoR/designee…" (Investigator decision), specify.

Infant Additional Study Procedures

Participant Type: Infant

Purpose:
This form is used to identify additional 'as-needed' study procedures conducted during study visit and to add the applicable forms to the infant 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 vital signs are performed as indicated, select the checkbox for "Infant Vital Signs?". Additional procedures that were not completed at this visit can be left blank.

Infant Ages and Stages Assessment

Participant Type: Infant

Purpose:
This form is used to record the results of the Ages & Stages Questionnaires completed at Screening, Enrollment, and Visit 7 – PUEV.

General Instructions:
If the assessment is conducted all score total fields and abnormality questions must have a response. If the score for an evaluation is 0, 0 must be entered into the score total field. If the answer to any abnormalities question is 'Yes', the 'If "Yes", explain' field must have something entered into it.
If there are any related AEs they must be selected from the Adverse Event drop down menu. The AE must already be entered on the Adverse Event Log form.

Infant Demographics

Participant Type: Infant

Purpose:
This form is used to document an infant participant's demographics.

General Instructions:
This form is completed upon infant Enrollment.
Item-specific Instructions:

Field	Instructions
Date of birth	Please provide the date of birth. A full date is required.
Age	Provide the infant's age in days. Numeric entry only.
Sex at birth?	Select the infant's sex at birth.
Ethnic group or tribe	Select one option based on parent/guardian's report. If the participant does not identify with any of the ethnic groups or tribes listed (see list in mother's Demographics table), select 'other' and provide the name of her ethnic group or tribe in the 'If other, specify' field.

Infant Follow-up Visit Summary

Participant Type: Infant

Purpose:
These forms are 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 through Visit 8 - SEV.

Item-specific Instructions:

Field	Instructions
Visit Date	A complete date is required.
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.
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).
Were any protocol deviations 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).
Were any additional study procedures or forms completed outside of the scheduled study visit per protocol?	If additional 'as-needed' study procedures were completed at this visit, select "Yes". The Infant Additional Study Procedures form will dynamically be added to the visit folder to be completed.

Infant HIV Confirmatory Results

Participant Type: Infant

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

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

Item-specific Instructions:

Field	Instructions
HIV RNA PCR	Complete the collection date. 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 HIV DNA PCR items.
HIV RNA PCR Kit	Select the HIV RNA PCR testing kit that was used.
HIV RNA PCR Kit Lower limit of detection	Select “20” or “40” as the lower limit of detection or record the viral copies/mL
HIV DNA PCR	Select the correct HIV DNA PCR response from the drop down menu: “Positive/reactive”, “Negative/non-reactive”, “Equivocal/Indeterminate”.
Were any additional tests besides RNA or DNA performed?	Select “yes” or “no”. If yes, specify in the text field provided.
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 Product Hold Log/Discontinuation of Study Product form for the mother 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. **Note:** If "Final HIV status" is "HIV infected", Plasma for storage is required. Please refer to the Infant Specimen Storage form for recording purposes.

Infant Inclusion/Exclusion

Participant Type: Infant

Purpose:
This form is required for each infant who is assigned a PTID. This form is used to document whether or not an infant enrolls in MTN-043, and if they do not enroll, the reason why.

General Information/Instructions:
Complete this form in the Participant folder when it is known that the infant will not enroll (e.g., when the mother screen fails) or when the infant enrolls.

Field	Instructions
Did the participant meet all eligibility criteria?	Select “Yes” or “No”, as appropriate.
Eligibility status	If the participant is eligible, but did not enroll in the study, select “Eligible/Not enrolled” and specify the reason in the text field provided. Select “Incomplete Screening” if the participant did not complete all screening procedures.
Did the infant enroll in MTN-043?	Select “Yes” or “No” to document if the infant is enrolled in MTN-043. If “No”, select from the dropdown menu the reason why the infant did not enroll.
If eligible, but participant did not enroll, specify reason	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 "E1. Has a condition that, per IoR/designee…" (Investigator decision), specify.

Infant Interim Visit Summary

Participant Type: Infant

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.
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.
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).
Were any protocol deviations 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 all that apply.)	Select the applicable checkboxes if an AE report or follow-up or completion of missed visit procedures or Other. If Completion of missed visit procedures select the appropriate missed visit from the drop down menu.
What study procedures were completed at this visit?	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 examination was performed, select the checkbox for **Physical Examination**. Procedures that were not completed at this visit should be left blank.

Infant Specimen Storage

Participant Type: Infant

Purpose:
This form is used to document collection and storage of Plasma or Dried Blood Spot for PK and plasma for archive specimens.

General Instructions:
Complete this form at Visit 4 through Visit 8 – SEV or when added as additional study procedures. Only one type of PK sample will be collected per infant participant. It is determined by the treatment arm of their mother.

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).
Date of Collection	Record the date that the specimen was collected, NOT the date the results were reported or recorded on the form for this visit. A complete date is required.
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.

Infant Vital Signs

Participant Type: Infant

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

General Instructions:
Complete this form at Screening, Enrollment, and Visit 7 – PUEV.

Item-specific Instructions:

Field	Instructions
Date of Assessment	Enter the date the participant's vital signs were measured. A complete date is required.
Length	Enter the participant's body length in centimeters.
Head circumference	Enter the participant's head circumference measured at forehead and occiput in centimeters.
Weight	Enter the participant's weight in kilograms.
Body Temperature	Enter the participant's temperature in Celsius. The value must be reported 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).
Pulse	Enter the participant's pulse in beats per minute (e.g. 60 beats/min).

Field	Instructions
Rate of 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.

Informed Consent

Participant Type: Mother and Infant

Purpose:
This form is used to document a participant's study consent. This form is completed at Screening for mother participants and when consent is obtained for infant participants.

General Instructions:
Complete this form for each participant, and her infant, who screens for MTN-043.

Item-specific Instructions:

Field	Instructions
Informed consent date	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. If the participant re-screens, enter the informed consent date of the second screening attempt. If a new version of the consent form is signed (e.g., if the consent is updated during the study and IRB requires that participants re-consent), do not update the informed consent date.
Did the participant 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.

Interim Visit Summary

Participant Type: Mother

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 Discontinuation of Study Product 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.
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).
Since her last visit, has the participant inserted anything in her vagina?	Select 'Yes' or 'No'. Select 'Yes' if she has inserted any non-medicated products (including non-medicated gels, water, soap, dry materials [such as paper, ashes, or powders]) vaginally. Complete the Vaginal Practices CRF. This field does not refer to vaginal sex (when a man puts his penis inside the vagina) **Note**: all medicated vaginal products (including prescription medications, over-the-counter preparations, vitamins and nutritional supplements, and herbal preparations) should be recorded as concomitant medications.
Were any protocol deviations 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 all that apply.)	Select the applicable checkboxes if an AE report or follow-up or completion of missed visit procedures or Other. If Completion of missed visit procedures select the appropriate missed visit from the drop down menu.
What study procedures were completed at this visit?	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 examination was performed, select the checkbox for **Physical Examination**. Procedures that were not completed at this visit should be left blank.

Missed Visit

Participant Type: Mother and infant

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

Participant Type: Mother and Infant

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-043 participant once the mother has provided written informed consent for study screening and enrollment for her and her infant.

Item-specific Instructions:

Field	Instructions
Participant ID	To add a participant to the study database, select the "Add Subject" link on the MTN-043 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:

CRS Name	DAIDS ID	Rave Site ID
MU-JHU, Uganda	30293	753
WRHI Shandukani, Johannesburg	8051	897
Zengeza, Zimbabwe	30320	774
Blantyre, Malawi	30301	760

Participant Type

Participant Type: Mother and Infant

Purpose:
The Participant Type form is used to indicate if a participant is a mother or an infant and will determine which visit folders are added to the participant's casebook. This form is within the Participant folder and is the second form completed within Medidata Rave for each participant.

General Instructions:
Complete this form for every MTN-043 participant once she has provided written informed consent for study screening and enrollment.

Item-specific Instructions:

Field	Instructions
Is this participant a mother or an infant?	Select 'mother' or 'infant'.
If this participant is a mother, what is the infant's PTID?	If participant is a mother, enter the infant's PTID and end of form.

Field	Instructions
What is the mother's PTID?	If participant is an infant, enter the infant's mother's PTID.
To which treatment arm was the mother assigned?	Select 'DPV vaginal ring' or 'Truvada oral tablet' to indicate the infant's mother's treatment arm.

Pelvic Exam

Participant Type: Mother

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

General Instructions:
Complete this form at Enrollment 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. Complete at Screening, Enrollment, and Visit 7 – PUEV.

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.
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 search list 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).

Pelvic Exam Diagrams Form (non-Medidata Rave form)

Participant Type: Mother

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 Enrollment and when 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-043 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

Participant Type: Mother

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
Randomization group (autopopulated from Medidata Balance)	The "Randomization group (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 dispensed 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 "Was a vaginal ring or tablet bottle dispensed at this visit?" 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.
How many vaginal rings or tablet bottles were dispensed?	Select the number of vaginal rings or Truvada bottles that were dispensed at this visit.
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.XX. 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.
Tablet bottle lot number:	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 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 Examination

Participant Type: Mother and Infant

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

General Instructions:
For mothers: complete this form at Screening, Enrollment, Visit 7 – 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.

For infants: complete this form at Screening, Enrollment, Visit 7 – 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. 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.

Field	Instructions
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'.
Breasts	Answer this question for mothers only. please specify whether findings were 'Abnormal' or 'Normal' or 'Not done'. If abnormal, describe the abnormality in the corresponding text field. 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.

Pregnancy History

Participant Type: Mother

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

General Instructions:
A Pregnancy History form is required at Screening.

Item-specific Instructions:

Field	Instructions
Date Pregnancy History Collected	**A full date is required.**
Number of full term live births (>=37 weeks)	Numeric entry required. If none, enter "0" (zero).
Number of premature live births (Less than 37 weeks)	Numeric entry required. If none, enter "0" (zero).
Number of spontaneous fetal deaths and/or still births (>=20 weeks)	Numeric entry required. If none, enter "0" (zero).
Number of spontaneous abortions (Less than 20 weeks)	Numeric entry required. If none, enter "0" (zero).
Number of therapeutic/elective abortions	Numeric entry required. If none, enter "0" (zero).

Number of ectopic pregnancies	Numeric entry required. If none, enter “0” (zero).
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 Outcome

Participant Type: Mother

Purpose:
This form is used to report pregnancy outcome information for any pregnancies after study enrollment during study follow-up.

General Instructions:
This form will be present in the Pregnancy folder.

Item-specific Instructions:

Field	Instructions
Pregnancy Outcome Date	A complete date is required.
Place of delivery/outcome	Enter the place of delivery/outcome from the drop-down menu. If “Other”, specify 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, 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.

Field	Instructions
Method	Select the method of delivery from the drop-down menu only if the outcome is 'full term live birth (≥37 weeks)' or 'premature term live birth (< 37 weeks)'. If "Vaginal delivery", indicate if delivery was breech. 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.
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 skip to 'Were any fetal/infant congenital anomalies identified?' If 'Hypertensive disorders of pregnancy' is 'Yes', select 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 "yes", check all that apply, describe the congenital anomaly/defect in the text field provided. If "No" or "Unknown", go to statement "Complete the infant items below for live births only"
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
Date pregnancy reported to site	A complete date is required.
Visit at which this pregnancy was reported	Use the dropdown menu to select the appropriate visit. If "Interim visit", specify Interim visit code.
Date of onset 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.
Estimated date of delivery	A complete date is required.
What primary information was used to estimate the date of delivery?	Use the dropdown menu to indicate what primary 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 "Other" and describe in the 'If other, specify' text field provided.
Is this the participant's first pregnancy since enrollment in this study?	Select "Yes" or "No".

Pregnancy Test Result
Participant Type: Mother

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 Screening, Enrollment, Visit 7 – PUEV , and if indicated throughout the study.

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".
Collection date	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.
Collection time	Record the time that the pregnancy test was collected
Pregnancy 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 log and Pregnancy Report form.

PrEP Provisions and Returns

Participant Type: Mother

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

General Instructions:
Complete this form at the Enrollment Visit up through the participant's Visit 7 - PUEV if 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.

Item-specific instructions:

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.
Date tablet bottle(s) returned by participant	A full date is required

Number of tablet bottle(s) returned at this study visit	Use the radio buttons to select 1 or 2 bottles
No tablet bottle(s) provided	If no tablet bottle(s) were provided at this visit, end of form.
Date tablet bottle(s) provided	A full date is required
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 Hold Y/N

Participant Type: Mother

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 "Product Hold" log to the "Ongoing Logs" folder.

Product Hold Log

Participant Type: Mother

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 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 or take the tablets. 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.xx.
Why is study product being held?	Record the reason that study product is being held. If "Infant adverse event", record infant adverse event number 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 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 of last study product use	Record the date the participant last used study product. A complete date is required. Use a best estimate if the actual date cannot be determined.
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 – 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’. Mark, “No – early termination” if the product hold was ongoing at the visit at which the participant terminated early from the study. Complete the Discontinuation of Study Product 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 Discontinuation of Study Product form. Mark, “No – permanently discontinued” if the participant was permanently discontinued from study product due the reason indicated on this form. Complete the Discontinuation of Study Product form.

Date study product resumed	Record the date that the participant was instructed to resume study product, if applicable
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.

Protocol Deviations Y/N

Participant Type: Mother and infant

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

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 Have any protocol deviations occurred?" prompt will add the "Protocol Deviations" log to the "Ongoing Logs" folder.

Protocol Deviations Log

Participant Type: Mother and infant

Purpose:
This form documents and reports protocol deviations identified for study participants during the implementation of MTN-043.

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.
Deviation date	Record the date the deviation occurred (start date). A complete date is required.
Has or will this deviation be reported to local IRB/EC?	Select "Yes" or "No".

Field	Instructions
Has or will this deviation be reported to DAIDS as a critical event?	Select “Yes” or “No”.
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 prevent future occurrences of the deviation	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: Select this option ONLY when participant declines product use.	**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	

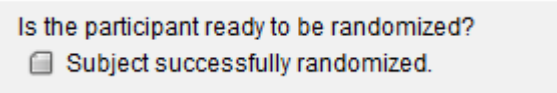
Randomization

Participant Type: Mother

Purpose:
This form is used to officially randomize a participant for MTN-043. 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 mother participant who will enroll in MTN-043 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 items "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 treatment arm 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.

Ring Adherence Y/N

Participant Type: Mother

Purpose:
This form documents if a participant has used the vaginal ring and populates the Ring Adherence form.

General Instructions:
This form is present within the Visits 3 and 4 (1 and 2 week visits), visits 5 and 6 (1 and 2 month visits), and visit 7 – PUEV folders. Selecting 'Yes' to the question "Since the participant's last adherence assessment (or since product use started, if this is the first adherence assessment), has she ever used a vaginal ring?" will add the Ring Adherence form to the respective visit folder.

Ring Adherence

Participant Type: Mother

Purpose:
This form documents ring adherence for those participants that have been randomized to the DPV Vaginal Ring.

General Instructions:
This form should be completed at Visits 3 and 4 (1 and 2 week visits), visits 5 and 6 (1 and 2 month visits), and visit 7 – PUEV folders, if the participant has reported using the ring since their last visit.

Item-specific Instructions:

Field	Instructions
1. .Since your last visit, how comfortable have you been wearing the vaginal ring every day?	Select the most appropriate answer from the options provided.
2. .Since your last visit, how often have you had the vaginal ring out (of your vagina), even for just a minute?	Select the most appropriate answer from the options provided.
3. .Since your last visit, how often was the vaginal ring removed for sex?	Select the most appropriate answer from the options provided.
4. .Since your last visit, how often was the vaginal ring out (of your vagina) for more than 12 hours in a row?	Select the most appropriate answer from the options provided.
5. .What are the reason(s) why the vaginal ring(s) were removed?	Do not read options outload. Check all of the reason(s) that apply.
6. .Did the ring come out on its own?	If “Did the ring come out on its own?” is “No”, end of form.
7. .If yes, what are the reason(s) why the vaginal ring came out on its own?	Select “Yes” for all of the reason(s) that apply. If “Other”, use the text box provided to explain.

Ring Assessment

Participant Type: Mother

Purpose:
This form is used to document assessment of ring insertion when the ring is inserted at the clinic.

General Instructions:
This form is completed at the Enrollment visit, and Visits 5 and 6 (1 and 2 month visits).

Item-specific Instructions:

Field	Instructions
2. Did the participant attempt to insert a ring herself?	If “No”, provide a response in the ‘2a. If “No”, please describe the reason.’ text box provided. If “Yes”, go to item 3.
3. 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.” Select “N/A” if the participant attempts to insert the ring, but is unable to keep it in.
4. Did the participant experience any of the following difficulties?	Mark “Yes” or “No” for each item listed. If “Other” = “Yes”, explain in the “if other, specify’ text box provided.
Did the participant require any help from the clinician to insert the ring?	If “Yes” provide a response for If “Yes”, specify.
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

Participant Type: Mother

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

General Instructions:
Complete this form at visits when a participant is scheduled to receive or return a ring, starting at the Enrollment visit through the participant’s scheduled Product Use End. If the participant permanently discontinues from study product prior to her PUEV, this form is discontinued.

Item-specific Instructions:

Field	Instructions
Date of assessment	A full date is required.
RING PROVISION No ring provided OR Date 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". If a ring was provided, enter the full date here
Number of rings provided	Select the number of rings provided
Was a ring inserted at this visit?	Select "Yes" or "No" If ring was not inserted, specify reason in the text box provided
Date of insertion	Enter the complete date the ring was inserted
Time of insertion	Enter the time the ring was inserted (HH:MM)
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.
RING RETURN Did the participant have a ring in place at the start of the visit?	Select "Yes" or "No
Ring not returned	If a vaginal ring was not returned at a study visit, end the form.
Date ring(s) returned	Enter the complete date ring(s) were returned.
Number of rings returned at this study visit	Select the number of rings returned
Date returned ring #1 was provided to the participant	Enter the complete date Ring #1 was provided to the participant.
Date of removal of ring #1	Enter the complete date the ring was removed
Time of removal of ring #1	Enter the time the ring was removed (HH:MM)
Date returned ring #2 was provided to the participant	Enter the complete date Ring #2 was provided to the participant.
Date of removal of ring #2	Enter the complete date the ring was removed
Time of removal of ring #2	Enter the time the ring was removed (HH:MM)

Screening Date of Visit

Participant type: Mother and Infant

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).

Seroconverter Results

Participant type: Mother and infant

Purpose:
This form is used to document HIV confirmatory results from 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 complete collection date is required. If "No", skip to "Were Absolute CD4+ collected for testing?"
Were Absolute CD4+ collected for testing?	If "Yes", a complete 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 complete collection date and result is required. If "No", skip to "Was seroconverter plasma collected for storage?"
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.

Field	Instructions
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 Impact

Participant Type: Mother

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

General Instructions:
This form should be completed at Visits 3 and 4 (1 and 2 week visits), Visits 5 and 6 (1 and 2 month visits), Visit 7 – PUEV, and Visit 8 – SEV. The question should be read aloud in the participant's preferred language. If a social harm is reported on this form, complete Social Impact Y/N and Social Impact log forms in the Ongoing Logs folder.

Item-specific Instructions:

Field	Instructions
At any time during your study participation, 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 please navigate to the "Ongoing Logs" folder to document on the "Social Impact Y/N" and "Social Impact Log" forms.

Social Impact Y/N

Participant Type: Mother

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 Log" form.

Social Impact Log

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

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.

Item-specific Instructions:

Field	Instructions
Date reported to site	A complete date is required
Concisely describe social impact:	Describe the social impact in the text field provided. 200 characters are allowed.
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.xx.
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.
Did this involve physical harm to the participant?	Select "Yes" or "No". If "Yes", record the applicable adverse event(s) by using the drop down search lists.

Field	Instructions
Did this involve physical or other harm to participant's child(ren)?	Select "Yes" or "No". If "Yes", was physical harm or other harm inflicted on the baby she is currently breastfeeding? If "Yes", record infant adverse event number.
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.
Describe what was done by staff and participant to address social impact	Describe participant and staff actions separately in the text fields provided. 200 characters are allowed for each text field.
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

Participant Type: Mother

Purpose:
This form is used to document collection and storage of plasma for PK and archive, dried blood spots, gram stain, vaginal swab for biomarkers and microbiota, and used vaginal rings by the local site laboratory.

General Instructions:
Complete this form at Enrollment, Visit 3 and 4 (1 and 2 week visits), Visits 5 and 6 (1 and 2 month visits), and Visit 7 – PUEV.

Item-specific Instructions:

Field	Instructions
Specimen type	Select the specimen from the drop down menu. To add another specimen type, click "Add new log line" at the bottom of the log table.
Was specimen collected?	Select 'Yes' or 'No'. If 'No', then do not complete the date of collection and storage item(s).
Specimen collection date	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
Was sample 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.
If "Breastmilk for drug concentration", what method was used to collect the breast milk sample?	If Specimen Type is not "Breastmilk for drug concentration", leave this item blank.

STI Test Results

Participant type: Mother

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

General Instructions:
Complete this form at Screening and as indicated throughout 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 History Log form, when applicable.

Item-specific Instructions:

Field	Instructions
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 sample?	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 no, skip to "Was a sample collected for Syphilis testing?" If a vaginal wet prep was performed but not all assays were completed, select "Not done" for each uncompleted wet prep assay.
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.

Field	Instructions
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.
Homogenous vaginal discharge	Select 'Positive' if homogeneous vaginal discharge was observed.
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 trichomonas 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 NAAT 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.
NAAT for GC/CT/Trich	If "NAAT for GC/CT/Trich" was not done or not collected, select the 'No' option for "Was a vaginal sample collected for NAAT for GC/CT/Trich?" and do not complete the "Date of collection" or corresponding test results.
N. gonorrhea	If "N. gonorrhea" was not done or not collected, select the 'Not done' option. If the specimen was collected, complete the test result (either 'Positive' or 'Negative').
C. trachomatis	If "C. trachamotis" was not done or not collected, select the 'Not done' option. If the specimen was collected, complete the test result (either 'Positive' or 'Negative').
Trichomonas test	If "Trichomonas test" was not done or not collected, select the 'Not done' option. If the specimen was collected, complete the test result (either 'Positive' or 'Negative').

Field	Instructions
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

Participant type: Mother and infant

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 or Infant 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.
Primary reason for completion/discontinuation	Select ‘Scheduled exit visit/end of study’ if at Visit 8 – SEV. Select another applicable reason 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.
If Adverse event or Death, select applicable adverse event	If Adverse Event or Death is selected as reason for completion/discontinuation, 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 Adherence Y/N

Participant Type: Mother

Purpose:
This form documents if a participant has used the Truvada tablet and populates the Tablet Adherence form.

General Instructions:
This form is present within the Visits 3 and 4 (1 and 2 week visits), visits 5 and 6 (1 and 2 month visits), and visit 7 – PUEV folders. Selecting ‘Yes’ to the question “Since the participant's last adherence

assessment (or since product use started, if this is the first adherence assessment), has she ever taken an oral Truvada pill?" will add the Tablet Adherence form to the respective visit folder.

Tablet Adherence

Participant Type: Mother

Purpose:
This form documents tablet adherence for those participants that have been randomized to the Truvada Tablet.

General Instructions:
This form should be completed at Visits 3 and 4 (1 and 2 week visits), visits 5 and 6 (1 and 2 month visits), and visit 7 – PUEV folders, if the participant has reported using the Truvada tablet since their last visit.

Item-specific Instructions:

Field	Instructions
1. .Since your last visit, how comfortable have you been taking a pill every day?	Select the most appropriate answer from the options provided.
2. .On average, how many times per week did you take the pill?	Enter the number of times per week the participant took the pill. Numeric entry only. You may enter up to two digits.
3. .Since your last visit, how often have you skipped using the pills?	Select the most appropriate answer from the options provided. If "Never", end of form.
4. .What are the reason(s) why you skipped using the pills? Check all of the reasons that apply.	Select "Yes" for all of the reason(s) that apply. If "Other", use the text box provided to explain.

Tablet Assessment

Participant type: Mother

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

General Instructions:
This form is completed at the Enrollment visit.

Item-specific Instructions:

Field	Instructions
2. Did the participant attempt to swallow the first pill under direct observation at the clinic?	Select 'Yes' or 'No'.
2a. If "No", specify reason	Select the most appropriate reason from the dropdown list. If 'Other', explain in the text box provided.
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.
4. Based on your assessment and her feedback, how easy or difficult was it for the participant to swallow the pill today in the clinic?	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." Select "N/A" if the participant attempts to swallow the pill, but is unable to keep it down.
5. Did she find it difficult to swallow for any of the following reasons?	Select "Yes" or "No" for each reason provided. If "Other", specify in the text box provided.

Urine Test Results

Participant Type: Mother

Purpose:
This form is used to document the participant's local urine test results.

General Instructions:
Complete this form when clinically indicated during Screening, Enrollment, and during follow-up.

Purpose: This form documents participant's local urine test results.

Item-specific Instructions:

Field	Instructions
Dipstick urinalysis	If a specimen was collected, enter specimen collection date (not the date results are reported or recorded on the form) and results for Leukocyte esterase, Nitrites, Protein, and Glucose. If a specimen was not collected, skip to 'Urine culture'.
Protein, Glucose	If collected, select laboratory value severity grade according to the *Division of AIDS (DAIDS) Table for Grading the Severity of Adult and Pediatric Adverse Events,* most current version. If gradable, select the applicable AE log entry from the drop-down list. Note: The applicable AE must first be entered on the AE form to be visible in the drop-down list. If not reportable as an AE, select the "Not reportable" checkbox. The field "Not reportable as an adverse event" should be used when a participant enters the study with a lab value outside of the normal range, but acceptable for enrollment in the study; participating in the study with a sustained abnormal lab value throughout the study. Select "Not gradable" for value that does not meet grading criteria. If severity grade for a given lab value is "Not gradable", "Not reportable as an adverse event" should be left blank.
Urine Culture	If a specimen was collected, enter specimen collection date (not the date results are reported or recorded on the form).

Vaginal Practices

Participant Type: Mother

Purpose:
This form is used to document participant report of vaginal practices.

General Instructions:
Complete this form at Screening, Enrollment, and at any visits when the participant reports having inserted any non-medicated items in her vagina since her previous visit. (Note that any medicated vaginal products are listed on the Concomitant Medications CRF). Select 'Yes' or 'No' for each item. If 'Other' equals 'Yes', specify in the text field provided.

Vital Signs

Participant Type: Mother

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

General Instructions:
Complete this form at Screening, Enrollment, and Visit 7 - PUEV), at early termination (if applicable) and when clinically indicated.

Item-specific Instructions:

Field	Instructions
Date of Assessment	Enter the date the participant's vital signs were measured. A complete date is required.
Height	Enter the participant's height in centimeters. Height is required at Screening only.
Weight	Enter the participant's weight in kilograms. The value can be reported up to one decimal (e.g. 57.8 kg).
Body Temperature	Enter the participant's temperature in Celsius. The value must be reported 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). Complete "Blood pressure severity grade" using the drop down menu and "Blood pressure adverse event" text field, if applicable, or select "Not reportable as an adverse event."
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.

Change History

Summary of Changes to Study CCGs

Version		Affected Section(s) or Form(s)	Summary of Revisions
Number	Date		