
# CRF Completion Guidelines

# MTN-042

# Version 7.0 (23-Jun-2022)

# CRF Completion Guidelines

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|---|---|
| **Protocol Name:** | Phase 3b, Randomized, Open Label Safety Trial of Dapivirine Vaginal Ring and Oral TRUVADA® Use in Pregnancy |
| **Protocol Number:** | MTN-042 |
| **Authors:** | Amanda Brown and Nina Lee |
| **Version:** | 7.0 |

## Approvals

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# TABLE OF CONTENTS

# 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-042. 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-042 Atlas web page: https://atlas.scharp.org/cpas/project/MTN/042/begin.view?.

## General Guidelines

- The database captures data collected from the signing of the ICF through termination. No data collected prior to the signing of the ICF or following termination should be entered.
- 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).
    - Infant Interim Visits (see section on "Infant Interim Visits" on how to add interim visits to a participant's casebook).
    - Seroconversion folders
    - Congenital Anomaly Report folder
- The following CRFs can be added, if needed, to a participant's Screening or Enrollment folder:
    - Pelvic Exam CRF at Screening
    - Physical Exam CRF at Enrollment
    - Vaginal Practices CRF at Screening and/or Enrollment
    - Vital Signs at Enrollment

## 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 "Infant Interim Visit" to add an infant's interim visit. An Interim Visit or Infant Interim Visit folder will appear in the participant's casebook.
- Open the Interim Visit or Infant Interim Visit 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 – Pre-PPO form
    - 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. The next Pre-PO visit folder will be added to the participant's casebook.
    - If item "Did the participant complete this visit?" is marked 'No – Missed visit', the Missed Visit form will be added to the visit folder and required forms for that visit will not appear in the visit folder. The next Pre-PO visit folder will be added to the participant's casebook.
    - If item "Did the participant complete this visit?" is marked 'No – Pregnancy outcome', no other forms will appear in the visit folder. The post-PO visit folders will be added to the participant's casebook.
  - **Example 2**: Interim Visit form
    - Forms under "Forms Completed at Interim Visit" on the Interim Visit form that are checked will be added to the Interim Visit folder.
    - Any "Procedures completed at Interim Visit" on the Interim Visit form that are marked will be added to the Interim Visit folder.

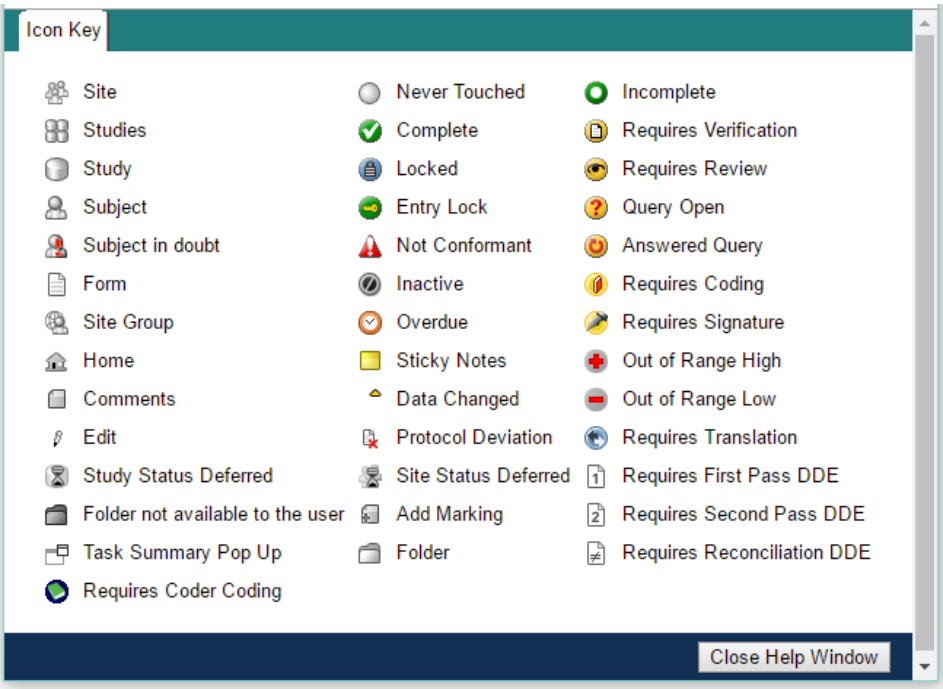
## Dynamic Search Lists

- 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**

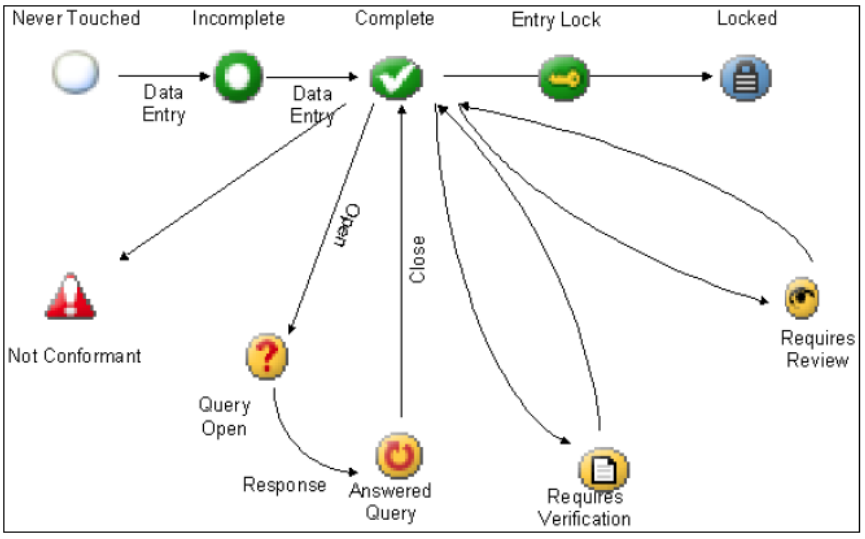



## Icon Progression

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**

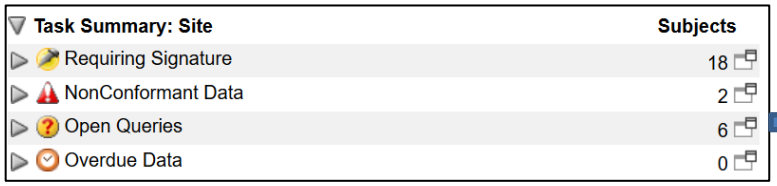
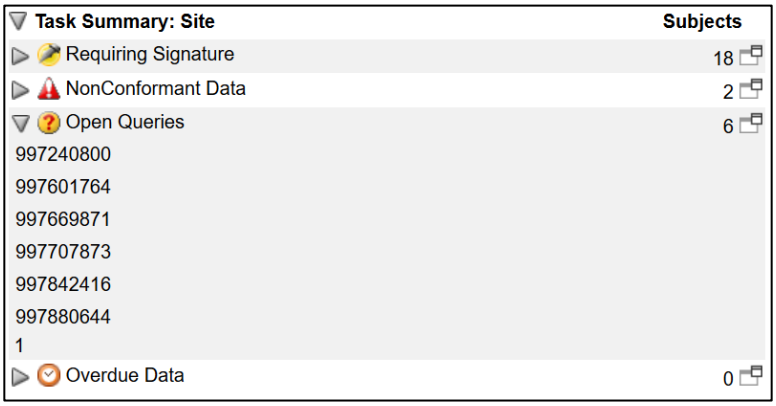
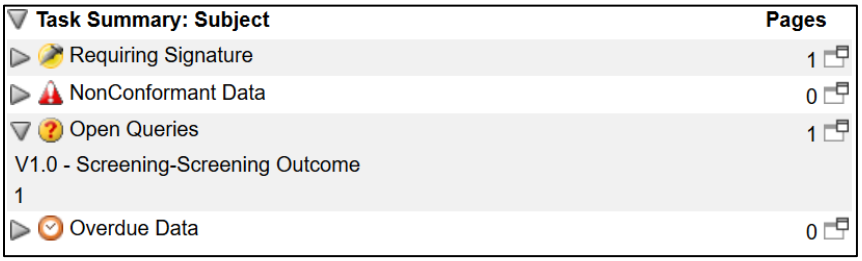



**Figure 4. Site-Level Task Summary**




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 Screening Outcome 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.

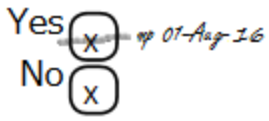
| Month | Abbreviation | Month | Abbreviation |
|---|---|---|---|
| **January** | **JAN** | July | **JUL** |
| **February** | **FEB** | August | **AUG** |
| **March** | **MAR** | September | **SEP** |
| **April** | **APR** | October | **OCT** |
| **May** | **MAY** | November | **NOV** |
| **June** |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

For example, record September 20, 2016 as: 

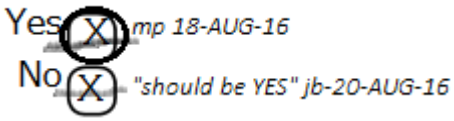

## Data Corrections and Additions - Rave Form and/or Paper CRF

- 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:



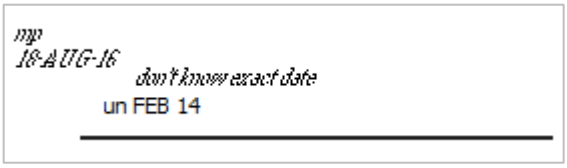

- If the correct answer has previously been crossed out, do the following:
  - circle the correct response,
  - write an explanation in the white space near the response, and
  - initial and date all corrections as shown below:




## 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. |

| Field | Instructions |
|---|---|
| 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.<br><br>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). |
| If Mother: At which visit was this AE first reported?<br><br>OR<br>If Infant: At which visit was this AE first reported? | If reporting an AE in a mother casebook, select a visit from the “If mother” dropdown list and leave the “If infant” dropdown list empty.<br><br>If reporting an AE in an infant casebook, select a visit from the “If infant” dropdown list and leave the “if mother” dropdown list empty. |
| 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.<br><br>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. |
| AE is associated with pregnancy | Select the checkbox if the AE is deemed related to pregnancy. |
| 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.<br><br>Select "Drug (dapivirine)" if the AE is believed to be related only to the product (dapivirine) within the ring.<br><br>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).<br><br>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.<br>***Dose reduced:*** This option does not apply and should not be selected in MTN-042.<br>***Dose increased:*** This option does not apply and should not be selected in MTN-042.<br>***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 "Primary reason for ending study product use" not equal to 'Scheduled study product use period completed'.<br>***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.<br>***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.<br>*Medication(s)*: Select 'Medication(s)' only if the participant reports taking the medication. Report the medication(s) on the Concomitant Medications Log form.<br><br>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.<br><br>If "Therapeutic procedure/surgery", or "Diagnostic procedure" is selected, then record applicable details in the Comments section at the bottom of the form.<br>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.<br><br>***Recovering/resolving****:* AE is continuing and has not yet resolved or returned to baseline severity/frequency.<br><br>***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.<br><br>***Not recovered/resolved****:* Select this option whenever an AE is continuing at the time of participant termination from the study.<br><br>***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".<br><br>***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.<br><br>If the AE is not an SAE, skip to "Has or will this AE be reported as an EAE?". |
| SAE/EAE Onset Date | Provide the date the adverse event first meets ICH criteria for seriousness.<br><br>A month and year are required. |
| Has or will this AE be reported as an EAE?<br><br>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.*<br><br>If this AE was/is reported as an EAE (indicated as 'yes'), provide the EAE number and complete any subsequent updates to this form on the applicable EAE form. |
| Comments | Comments are required for every AE.<br>• Record pertinent details for relationship assessments.<br>• Record pertinent clinical information |

## ***Baseline Behavioral Assessment***

**Participant Type:** Mother

**Purpose:**
This form is used to collect baseline behavioral data from the participant.

**General Instructions:**
Complete this form at the participant's Enrollment visit. This form is translated and should be interviewer-administered; read each question and all response options aloud to the participant. When "[pills/ring]" is present, only the participant's assigned study product should be read aloud.

| Field | Instructions |
|---|---|
| 2. .In general, how worried are you about the effect of the [pills/ring] on your own health? | Select the most appropriate answer from the options provided. |
| 3. .In general, how worried are you about the effect of using the [pills/ring] on your baby's health? | Select the most appropriate answer from the options provided. |
| 4. .Have you received pregnancy-related advice or care from any of the following people? | Check all of the fields that apply.<br>If "Another family member" or "Other", use the text box provided to specify. |
| 5. .Besides yourself, who has the most influence on your decisions during this pregnancy? | Select an option from the dropdown menu.<br>If "Another family member" or "Other", use the text box provided to specify. |
| 6. .Do the following people in your life know about your use of the [pills/ring]? | Read each response option out loud, and select "Yes" or "No" for each person.<br>If "Yes" is selected for "Another family member" or "Other", use the text box provided to specify.<br>If "Yes" for any field, select "Supportive" or "Not supportive". |
| 7. . Outside of this study team, has a doctor, nurse, or other professional ever talked with you about depression (or problems with emotions, nerves or mental health)? | Select the most appropriate answer from the options provided.<br>If "No" or "Don't remember", skip to item 9. |
| 8. .When did the health professional talk to you about depression (or problems with emotions, nerves or mental health)? | Check all of the fields 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 the most appropriate answer from the options provided.<br>If "No" or "Don't remember", skip to item 13. |
| 11. .When did the health professional tell you that you had depression (or problems with emotions, nerves or mental health)? | Check all of the fields that apply. |

| | |
|---|---|
| 12. .Did you get counseling or any medical treatment for your depression (or problems with emotions, nerves or mental health)? | Select “Yes” or “No”. |
| 13. .Now we will ask some questions about taking the pills or wearing the vaginal ring while pregnant.<br><br>For you, how acceptable is [taking a daily pill/wearing a monthly ring] for HIV prevention? | Select the most appropriate answer from the options provided. |
| 14. .Please indicate how much you agree with the following statement: It is clear to me how [taking a daily pill/wearing a monthly ring] would help me prevent HIV infection. | Select the most appropriate answer from the options provided. |
| 15. . .How much do you expect/anticipate that using the [pills/ring] will interfere with other priorities in your life? | Select the most appropriate answer from the options provided. |
| 16. .How do you think the community will react to this [pills/ring] for HIV prevention in pregnant women? | Select the most appropriate answer from the options provided. |
| 17. .We are interested in learning more about women’s wellbeing in their relationships…<br><br>The next questions are about your relationship with your primary sex partner or any other partners.<br><br>Has your primary sex partner or ANY other current or previous partner ever: | Select “Yes” or “No” for each of the scenarios listed.<br><br>If “Yes” for any field, select “Yes” or “No” if it has happened during this pregnancy. |
| 18. .I am now going to read you some statements about how often you are supported by the people around you. Being "supported" may include receiving help that is 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. | For each field, select an option from the dropdown menu.<br><br>If “N/A (no primary partner)” for “c. My primary partner helps me”, then end of form. |

## ***Baseline Medical History Y/N***

**Participant Type:** Mother

**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'.<br><br>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.<br><br>If 'No' is selected, no further action is required.<br><br>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

**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 via obstetric abdominal exam, pelvic exam, physical exam, or laboratory testing.
- At the Enrollment Visit, review and update as needed. Those conditions that are ongoing at the time of enrollment (including ongoing chronic conditions) are considered the participant's pre-existing conditions.

- If a medical condition increases in severity or frequency during follow-up and is captured as an AE, the medical history **should not** be updated to include an End Date.
- Do record baseline medical conditions identified during follow-up. Write a chart note to explain why the entry was added after the Enrollment Visit.

Complete a separate entry (e.g., log line) for each baseline medical history condition/event when entering into the study database.

**Item-specific Instructions:**

| Field | Instructions |
|---|---|
| Date medical history collected | Record the date the medical history condition/event was reported by the participant. A complete date is required. |
| Description of medical history condition/event | Whenever possible, provide a diagnosis instead of listing a cluster of symptoms. If no diagnosis is identified, each symptom must be recorded as a separate term. If an abnormal lab value is reported at the Enrollment visit, record the lab assay with the direction (i.e., increased or decreased) of the abnormality. For example, “decreased hematocrit” or “increased ALT”.<br><br>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.<br><br>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’.<br><br>Select from the options provided in the drop-down list.<br><br>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.<br><br>• 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.<br>• If the item improves severity or resolves during the study, then the Toxicity Grade should remain unchanged on this form.<br>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.<br><br>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.<br><br>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.<br><br>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 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.<br><br>Record the date the medical condition was considered resolved. For surgeries/procedures, record the date the surgery/procedure was completed.<br><br>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. |

## ***Chemistry Panel***

**Participant Type:** Mother and infant

**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, Enrollment, the 1st 4-week visit (cohorts 2 – 3), the 4-week visit corresponding to or immediately before 36th week gestation (cohort 3), and the 6-week PPO visit, and as indicated during the study. For infants born to mothers in the oral Truvada group, complete at V201.0 – PPO Visit, V203.0 – 6 week PPO Visit, V204.0 – 6 month PPO Visit, V205.0 – 12 month visit. For infants born to mothers in the DPV ring group, complete as indicated. Record results on this form as they become available. Creatinine clearance calculation is not required for infants.

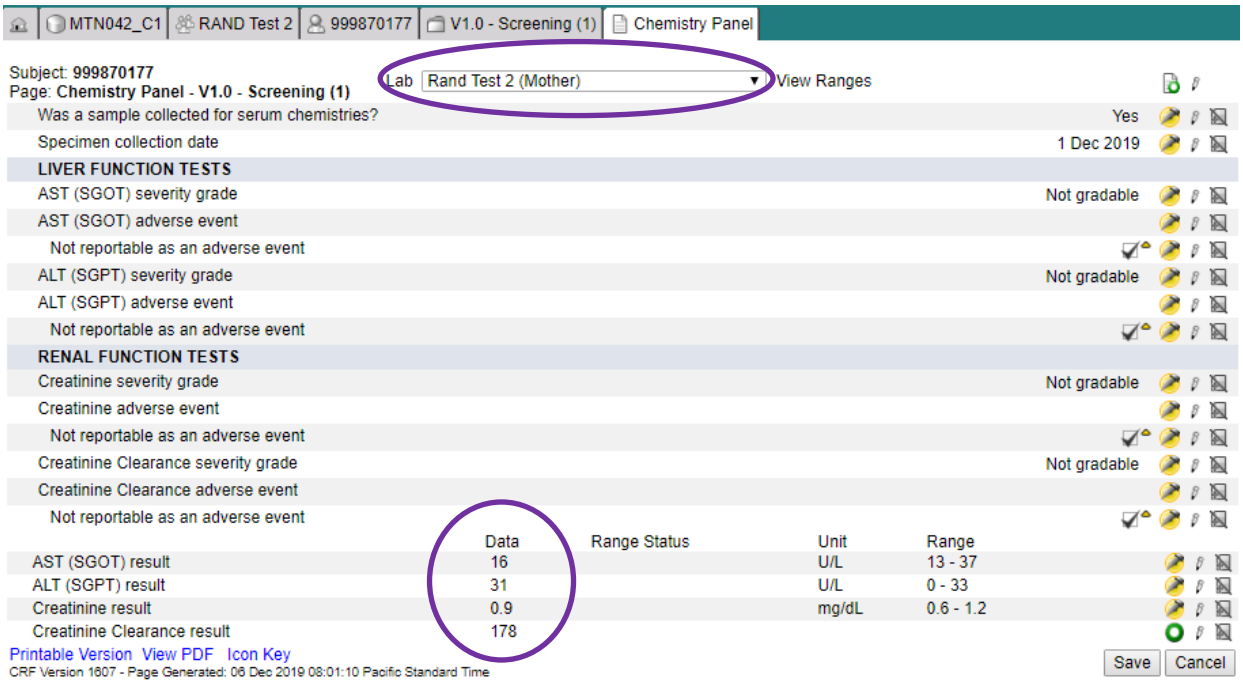
If any or all of the lab tests listed on this form are repeated (re-drawn) between the Screening and Enrollment Visit, document the repeated results on the same Chemistry Panel form. If the participant enrolls, the updated results should be submitted into the study database.

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 or Infant Demographics and Infant Follow-up Visit Summary eCRFs 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.

*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  l/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 (for mothers) or after birth (for infants). This includes, but is not limited to: prescription medications, non-prescription (i.e., over-the-counter) medications, medications administered during labor, 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.<br><br>**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.<br><br>**Implants/IUD**: Record each implant/IUD on a new log line. The start date should be the date of implant or insertion.<br><br>No medications initiated after the termination date should be entered. |

| | |
|---|---|
| Date stopped | Enter the stop date of this medication if known. At a minimum, the month and year is required.<br><br>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.<br><br>**Oral contraceptive birth control pills**: Indicate the stop date as the date the last pill of the pack was taken.<br><br>**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").<br><br>For combination drugs, use the '/' or '-' to distinguish the different doses (i.e., hydrocodone/acetaminophen 5/500).<br><br>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.<br><br>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.<br><br>If the participant does not know the exact dose units (e.g., "250 mg"), record an estimate (e.g., "1 tablet").<br><br>If no information on units is known, select the 'Unknown' option.<br><br>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.<br><br>Below is a list of common frequency abbreviations:<br><br>• PRN: as needed<br>• QD: every day<br>• BID: twice daily<br>• TID: three times daily<br>• QID: four times daily<br>• QM: once a month<br>• QH: each hour<br>• ONCE: one time<br>• Other: alternative dosing schedule or unknown<br><br>If 'Other' is selected, specify in the corresponding "If other frequency, specify" text field provided.<br><br>**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.<br><br>If 'Other' is selected, specify in the corresponding "If other route, specify" text field provided.<br><br>**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 2 AEs can be selected. If the medication was not administered to treat an AE, select 'No', and end the form. |

## ***Congenital Anomaly Review***

**Participant Type:** Mother or infant

**Purpose:**
This form is used to summarize where in the database information about a congenital anomaly is captured and to document the geneticist's review of the congenital anomaly.

**General Instructions:**
This form is present in the Congenital Anomaly Report folder. If a congenital anomaly is being reported for an enrolled infant, the Congenital Anomaly Report folder should be added to the infant's casebook; if a congenital anomaly is being reported for a non-enrolled infant, the Congenital Anomaly Report folder should be added to the mother's casebook. The first section of this form is completed by the site to summarize what information about the congenital anomaly is available. The second section of the form will be completed by the geneticist to document their determination of the congenital anomaly.

**Item-specific Instructions:**

| Field | Instructions |
|---|---|
| Date of report | Site to complete. Enter the date the form is completed. |
| Infant age (in days) at report | Site to complete. Enter the infant age when the anomaly is reported. |
| Description of anomaly | Site to complete. Describe the congenital anomaly being reported. Be as descriptive as possible. |

| Field | Instructions |
|---|---|
| On which form(s) is the anomaly reported? (select yes or no for each) | Site to complete.<br><br>**Non-Enrolled Adverse Event Log (in mother's casebook)**: Select “yes” if the congenital anomaly was reported on the Non-Enrolled AE Log in the mother’s casebook. If "yes", enter the applicable AE term and AE grade.<br><br>**Adverse Event Log (in infant's casebook):** Select “yes” if the congenital anomaly was reported on the AE Log in the infant’s casebook. If "yes", enter the applicable AE term and AE grade.<br><br>**Was an EAE report uploaded?:** Select “yes” if an EAE report was uploaded to the EAE Upload CRF.<br><br>**Are photographs available?**: Select “yes” if photographs were uploaded to the Photographic Survey CRF. |
| Date of review | Geneticist to enter the date of their review. |
| Diagnosis | Geneticist to enter a diagnosis after their review of all available data. |
| Anomaly category | Geneticist to select an anomaly category: “Major”, “Minor”, “Not an anomaly” or “Not enough information”.<br><br>If "not enough information", geneticist to explain in the text field provided what additional information is needed. |
| Comments | Geneticist to explain rationale for diagnosis and anomaly category provided. |

## ***COVID-19 Behavioral Assessment***

**Participant Type:** Mother

**Purpose:**
This form is used to capture information about the impact of COVID-19 pandemic on the participant during the study.

**General Instructions:**
This form is completed at Enrollment and V103.0 – 6 week PPO Visits. Responses should reflect the participant’s status at the relevant visit and should not be changed afterwards unless correction is needed. The form’s questions are translated and should be read aloud word for word to the participant.

**Item-specific Instructions:**

| Field | Instructions |
|---|---|
| Date of assessment | Enter the date the form is completed. |

| Field | Instructions |
|---|---|
| As you may know, there is an outbreak of respiratory disease caused by the novel coronavirus. | Only read this label at Enrollment visit assessment. |
| Were you infected (or suspected to be infected) with COVID-19? | Do not read the possible out loud to participant, select the response that best describes their response. |
| Did you experience any of the following situations because of COVID-19 and the plans used to manage the outbreak? | Skip this question at Enrollment visit.<br>This is the last question at V103.0 – 6 week PPO visit. |

## ***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:**

| Field | Instructions |
|---|---|
| Date of birth | Please provide the date of birth. At a minimum, the year is required. |
| Age | This field is automatically derived by Medidata Rave based on the participant's date of birth and the screening date of visit. No data entry is required. |
| Sex at birth? | This field has been pre-selected as "Female" per protocol Inclusion Criteria. This field is locked and cannot be edited. |

<table>
<tr><th>Field</th><th>Instructions</th></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.<br><br>
<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’.<br><br>If ‘No’, skip to question 11.</td></tr>
<tr><td>11. How many sex partners have you had in your lifetime?</td><td>Enter a number. Only numeric characters are allowed.</td></tr>
</table>

| Field | Instructions |
|---|---|
| 14. During this pregnancy, how often did you have a drink containing alcohol? By alcohol, we mean beer, wine, liquor, and home or local brews. | Select 'Yes' or 'No'.<br><br>If 'No', skip to question 17. |
| 17.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. The date of product use discontinuation should align with the reason selected for discontinuation. (e.g, if the reason for ending product use is admission for labor and delivery management, the date of product use discontinuation should match the date of admission).<br><br>This date may or may not match the date the participant reports last using product or the date the product is returned to the clinic. |
| Primary reason for ending study product use | Record the primary reason from the drop-down menu.<br><br>Multiple response options for "Primary reason for ending study product use" align with scheduled discontinuation of study product:<br>• Scheduled study product use period completed<br>• Report of admission to care for labor and delivery management including induction of labor and cesarean delivery<br>• Pregnancy loss<br>• Labor or rupture of membranes is confirmed<br><br>The most specific option should be selected for each participant. It is expected that "Scheduled study product use period completed" will be |

| | |
|---|---|
| | selected primarily for participants who discontinue study product due to reaching 41 6/7 weeks gestation.<br><br>If 'Adverse Event' or 'Death' is selected, specify the AE entry (in Medidata Rave, choose the AE from the AE dynamic drop-down list).<br><br>**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.<br><br>If "Other", then specify relevant details in the "If, Other, specify" text field provided. |

## *EAE Upload*

**Participant Type:** Mother or Infant

**Purpose:**
This form is used to upload EAE reports to Rave for geneticist review when a congenital anomaly is reported.

**General Instructions:**
This form is present in the Congenital Anomaly Report folder. Once the initial EAE report is finalized, the report should be exported from DAERS as a PDF and uploaded to the Rave EAE Upload CRF. Whenever an update is made in DAERS, a new PDF should be generated and the new PDF uploaded to a new log line on the EAE Upload CRF; the previous log line should be inactivated.

**Item-specific Instructions:**

| Field | Instructions |
|---|---|
| Date of EAE report | A full date is required. The data should match the "Report status date" of the EAE report. |
| EAE report | Upload a PDF file of the EAE report. |

## *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 and V103.0 – 6-week PPO Visit.

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.<br><br>Select 'yes' or 'no' based on whether referrals to additional support, evaluations, or treatments were subsequently made. |
| EPDS Score | The final EPDS score will be calculated and auto-populated by Rave. No data entry is required. |

## ***Enrollment***

**Participant Type:** Mother

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

**General Instructions:**
Complete this form for each mother participant who is enrolled into MTN-042.

**Item-specific Instructions:**

| Field | Instructions |
|---|---|
| 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. |
| Was the participant purposively selected to participate in IDI (In Depth Interview)? | Refer to the SSP procedures to determine whether the participant should be selected to participate in the IDI. |
| Will this participant participate in serial IDIs? | Indicate whether the participant will participate in the IDI. |

## ***Follow-up Behavioral Assessment***

**Participant Type:** Mother

**Purpose:**
This form is used to collect follow-up behavioral data from the participant.

**General Instructions:**

Complete this form at the participant's Visit 6 (4-week visit) for cohort 2 participants. This form is translated and should be interviewer-administered; read each question and all response options aloud to the participant. When "[pills/ring]" is present, only the participant's assigned study product should be read aloud.

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

| Field | Instructions |
|---|---|
| 2. .Overall, how satisfied have you been with the [pills/ring] for preventing HIV? | Select the most appropriate answer from the options provided. |
| 3. .Let's talk about your current comfort [wearing the vaginal ring for a month/taking a pill every day]…. | Read each item out loud, and select a response for each item. |
| 4. .Which product would you prefer to use? | Select the most appropriate answer from the options provided. |
| 5. .Would you be willing to use the [pills/ring] for HIV prevention when pregnant in the future? | Select the most appropriate answer from the options provided. |
| 6. .When you're not pregnant in the future, would you be willing to use the [pills/ring] for HIV prevention? | Select the most appropriate answer from the options provided. |
| 7. .Overall, how much do you like or dislike male condoms for HIV prevention? | Select the most appropriate answer from the options provided. |
| 8. .Overall, how much do you like or dislike the [pills/ring] for HIV prevention? | Select the most appropriate answer from the options provided. |
| 9. .In general, how worried are you about the effect of the [pills/ring] on your own health? | Select the most appropriate answer from the options provided. |
| 10. .Some women may have worries about the effect of the [pills/ring] on their own health or wellbeing. Are you worried the [pills/ring] could…? | Select "Yes" or "No" for each of the fields listed. |
| 11. .In general, how worried are you about the effect of using the [pills/ring] on your baby's health? | Select the most appropriate answer from the options provided. |

| Field | Instructions |
|---|---|
| 12. .Some women may have worries about the effect of the [pills/ring] on their delivery or baby's health. Are you worried the [pills/ring] could…? | Select "Yes" or "No" for each of the fields listed.<br><br>If "Yes" for "Anything else related to the [pills/ring]?", then specify in the provided text box. |
| 13. .How easy or difficult is it for you to insert the vaginal ring? | If participant is using Truvada oral tablet, skip to item 15.<br><br>Select the most appropriate answer from the options provided. |
| 14. .How easy or difficult is it for you to remove the vaginal ring? | Select the most appropriate answer from the options provided. |
| 15. .How much does using the [pills/ring] interfere with other priorities in your life? | Select the most appropriate answer from the options provided. |
| 16. .We know that the vaginal ring may come out on its own or may be difficult to use all the time. There are no right or wrong answers to these questions, and none of your answers will prevent you from participating in the study.<br><br>.How much effort does it require to wear the vaginal ring monthly? | If participant is using Truvada oral tablet, skip to item 18.<br><br>Select the most appropriate answer from the options provided. |
| 17. .Did you mind wearing the monthly ring … | Select the most appropriate answer for each of the fields listed. |
| 18. .How easy or difficult is it for you to swallow the pills? | If participant is using DPV vaginal ring, skip to item 22.<br><br>Select the most appropriate answer from the options provided. |
| 19. .We know the tablets may be difficult to take every day. There are no right or wrong answers to these questions, and none of your answers will prevent you from participating in the study.<br><br>.How much effort does it require to take the oral pills daily? | Select the most appropriate answer from the options provided. |
| 20. .Did you mind swallowing the pills daily… | Select the most appropriate answer for each of the fields listed. |

| Field | Instructions |
|---|---|
| 21. .In the last 4 weeks, how often did you experience nausea after swallowing the pill? | Select the most appropriate answer from the options provided. |
| 22. .Have you received pregnancy-related advice or care from any of the following people? | Check all fields that apply.<br>If “Another family member” or “Other” is checked, use the provided text box to specify. |
| 23. .Besides yourself, who has the most influence on your decisions during this pregnancy? | Select an option from the dropdown menu.<br>If “Another family member” or “Other”, use the provided text box to specify. |
| 24. .Do the following people in your life know about your use of the [pills/ring]? | Read each response option out loud, and select “Yes” or “No” for each person.<br>If “Yes” is selected for “Another family member” or “Other”, use the text box provided to specify.<br>If “Yes” for any field, select “Supportive” or “Not supportive”. |
| 25a. .Now I want to ask you a few questions about your sexual behaviors. Please feel free to answer honestly and remember that aside from the study staff, no one will be able to link your answers back to you. | Select the most appropriate answer from the options provided.<br>Questions can always be skipped if the participant prefers not to answer. |
| 25b. .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, including your primary partner. | Numeric entries only permitted. |
| 25c. .Since joining the study, have you had anal sex? By anal sex, I mean when a man puts his penis inside your anus. | Select “Yes” or “No”.<br>If “No”, skip to item 26. |
| 25d. .During the last act of anal sex that you had, was a male condom used? | Select “Yes” or “No”. |

| Field | Instructions |
|---|---|
| 26. .The next questions I will ask you are about drinking alcohol.<br><br>Since joining the study, 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.<br><br>If “Never”, skip to 29. |
| 27. .How many drinks containing alcohol do you have on a typical day when you are drinking? | Select an option from the dropdown menu. |
| 28. .How often do you have six or more drinks on one occasion? | Select an option from the dropdown menu. |
| 29. .How do you think the community will react to this [pills/ring] for HIV prevention in pregnant women? | Select the most appropriate answer from the options provided. |
| 30. .Please indicate how much you agree with the following statement: It is clear to me how [taking a daily pill / wearing a monthly ring] would help me prevent HIV infection. | Select the most appropriate answer from the options provided. |
| 31. .I am now going to read you some statements about how often you are supported by the people around you. Being "supported" may include receiving help that is 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.<br><br>If “N/A (no primary partner)” for “c. My primary partner helps me”, end of form. |

## ***Follow-up Visit Y/N – Pre-PO***

**Participant type:** Mother

**Purpose:**
This form is documents whether a pre-pregnancy outcome 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 - Week 1 Phone Contact through V7.0 - Week 5 Phone Contact.

**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. The next pre-PO visit folder will be automatically added to the participant's casebook.<br><br>Select 'No – Missed Visit' if the visit was missed and the pregnancy outcome did not occur (i.e., no part of the visit occurred during the visit window, and the pregnancy outcome did not occur during the visit window). A Missed Visit form will automatically add to the visit folder to be completed. The next pre-PO visit folder will be automatically added to the participant's casebook.<br><br>Select 'No – pregnancy outcome' if the visit did not occur but the pregnancy outcome did occur within the visit window. No other forms will be added to the visit folder. The post-PO follow-up visits (Visits 101 – 103) will be automatically added to the participant's casebook. |

## ***Follow-up Visit Y/N***

**Participant type:** Mother and infant

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

**General Instructions:**
This form is completed for each scheduled post-PO visit and is present in each post-PO follow-up visit folder for mother (V101.0 – PPO Visit through V103.0 – 6 week PPO Visit) and infants (V201.0 – PPO Visit through V205.0 – 12 month PPO Visit).

**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.<br><br>Select 'No' if the visit was missed. A Missed Visit form will automatically add to the visit folder to be completed.<br><br>Select 'No - skipped because v101 or v201 completed' if v102 or v202 was skipped because v101 or v201 was completed within the visit window. No other forms will be required. |

## ***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 Phone Contact through V103.0 - 6 week PPO Visit.

**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'.<br><br>If 'Yes', then complete a Product Discontinuation form within the Discontinuations Logs folder. |
| Was study product held at this visit? | Select 'Yes' or 'No'.<br><br>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'.<br><br>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'.<br><br>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'.<br><br>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'.<br><br>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'.<br><br>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.<br><br>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 Infant Additional Study Procedures form will dynamically be added to the visit folder to be completed. |

## ***Hematology***

**Participant Type:** Mother and infant

**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, Enrollment, the 1st 4-week visit (cohorts 2 – 3), the 4-week visit corresponding to or immediately before 36th week gestation (cohort 3), and the 6-week PPO visit, and as indicated during the study. For infants, complete as indicated. Record results on this form as they become available. Creatinine clearance calculation is not required for infants.

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.

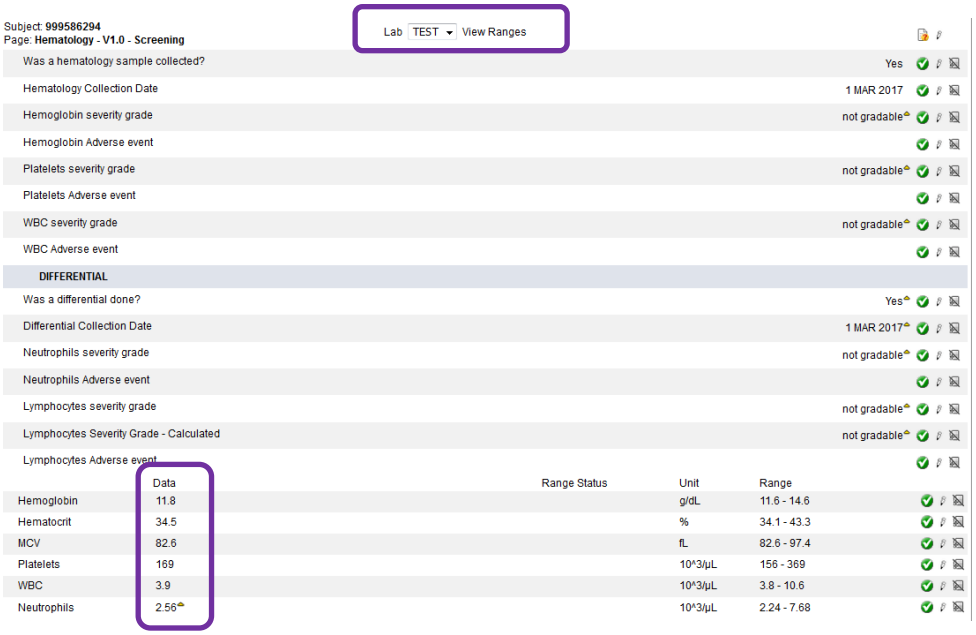
At Screening, record any applicable diagnoses within the Baseline Medical History Log eCRF, when applicable.

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 or Infant Demographics and Infant Follow-up Visit Summary eCRFs 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 (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.

*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:

  - **Hemoglobin**: g/dL, report up to 5 decimals
  - **MCV:** fl, report up to 5 decimals
  - **Platelets**: cells/mm$^3$, report up to 5 decimals
  - **WBC:** cells/mm$^3$, report up to 5 decimals
  - **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. |
| Was plasma stored for HIV confirmatory testing? | If plasma was not stored or was not required to be stored, skip to the HIV RNA PCR item.<br><br>If plasma was stored for confirmatory testing, complete the Specimen Storage CRF to document that "Plasma for archive" was collected and stored. |
| Plasma for HIV confirmatory testing collection date: | A complete date is required if plasma for HIV confirmatory testing was stored. |
| HIV RNA PCR | Note that the ">" symbol is "greater than", the "<" symbol is "less than" and the "=" is "equal to" the result provided.<br><br>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.<br><br>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.<br><br>If HIV RNA PCR testing is not done/not collected, skip to the Seroconverter Plasma Storage items. |
| HIV RNA PCR Kit | Select the HIV RNA PCR testing kit that was used. If completing a paper form mark the kit from the response options provided. When completing the form within Rave, select the kit from the drop-down field. |
| HIV RNA PCR Kit Lower limit of detection | Select "20" or "40" as the lower limit of detection or record the viral copies/mL |
| CD4% | If automatically calculated, record the CD4+ percentage that was reported for the specimen in the item, "Absolute CD4". If the CD4+ percentage is not available (i.e., it was not reported and would have to be manually calculated), mark the "not available" box. |

| 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 Clinical Product Hold/Discontinuation Log to reflect permanent discontinuation of study product. If the participant status is not clearly negative or clearly positive, mark the "pending" box and updated this item once the participant's final HIV status is known.<br><br>When completing the paper form, mark the participant's final HIV status from the list of outcomes provided. When completing the form, select the participant's HIV status from the drop-down field. |

## ***HIV Test Results***

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

## ***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-042, and if applicable, type of ineligibility.

**General Instructions:**
Complete this form for each participant screened in MTN-042. Complete this form when it is determined whether the participant will enroll in the study. If a participant completes a second screening attempt, add a second Screening folder and complete this form again in the second folder.

**Item-specific Instructions:**

| Field | Instructions |
|---|---|
| Eligibility Status | If the participant is eligible, but did not enroll in the study, select "Eligible, but participant declined enrollment" and specify the reason in the text field provided.<br><br>Select "Incomplete Screening" if the participant did not complete all screening procedures. |
| Date participant was found "Eligible/Not Enrolled" or "Ineligible" or "Incomplete screening". | If the participant is not enrolled, enter the date it was determined that the participant would not enroll. |
| 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 "Investigator decision", specify (max 200 comments) | This field is required if "E7. Has a condition that, per IoR/designee, preclude informed assent/consent, make study participation unsafe, complicate interpretation of outcome data or interfere with achieving study objectives" is selected for the reason why the participant is ineligible. A maximum 200 characters is allowable. |
| Mark if additional Screening folder is needed to document an additional screening. | If a participant has a second screening attempt, select this checkbox to add a new Screening folder. Record all data from the second screening attempt in the second screening folder. |

## ***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 vitals 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 the V204.0 – 6 month PPO visit and V205.0 – 12 month PPO visit.

**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. |
| 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 Feeding Assessment***

**Participant Type:** Infant

**Purpose:**
These forms are used to capture feeding practices for the infant at each infant visit.

**General Instructions:**
This form is completed for each scheduled visit and is present in each follow-up visit folder, starting at V201.0 – PPO Visit through V205.0 – 12 month PPO Visit.

**Item-specific Instructions:**

| Field | Instructions |
|---|---|
| Date of assessment | A complete date is required. |
| What have you fed your baby since your baby's last visit? | Do not read out responses. Check the applicable responses from the participant. Use the text box to describe any 'other' responses.<br><br>When completing at the infant's first visit (either v201 or v202), indicate what the infant has been fed **since birth**. |
| Has the mother taken any medications since the last visit while she has been breastfeeding the infant? | Only complete the medications question and enter medications on the log lines when both conditions have been met: a) Assessment is being completed after V203 – 6 week PPO and b) Breastmilk was selected under 'What have you fed your baby since your baby's last visit?'. |

## ***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 V201.0 – PPO Visit through V205.0 – 12 month PPO Visit.

**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'.<br><br>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'.<br><br>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'.<br><br>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'.<br><br>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 | Note that the ">" symbol is "greater than", the "<" symbol is "less than" and the "=" is "equal to" the result provided.<br><br>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.<br><br>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.<br><br>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 Clinical Product Hold/Discontinuation Log to reflect permanent discontinuation of study product. If the participant status is not clearly negative or clearly positive, mark the "pending" box and updated this item once the participant's final HIV status is known.<br><br>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. |

## ***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-042, 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 (e.g., when the infant is born alive and has had consent provided).

| Field | Instructions |
|---|---|
| Did the infant enroll in MTN-042? | Select “Yes” or “No” to document if the infant is enrolled in MTN-042.<br><br>If “No”, select from the dropdown menu the reason why the infant did not enroll and enter the date it was determined that the participant would not enroll.<br><br>If the reason the infant did not enroll is “Other”, explain in the text box provided. |

## ***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'.<br>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'.<br>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'.<br>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'.<br>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.<br>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**.<br>Procedures that were not completed at this visit should be left blank. |

## ***Infant Participant Transfer***

**Participant Type:** Infant

**Purpose:**
This form documents when an infant participant is permanently transferring to another study site.

**General Instructions:**

- The transferring site adds the Participant Transfer form to the appropriate visit folder by marking it on the Follow-up Visit Summary form or the Interim Visit Summary form.
- For more information, contact the CDM.

**Field-specific Instructions:**

| Field | Instructions |
|---|---|
| Name of transferring study site | Record the name of the transferring site. |
| Name of receiving study site | Record the name of the receiving site. |
| Visit of last completed contact with participant | Select the last completed visit at the transferring site with the participant from the dropdown list. |
| If "Interim visit", specify Interim visit code | If "Interim visit", record the applicable interim visit code. Refer to the Manual of Procedures for more information on visit codes. |
| Date participant's records were sent to receiving study site | Enter the date that the source documents were sent from the transferring site to the receiving site. |

## ***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 V201.0 – PPO Visit 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 V201.0 – PPO Visit, V203.0 – 6-week PPO Visit, V204.0 – 6-month PPO Visit, and V205.0 – 12-month PPO Visit.

**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. |
| If less than 28 days, calculate weight-for-age percentile | If the infant is less than 28 days old, determine the weight-for-age percentile and select the appropriate option:<br>• < 3rd percentile<br>• >= to 3rd but < 10th percentile<br>• At or above 10th percentile |
| Weight-for-age severity grade per FGGT grading scale | If the infant is less than 28 days old, select the appropriate severity grader per FGGT grading scale:<br>• Grade 1=Mild<br>• Grade 3=Severe<br>• Not gradable |
| If > or = 28 days, calculate WHO weight-for-length z-score | If the infant is greater than or equal to 28 days old, calculate the WHO weight-for-length z-score and report to two decimals. |
| WHO weight-for-length severity grade per DAIDS tox scale | If the infant is greater than or equal to 28 days old, select the appropriate severity grade per DAIDS tox scale:<br>• Grade 1 (Mild)<br>• Grade 2 (Moderate)<br>• Grade 3 (Severe)<br>• Grade 4 (Potentially life-threatening)<br>• Not gradable |
| Was the status of anterior fontanel closure assessed? | Complete 'Yes' or 'No' for if assessment was done. If 'Yes' select 'Open' or 'Closed' below. |
| Was the status of posterior fontanel closure assessed? | Complete 'Yes' or 'No' for if assessment was done. If 'Yes' select 'Open' or 'Closed' below. |
| Body Temperature | Enter the participant's temperature and associated units (Celsius or Fahrenheit). The value must be reported to one decimal (e.g. 37.2° C). |

| Field | Instructions |
|---|---|
| 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). |
| Rate of Respirations | Enter the participant's respiratory rate in breaths per minute (e.g. 14 breaths/min). |
| Oxygen saturation | As measured by oximeter |

* 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. It is updated throughout a participant's study participation any time a new consent is signed.

**General Instructions:**
Complete this form for each participant, and her infant, who screens for MTN-042.

**Item-specific Instructions:**

| Field | Instructions |
|---|---|
| Date informed consent initially signed | 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, retain the initial ICF date in the original screening folder and enter the second informed consent date in the subsequent screening folder.<br><br>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 these informed consent date(s). |
| Consent type | Select "Screening" or "Screening and Enrollment". |
| Consent version | Enter the version number of the consent signed |

| Field | Instructions |
|---|---|
| Additional Informed Consents | Add a log line to document each consent that is signed by the participant (or for the infant). For each consent, enter consent date, consent type, and consent version. |
| Did the participant consent to long-term specimen storage and future testing? | Select 'Yes' or 'No'.<br><br>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. |
| Did the participant consent to have photographs taken? | Select 'Yes' or 'No' for infants. Leave empty for mothers. |

## ***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 use permanently discontinued (scheduled or early) at this visit? | Select 'Yes' or 'No'.<br><br>If 'Yes', then complete a Product Discontinuation form within the Discontinuations Logs folder. |
| Was study product held at this visit? | Select 'Yes' or 'No'.<br><br>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'.<br><br>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'.<br><br>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'.<br><br>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.<br><br>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'.<br><br>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.<br><br>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**.<br><br>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. |

## ***Non-Enrolled Infant Adverse Event Y/N***

**Participant Type:** Mother

**Purpose:**
This form documents, in the mother's casebook, if an adverse event was experienced by an infant who has not been enrolled in the study, including infant AEs discovered in-utero.

**General Instructions:**
This form is present within the "Ongoing Logs" folder. Selecting 'Yes' to the "Has the participant's non-enrolled infant experienced an adverse event?" prompt will add the "Non-Enrolled Infant Adverse Event Log to the "Ongoing Logs" folder.

## ***Non-Enrolled Infant Adverse Event Log***

**Participant Type:** Mother

**Purpose:**
To document, in the mother's casebook, any Adverse Event (AE) for an infant who has not yet been enrolled in the study, including any infant AEs discovered in-utero.

**General Instructions:**
Follow instructions for Adverse Event Log. If an infant subsequently enrolls in MTN-042, any AEs reported on the Non-Enrolled Infant AE CRF should be transferred to the Adverse Event Log in the infant's casebook and all Non-Enrolled Infant AE Log lines should be deactivated.

**Item-specific Instructions:**
Follow instructions for Adverse Event Log.

## ***Obstetric Abdominal Exam***

**Participant Type:** Mother

**Purpose:**
This form is used to document a participant's abdominal exam results.

**General Instructions:**
Complete this form at Screening, Enrollment, and all follow-up clinic visits prior to a participant's pregnancy outcome.

**Item-specific Instructions:**

| Field | Instructions |
|---|---|
| Appearance | Indicate whether the findings were normal or abnormal. If abnormal, describe the abnormality in the corresponding text field.<br><br>If not evaluated, select 'Not Done'. |
| Palpation of abdomen | Indicate whether the findings were normal or abnormal. If abnormal, describe the abnormality in the corresponding text field.<br><br>If not evaluated, select 'Not Done'. |
| Fundal height | Enter in cm. Round to 1 decimal place. |
| Was auscultation of fetal heart tones performed? | Select 'yes' or 'no'. If 'no', explain in the text field provided.<br><br>If 'yes', select a method and enter beats per minute. |

## ***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-042 participant once she has provided written informed consent for study screening and enrollment.

**Item-specific Instructions:**

<table>
<tr><th>Field</th><th>Instructions</th></tr>
<tr><td>Participant ID</td><td>To add a participant to the study database, select the “Add Subject” link on the MTN-042 site-specific home page. The Participant Identifier page will appear. This is the first page that should be completed for each participant.<br><br>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.<br><br>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:<br><br>
<table>
<tr><th>CRS Name</th><th>DAIDS ID</th><th>Rave Site ID</th></tr>
<tr><td>MU-JHU, Uganda</td><td>30293</td><td>753</td></tr>
<tr><td>WRHI Shandukani, Johannesburg</td><td>8051</td><td>897</td></tr>
<tr><td>Zengeza, Zimbabwe</td><td>30320</td><td>774</td></tr>
<tr><td>Blantyre, Malawi</td><td>30301</td><td>760</td></tr>
</table>
</td></tr>
</table>

## ***Participant Receipt***

**Participant Type:** Mother and Infant

**Purpose:**
This form documents when a transferred participant has signed informed consent at the receiving study site.

**General Instructions:**

- The participant will retain the PTID assigned by the original study site. **Do not assign a new PTID.**
- The receiving site will gain access to the participant’s electronic casebook after the transfer procedures are complete at the transferring site.
- The receiving site adds the Participant Receipt form to the visit folder by marking it on the Follow-up Visit Summary form or the Interim Visit Summary form.
- The Participant Receipt form must be added to the same visit folder as the corresponding Participant Transfer form.

**Field-specific Instructions:**

| Field | Instructions |
|---|---|
| Name of receiving study site | Record the name of the receiving site. |

| Field | Instructions |
|---|---|
| Name of transferring study site | Record the name of the transferring site. |
| Date participant received at receiving site | A complete date is required. |

## ***Participant Transfer***

**Participant Type:** Mother

**Purpose:**
This form documents when a mother participant is permanently transferring to another study site.

**General Instructions:**

- The transferring site adds the Participant Transfer form to the appropriate visit folder by marking it on the Follow-up Visit Summary form or the Interim Visit Summary form.
- For more information, contact the CDM.

**Field-specific Instructions:**

| Field | Instructions |
|---|---|
| Name of transferring study site | Record the name of the transferring site. |
| Name of receiving study site | Record the name of the receiving site. |
| Visit of last completed contact with participant | Select the last completed visit at the transferring site with the participant. |
| If "Interim visit", specify Interim visit code | If “Interim visit”, record the applicable interim visit code. Refer to the Manual of Procedures for more information on visit codes. |
| Date participant's records were sent to receiving study site | Enter the date that the source documents were sent from the transferring site to the receiving site. |

## ***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-042 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. |
| 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.

**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.<br>Select 'abnormal findings' or 'no abnormal findings' to indicate any findings from the pelvic exam.<br>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.<br><br>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.<br>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.<br><br>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 | Record whether an AE was identified and reported at this visit as part of the pelvic exam assessment by selecting 'Yes' or 'No'. If an AE was reported at the study visit, select the corresponding AE log form within the dynamic searchlist function on the form. Up to 3 AEs can be selected. |

| | |
|---|---|
| AEs reported at this visit? | 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-042 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 (auto-populated 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)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. |

## ***Photographic Survey and Congenital Anomaly Documentation***

**Participant Type:** Mother or Infant

**Purpose:**
This form is present in the Congenital Anomaly Report folder. It is used to upload photographs or other supporting documents when a congenital anomaly is reported.

**General Instructions:**
Complete this form when photographs are available for geneticist review of a congenital anomaly. Upload a full photographic survey.

**Item-specific Instructions:**

| Field | Instructions |
|---|---|
| Anatomical location/document type | The anatomical locations for a full photographic survey are pre-selected. One log line should be completed for each location (items 1 – 13).<br><br>If additional photographs or non-photograph documents are available for upload, select "Add a new log line" and choose "Other". Specify in the "If "Other", specify" text field. |
| Comments | Enter any comments about the uploaded photograph that may be helpful to the geneticist who reviews the photographic survey. |
| Date photograph taken/document created | Enter the date the photo was taken or the document was created. |

| Field | Instructions |
|---|---|
| Photograph/document | Upload the photograph or document. |

## ***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 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 at V201.0 – PPO Visit, V203.0 – 6-week PPO visit, V204.0 – 6-month PPO Visit, and V205.0 – 12-month PPO visit. If abnormal findings are found for any of the assessments, enter the information on the Adverse Event Log form(s).

**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.<br><br>Normal findings may also be described in the text field/space, but it is not required.<br><br>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. |
| 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'. |

## ***Post-PO Behavioral Assessment***

**Participant Type:** Mother

**Purpose:**
This form is used to collect post-PO behavioral data from the participant.

**General Instructions:**

Complete this form at the participant's Visit 103 (6-week PPO visit). This form is translated and should be interviewer-administered; read each question and all response options aloud to the participant. When "[pills/ring]" is present, only the participant's assigned study product should be read aloud.

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

| Field | Instructions |
|---|---|
| 2. .When was your vaginal ring last removed? | If participant is using Truvada oral tablet, skip to item 4.<br>Select the most appropriate answer from the options provided.<br>If "Other", use provided text box to specify. |
| ."If prior to when labor began" or "During labor", who removed the ring? | Select the most appropriate answer from the options provided.<br>If "Other", use provided text box to specify.<br>If "Prior to when labor began", use text box to explain why the ring was removed. |
| 3. .If "Prior to when labor began", from the time you received your last vaginal ring to the time of removal, how long was it? | Select the most appropriate answer from the options provided. |
| 4. .Have you swallowed any study pills since your baby was born? | If participant is using DPV vaginal ring, skip to item 5.<br>Select "Yes" or "No". |
| 5. .I am now going to ask you some questions regarding mental health or problems with emotions or nerves…At any time since you joined the study, has a doctor, nurse, or other professional talked with you about depression (or problems with emotions, nerves or mental health)? | Select "Yes" or "No". |
| 6. .Since you joined the study, has a doctor, nurse, or other professional told you that you had depression (or problems with emotions, nerves or mental health)? | Select the most appropriate answer from the options provided.<br>If "No" or "Don't remember", skip to item 8. |

| Field | Instructions |
|---|---|
| 7. .Did you get counseling or any other treatment for your depression (or problems with emotions, nerves or mental health)? | Select the most appropriate answer from the options provided. |
| 8. .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? | Select "Yes" or "No" for each of the fields listed.<br>If "Other", use the provided text box to specify. |
| 9. .We are interested in learning more about women's wellbeing in their relationships…Has your primary sex partner or ANY other current or previous partner: | Select "Yes" or "No" for each of the scenarios listed. |
| 10. .How do you think your use of the [pills/ring] affected your delivery process? | Select the most appropriate answer from the options provided.<br>If "A positive effect" or "A negative effect", use the provided text box to explain. |
| 11. .How worried are you at this point in time about the effect of the [pills/ring] used during your pregnancy on your own health? | Select the most appropriate answer from the options provided. |
| 12. .Some women may have worries about the effect of the [pills/ring] on their own health or wellbeing. Are you worried that the use of the product during your pregnancy could… | Select "Yes" or "No" for each of the scenarios listed.<br>If "Yes" for "h. Anything else related to the [pills/ring]?", then use the provided text box to specify. |
| 13. .How worried are you at this point in time about the effect of using the [pills/ring] on your baby's health? | Select the most appropriate answer from the options provided. |
| 14. .Some women may have worries about the effect of the [pills/ring] on their delivery or baby's health. Are you worried that your use of the product during your pregnancy could… | Select "Yes" or "No" for each of the scenarios listed.<br>If "Yes" for "d. Anything else related to the [pills/ring]?", then use the provided text box to specify. |

| Field | Instructions |
|---|---|
| 15. .Would you be willing to use the [pills/ring] for HIV prevention when pregnant in the future? | Select the most appropriate answer from the options provided. |
| 16. .When you're not pregnant, would you be willing to use the [pills/ring] for HIV prevention in the future? | Select the most appropriate answer from the options provided. |

## ***Pregnancy Assessment***

**Participant Type:** Mother

**Purpose:**
Complete this form to document information about the participant's current pregnancy.

**General Instructions:**
This form will be in the Enrollment folder and must be completed prior to the Randomization form.

**Item-specific Instructions:**

| Field | Instructions |
|---|---|
| Date of assessment | Enter the date the form completed. This should match the date of Randomization. |
| Date of onset of last menstrual period | Enter a complete date if possible. A month and year are required. |
| Estimated date of delivery | A complete date is required. |
| What primary information was used to estimate the date of delivery? | Select from the drop-down list the primary information used to estimate the date of delivery. If another method was used which are not covered by the currently listed methods, select "Other" and describe them in the 'If other, specify' text field provided. |
| Estimated gestational age – weeks and days | Enter the participant's estimated gestation age at the enrollment visit. For cohort 2, gestational age – weeks must equal 30, 31, 32, 33, 34, or 35. Note that this field should not be updated after a participant is randomized. |

## ***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 |
|---|---|
| Has the participant ever been pregnant before? | If the participant has never been pregnant before, select "No" and end the form.<br><br>If 'yes', an entry is required for each of the following: Number of full term live births (>=37 weeks), Number of premature live births (less than 37 weeks), Number of spontaneous fetal deaths and/or still births (>=20 weeks), Number of spontaneous abortions (less than 20 weeks), Number of therapeutic/elective abortions, Number of ectopic pregnancies. Enter '00' for any that do not apply. |
| Does the participant have a history of pregnancy complication or fetal/infant congenital anomalies? | If the participant does not have a history of pregnancy complications, select 'No' and end the form.<br><br>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. Also document any pregnancy complications on the Baseline Medical History Log. |

## ***Pregnancy Outcome***

**Participant Type:** Mother

**Purpose:**
This form is used to report pregnancy outcome information.

**General Instructions:**
This form will be added present in the V101 – PPO Visit folder.

**Item-specific Instructions:**

| Field | Instructions |
|---|---|
| Is the outcome of this pregnancy obtainable? | If pregnancy outcome is unable to be obtained then no other fields should be entered. |
| Outcome Date | A complete date is required. |

| Field | Instructions |
|---|---|
| Place of delivery/outcome | Enter the place of delivery/outcome from the drop-down menu.<br><br>If "Study designated delivery facility", select the applicable facility from the drop-down menu. If “Other”, specify in the “If, Other, specify” text field provided.<br><br>If “Other”, then specify relevant details in the “If, Other, specify” text field provided. |
| Specify Outcome | Specify the outcome from the drop-down menu. If the outcome is still birth/intrauterine fetal demise, spontaneous abortion, therapeutic/elective abortion, or ectopic pregnancy, the outcome itself is not an adverse event (AE). If a therapeutic/elective abortion is performed due to a pregnancy complication, the pregnancy complication should be reported on an Adverse Event (AE) Log, with ‘therapeutic procedure/surgery’ checked for response option “Other action(s) taken” for the item “Action taken with study product”.<br><br>If there are any maternal complications as a result of the pregnancy outcome, refer to the protocol, Study-specific Procedures (SSP) manual, and *Manual for Expedited Reporting of Adverse Events to DAIDS, Version 2* for guidance on AE and expedited AE reporting requirements. If “Other”, then specify relevant details in the “If, Other, specify” text field provided. |
| Method of delivery | Select the method from the drop-down menu only if the outcome is ‘full term live birth (≥37 weeks)’ or ‘premature term live birth (< 37 weeks)’. “Operative Vaginal” delivery includes delivery with forceps and/or vacuum.<br><br>If “Vaginal delivery”, indicate if delivery was breech.<br><br>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.<br><br>If ‘no’, then skip to ‘Were any fetal/infant congenital anomalies identified?’<br><br>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. |

| Field | Instructions |
|---|---|
| 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.<br><br>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 sex, Infant birth weight, intergrowth weight-for-age percentile and severity grade, Infant birth length, Infant birth head circumference, infant body temperature, infant pulse, infant rate of respiration, infant oxygen saturation* | 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.<br><br>If birth weight is available, determine the intergrowth weight-for-age percentile and select the appropriate option:<br><br>• < 3rd percentile<br>• >= to 3rd but < 10th percentile<br>• At or above 10th percentile<br><br>Select the appropriate severity grade. |
| *Infant Gestational age by best estimation at delivery* | Record the infant's gestational age at birth. Check the "unavailable" box if no medical record documentation of the infant's gestational age is available and end the form. |
| Pregnancy Outcome Number and Infant PTID | Only record this information if more than one pregnancy outcome was reported for the mother participant. |

## ***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 PPO Visit 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. |

| | |
|---|---|
| No tablet bottle(s) provided | If no tablet bottle(s) were provided at this visit, end of form. |
| Number of tablet bottles provided | If at least one tablet bottle is provided at this visit, the Tablet Assessment form will be added to the visit folder for completion. |

## ***Product 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. A complete date is required. |
| Visit when study product hold was initiated | If "Interim visit" is chosen, provide a response for "If Interim visit" is chosen, provide interim visit code" and record the interim visit code using the following format: (x)x.xx. |
| Why is study product being held? | Record the reason that study product is being held.<br><br>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.<br><br>**Note**: If study product is being held due to an AE, the AE log page must be entered into Rave prior to completion of the Clinical Product Hold log form in order for the AE to be available to select with the drop-down field. |
| Concomitant Medication | If study product is being held due to "Reported use of PEP", specify the corresponding concomitant medications log form on which the medication was reported in from the drop-down field provided with Rave. At least one medication must be specified and up to four medications can be recorded.<br><br>**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.<br><br>Mark, "No – permanently discontinued" if the participant was permanently discontinued from study product due the reason indicated on this form.<br><br>Mark, "No – early termination" if the product hold was ongoing at the visit at which the participant terminated early from the study. Complete the Product Discontinuation form.<br><br>Mark, "No – hold continuing at scheduled PUEV" if the product hold was ongoing at time of the participant's scheduled Product Use End Visit. Complete the Product Discontinuation form.<br><br>Mark, "No – hold continuing for another reason" if the participant would have been instructed to resume study product based on the resolution of the reason indicated on this form. If 'No – hold continuing for another reason', enter below the 'date study product hold continuing for another reason'. |
| Date study product resumed | Record the date that the participant was instructed to resume study product. |
| 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-042.

**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. |
| Type of deviation | Record the applicable deviation by selecting from the drop-down menu.<br><br>*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.<br><br>Record "other" if none of the listed categories match. |
| Description of deviation | Use the text field to briefly describe the specific details of the deviation. |
| Plans and/or actions to address the deviation | Use the text field to provide a brief description of the plans to address the deviation. |
| Plans and/or actions to address for future deviations | Use the text field to provide a brief description of the plans to address future deviations. |

| Field | Instructions |
|---|---|
| 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<br><br>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** | |

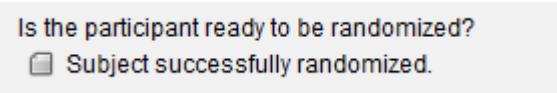
## ***Randomization***

**Participant Type:** Mother

**Purpose:**
This form is used to officially randomize a participant for MTN-042. This form is completed at Enrollment for participants who have provided informed consent and who are eligible to participate in the study.

**General Instructions:**
Complete this form for each participant who will enroll in MTN-042 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 and "Gestational Age" on the Pregnancy Assessment 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:<br><br>  <br><br>If randomization was not successful, this message will not appear, and the Randomization Date and Time will not automatically populate.<br><br>If successful, the participant will be assigned to a treatment arm and to participation in IDI in the Medidata Balance module. |
| Randomization Date and Time | Once "Is the participant ready to be randomized?" is saved as 'Yes', then the randomization Date and Time will automatically populate.<br><br>The Randomization Time will be auto-populated in Coordinated Universal Time (UTC). |

| Field | Instructions |
|---|---|
| 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.<br><br>The Randomization ID should be used to identify those participants who are randomized to IDI. Refer to the study SSP for instructions for IDI randomization. |

## ***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 Visit 6 (4-week visit) and the Visit 101 (PPO visit) 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 the Visit 6 (4-week visit) and Visit 101 (PPO visit) folders, if the participant has reported using the ring since their last visit.

**Item-specific Instructions:**

| Field | Instructions |
|---|---|
| 2. .In the last 4 weeks, how comfortable were you wearing the vaginal ring every day? | Select the most appropriate answer from the options provided. |
| 3. .In the past 4 weeks, how often was the ring out of your vagina for any extended period of time, that is more than 12 hours in a row? | Select the most appropriate answer from the options provided. This question is asking about the ring being out of her vagina for any reason (i.e. being removed intentionally or accidentally, or falling out.) |

| Field | Instructions |
|---|---|
| 4. .In the past 4 weeks, how often was the ring out of your vagina during sex? | Select the most appropriate answer from the options provided. This question is asking about the ring being out of her vagina for any reason (i.e. being removed intentionally or accidentally, or falling out.) |
| 5. . In the past 4 weeks, how often was the ring out of your vagina, even for just a minute excluding expected instances when a ring was briefly removed and replaced with a new ring? | Select the most appropriate answer from the options provided. This question is asking about the ring being out of her vagina for any reason (i.e. being removed intentionally or accidentally, or falling out.)<br>If "Never", end of form. |
| 6. .Was the ring ever removed (in the last 4 weeks)? | Select "Yes" or "No".<br>If "No", skip to 8. |
| 7. .What are the reason(s) why the vaginal ring(s) were removed? (choose all that apply) | Do not read options out loud.<br>Check all of the reason(s) that apply.<br>If "Other", use the text box provided to explain. |
| 8. .Did the ring ever come out on its own (in the last 4 weeks)? | Select "Yes" or "No".<br>If "No", end of form. |
| 9. .What are each of the reason(s) why the vaginal ring came out on its own? (choose all that apply) | Do not read options out loud.<br>Check all of the reason(s) that apply.<br>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 at the Enrollment visit and bi-weekly visits when a participant is scheduled to receive a ring.

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

**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.<br>If "Yes", skip to item 3. |

| Field | Instructions |
|---|---|
| Based on your assessment and her feedback, how easy or difficult was it for the participant to insert the ring? | Use the following guidelines to categorize the level of ease or difficulty:<br>- Very difficult: Required 3+ attempts and/or caused pain, severe discomfort<br>- Difficult: Required 2 attempts and/or caused moderate discomfort<br>- Easy: Required 1 attempt with some ring repositioning and/or caused mild discomfort<br>- Very easy: Smooth insertion and positioning in one attempt with no discomfort<br>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."<br>Select "N/A" if the participant attempts to insert the ring, but is unable to keep it in. |
| Did the participant require any help from the clinician to insert the ring? | If "Yes" provide a response for If "Yes", specify.<br>If "No", skip to item 6. |
| Did study staff verify that the ring was in place? | If "No" provide a response for If "No", specify and end the form.<br>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.<br>If "Yes", end of form. |

## ***Ring Insertion and Removal***

**Participant Type:** Mother

**Purpose:**
This form documents if a vaginal ring was provided to or returned by 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.

| Field | Instructions |
|---|---|
| No ring provided | If a vaginal ring was not provided at a study visit, skip the remaining questions within the RING PROVISION section and go to "RING RETURN". |
| Was a ring inserted at this visit? | If "Yes', the Ring Assessment form will be added to the visit folder for completion. |

| | |
|---|---|
| | If "No", specify the reason(s) why the ring was not inserted. |
| Ring not returned | If a vaginal ring was not returned at a study visit, end the form.<br>If a vaginal ring was returned, provide the date the ring was returned in the specified field. |
| Date returned ring #1 was **provided** | If a ring is being returned at this visit record the date that ring was provided. |
| Date returned ring #2 was **provided** | If multiple rings were dispensed and are being returned at this visit record the date the second ring was provided |

## ***Screening Date of Visit***

**Participant type:** Mother

**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.<br>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.<br>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. |

| Field | Instructions |
|---|---|
| Was HIV RNA PCR testing completed? | If "Yes", a complete collection date and result is required.<br><br>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.<br><br>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.<br><br>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.<br><br>If HIV RNA PCR testing is not done/not collected, skip to the Seroconverter Plasma Storage items. |
| HIV RNA PCR Kit | Select the HIV RNA PCR testing kit that was used. If completing a paper form, mark the kit from the response options provided. When completing the form within Rave, select the kit from the drop-down field. |
| HIV RNA PCR Kit Lower limit of detection | Select "20" or "40" as the lower limit of detection or record the viral copies/mL |
| Seroconverter Plasma storage collection date | A complete date is required if Seroconverter plasma for storage was collected. |
| Seroconverter Plasma storage | Mark "Stored" or "Not stored", if not stored, provide a reason it was not stored in the "Seroconverter Plasma storage reason not stored" field. |

## ***Social Benefits***

**Participant Type:** Mother

**Purpose:**
This form records what the participant considers to be benefits of participating in MTN-042.

**General Instructions:**
This form should be completed at the 1st 4-week visit (cohorts 2 – 3), the 4-week visit corresponding to or immediately before 36th week gestation (cohort 3), and the 6-week PPO visit. The form should be read to the participant.

| Field | Instructions |
|---|---|
| From your perspective, what are all the benefits of participating in this study? | Read each option to the participant. Select 'yes' or 'no' for each. If the response to 'Other' is 'yes', specify in the text field provided. |
| What is the most important benefit or reason for your participation in this study? | Read each option to the participant. Select one option (the most important benefit or reason for participation). If 'Other', specify in the text field provided. |

## ***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 the 1st 4-week visit (cohorts 2 – 3), the 4-week visit corresponding to or immediately before 36th week gestation (cohort 3), and the 6-week PPO visit. It is a participant administrated form. The question should be read aloud in the participant's preferred language. If a social harm is reported on this form, complete a Social Impact log form.

| 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'.<br><br>If 'Yes' is selected, then the "Social Impact" form appears in the visit folder and can then be completed |

## ***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 the study.

**General Instructions:**

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

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

| Field | Instructions |
|---|---|
| Onset date | Record the date the negative experience first started. At a minimum, a month and year are required. |
| Reported at Visit | Select the visit at which the social harm was reported. If the social harm was reported at an interim visit, select "interim visit" and record the interim visit code using the following format: (x)x.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. |
| What impact did this situation have on the participant's quality of life? | Assess the impact of the social harm on the participant's quality of life based on participant self-report. |
| Record current status | This item may be updated at subsequent visits. |
| Closure Date | Record the closure date if the current status is selected as "unable to resolve; no further action taken", or "resolved".<br><br>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, 2-week visits (cohorts 2 – 3 only), 4-week visits (cohorts 2 – 3 only), Bi-weekly visits, V101.0 – PPO Visit, and V103.0 – 6 week PPO Visit.

**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 first specimen(s) was collected, NOT the date the results were reported or recorded on the form for this visit. A complete date is required. |

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

## ***STI Test Results***

**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, Enrollment, V103.0 – 6 week PPO, and as indicated during the study.

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

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

**Item-specific Instructions:**

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

| Field | Instructions |
|---|---|
| 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.<br><br>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).<br><br>If the test result is 'Reactive', then complete the remaining Syphilis items.<br><br>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'). |
| 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 | For mothers, select 'Scheduled exit visit/end of study' if the participant completed her v103.0 – 6 week PPO visit.<br><br>For infants, select 'Scheduled exit visit/end of study' if the participant completed her v205.0 – 12 month PPO visit.<br><br>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, 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 Visit 6 (4-week visit) and the Visit 101 (PPO visit) 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 the Visit 6 (4-week visit) and the Visit 101 (PPO Visit) 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.<br>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.<br>If "Never", end of form. |
| 4. .What are the reason(s) why you skipped using the pills?<br>Check all of the reasons that apply. | Select “Yes” for all of the reason(s) that apply.<br>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 and bi-weekly visits when a participant is scheduled to receive new tablets.

**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’. |

| Field | Instructions |
|---|---|
| 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. |
| 5. Based on your assessment and her feedback, how easy or difficult was it for the participant to swallow the tablet? | Use the following guidelines to categorize the level of ease or difficulty:<br>- Very difficult: Required 3+ attempts and/or caused pain, severe discomfort<br>- Difficult: Required 2 attempts and/or caused moderate discomfort<br>- Easy: Required 1 attempt and/or caused mild discomfort<br>- Very easy: Smooth swallowing in one attempt with no discomfort<br>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."<br>Select "N/A" if the participant attempts to swallow the pill, but is unable to keep it down. |

## ***Ultrasound Results***

**Participant Type:** Mother

**Purpose:**
This form is used to document the participant's ultrasound results.

**General Instructions:**
Complete this form at Enrollment and whenever an ultrasound is performed during follow-up.

**Item-specific Instructions:**

| Field | Instructions |
|---|---|
| Crown-rump length | If measured, enter in cm. The values can be reported up to one decimal. Per SSP section 7.7, required at Enrollment visit if gestational age is <14 0/7 weeks.<br>If not measured, select "Not done/not collected". |

| Field | Instructions |
|---|---|
| Biparietal diameter,<br>Femur length,<br>Abdominal circumference | If measured, enter in cm. The values can be reported up to one decimal. Per SSP section 7.7, required at Enrollment visit if gestational age is 14 0/7 weeks or greater.<br><br>If not measured, select "Not done/not collected". |
| Was an anatomic survey completed? | If 'yes', indicate if any abnormalities were observed. If abnormalities were observed, describe in the text field provided. |
| Estimated gestational age | Enter gestational age as recorded on the ultrasound report. |

## ***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 at Screening, Enrollment, the 1st 4-week visit (cohorts 2 –3), 4-week visit corresponding to or immediately before 36 weeks gestation (cohort 3), V103.0 – 6 week PPO visit, and when clinically indicated during follow-up.

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

**Field-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,<br>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.<br><br>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.<br><br>Select "Not gradable" for value that does not meet grading criteria. |
| 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 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, 4-week visits, and the V101.0 – PPO Visit 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.<br><br>Height is required at Screening. |
| Weight | Enter the participant's weight in kilograms. The value can be reported up to one decimal (e.g. 57.8 kg).<br><br>Weight is required at Screening, 4-week visits, and the V101.0 – PPO Visit, and whenever calculated creatinine clearance is performed. Refer to MTN-042 SSP section 7 for additional guidance. |
| Body Temperature | Enter the participant's temperature and associated units (Celsius or Fahrenheit). 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). |
| 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** | | |
| 2.0 | 5-Feb-2020 | Add Event | Added “Congenital Anomaly Review” folder. |
| | | Adverse Event Log | Added “AE is associated with pregnancy” and “If “related” to the DPV vaginal ring, is the AE related to the drug (dapivirine) or device (ring itself or ring insertion)?” fields. |
| | | Chemistry Panel | Added information about reporting decimals |
| | | Congenital Anomaly Review | Added form. |
| | | EAE Upload | Added form. |
| | | Hematology | Added information about reporting decimals |
| | | Infant Demographics | Removed “age” field. |
| | | Infant HIV Confirmatory Results | Added “Were any additional tests besides RNA or DNA performed?” field. |
| | | Infant Inclusion/Exclusion | Added form. |
| | | Infant Specimen Storage | Indicated that “plasma for archive” specimens are documented on this form. |
| | | Participant Type | Added "If this participant is a mother, what is the infant's PTID?” field. |
| | | Photographic Survey | Added form. |
| | | Pregnancy Outcome | Indicated that if “Other” is selected for “Study designated delivery facility”, the “If, Other, specify” text field must be completed. |
| 3.0 | 30-Mar-20 | Infant Feeding Assessment | Added form |

| | | | |
|---|---|---|---|
| 4.0 | 29Oct20 | COVID-19 Behavioral Assessment | Added form |
| | | Pregnancy Outcome | Added field |
| | | Ring Insertion and Removal | Added fields |
| | | Ring Assessment | Updated timing of CRFcompletion |
| | | Tablet Assessment | Updated timing of CRFcompletion |
| 5.0 | 1-Jul-2021 | Baseline Behavioral Assessment | Added form |
| | | Discontinuation of Study Product | Updated instructions for reporting date study product use ended and primary reason for ending study product use |
| | | Follow-up Behavioral Assessment | Added form |
| | | Inclusion/Exclusion Criteria CRF | Added instructions for completing date participant was found ineligible and for adding a second screening folder. |
| | | Infant Feeding Assessment | Updated instructions for completing “what have you fed your baby since your baby’s last visit” to specify it should include anything the infant has been fed **since birth** when completing at the infant’s first visit. |
| | | Infant Inclusion/Exclusion | Added instructions for completing date it was determined the participant would not enroll. |
| | | Informed Consent | Added instructions for recording each time a consent form is signed. |
| | | Photographic Survey | Updated name to “Photographic Survey and Congenital Anomaly Documentation” and added instructions for uploading non-photo documents. |
| | | Post-PO Behavioral Assessment | Added form |
| | | Pregnancy Assessment | Updated allowable gestational age - weeks |

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|---|---|---|---|
| | | Ring Adherence Y/N and Ring Adherence | Added forms |
| | | Tablet Adherence Y/N and Tablet Adherence | Added forms |
| | | n/a | Removed reference to cohort 4 throughout document |
| 6.0 | 22Feb2022 | Approvals | Updated Clinical Safety Associate and Clinical Programmer |
| | | Enrollment | Updated IDI instructions |
| | | Infant Vital Signs | Added fields for infant weight-for-age and weight-for-length fields, and severity grade fields for each |
| | | Pregnancy Outcome | Specified reporting requirements for multiple pregnancy outcomes and weight-for-age |
| 7.0 | 08Jun2022 | Author & Approvals | Updated to reflect CDM change |
| | | General Guidelines | Specified data collection timeframe |
| | | Adverse Event Log | Updated Comments field |
| | | Concomitant Medications Log | Updated Date Started field |
| | | Infant Participant Transfer | Added form |
| | | Informed Consent | Updated “Date informed consent initially signed” field |
| | | Participant Receipt | Added form |
| | | Participant Transfer | Added form |