CRF Completion Guidelines

HPTN083-01

Version 2.0

CRF Completion Guidelines

Protocol Name:	Safety, Tolerability and Acceptability of Long-Acting Cabotegravir (CAB LA) for the Prevention of HIV among Adolescent Males – A sub-study of HPTN 083
Protocol Number:	HPTN083-01
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CRF Completion Guidelines

The following instructions are study-specific data completion instructions intended to assist site staff when completing electronic case report forms (eCRFs) and paper case report forms (CRFs). 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 found on the HPTN083-01 Protocol page: https://atlas.scharp.org/cpas/project/HPTN/083-01/begin.view?

General Guidelines

- The Participant ID is automatically assigned by Rave EDC as a 9-digit field, starting with the 3-digit site number followed by a randomly assigned 5-digit participant number, and 1-digit check number.
- All data entered in Rave must match the data on any source documents/paper CRFs.
- Complete all required data fields. Ensure that all entries are in English and are accurate, consistent, complete and medically logical.
- If “Other” is chosen as a response, further details must be provided by responding to the “If ‘Other’, specify” field.
- Text box fields have character limits. Text exceeding the limit will not be saved and a “Non-conformant” icon will appear.
- Visit dates must be complete and in chronological order according to the protocol.
- Most date fields must be entered as Day/Month/Year (dd/mmm/yyyy) (e.g., 01 NOV 2017). Exceptions are detailed in specific form sections where applicable.
- Drop-down menus are available for many fields. Use these menus, when available, to select the appropriate response.
- Avoid using abbreviations, symbols or special characters.
- Avoid hitting the return or enter key in text fields.
- If a scheduled visit is missed, do not enter data on the forms required for the visit, except for the Date of Visit form. Marking “no” on the Date of Visit form will add the Missed Visit form to the visit folder for completion.
- Log forms allow you to make multiple entries over the course of the study. All entries at the same time in ‘Complete View’ and View individual entries in portrait view.

- The following log forms for this study are available in the Ongoing logs folder at the bottom of the sidebar on the Participant's home page:
    - Adverse Event
    - Concomitant Medications
    - Medical History
    - Protocol Deviations
    - Product Hold
    - Social Impact
    - Injection Site Reactions
- Correct/update data fields by clicking the pencil icon at the far right of the field, correct/update the value and give the reason for the change, if applicable. Save the form to apply the changes.
- If an incorrect data entry is made, a system query will fire. Correct the error and save the form.
    - System generated queries with no query response will automatically close with a form correction.
    - System generated queries with a query response will change into a manual query that will need to be closed by the data management team.
- All actions performed on a data field are tracked in the audit trail. If data is modified inadvertently, the change is also shown in the audit trail for that field.
- The Investigator of Record (IoR) will sign all forms after the participant's data has been reviewed. After the signature is applied, no further changes or additions to the forms are expected.
- Any modifications that are made to forms after the IoR has signed off will remove the signature. Once the data has been reviewed, the signature will need to be applied again.
- The SCHARP Clinical Data Manager will provide direction for when the Investigator should perform the final review and sign the eCRF pages.

Add Event

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

Interim Visits

- Add an Interim Visit folder to a participant's casebook by clicking on the **Add Event** button on the PTID (Subject)-level page and selecting "Interim Visit", then clicking "Add". An Interim Visit folder will appear in the participant's casebook.
- Open the Interim Visit folder to access the Interim Visit form. On the Interim Visit form, select the forms that were completed at the interim visit. The selected forms will then load in the folder.
- On the Interim Visit form, enter the visit date as the earliest date visit procedures were performed for that interim visit.

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 form
  - If question "Did the participant complete this visit" is marked "No", the Missed Visit form will add to the visit folder and the required forms for that visit will not appear in the visit folder.
  - Most forms under "Additional Procedures/Forms" on the Follow-up Visit Summary form that are checked will be added to the visit folder. If a checked form does not load, please contact the study clinical data manager, who will load the form manually.
- **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.

Loading of Folders in Participant Casebook

- Medidata Rave will add folders to a participant's casebook based on how certain forms are completed. See Table 1 for actions required to add folders to a participant's casebook.

Table 1. Folder Dynamics

Folder	Action Required to Add Folder
V1.0 – Screening V2.0 – Day 0/Enrollment Ongoing Logs Discontinuation	Save Participant Identifier form.
V3.0	Select "Yes" for "Is the participant ready to be randomized?" on the Randomization form in V2.0 folder.
V4.0-V11.0	• Select "Yes" for "Did the participant complete this visit?" on the Follow-up Visit Y/N form in the visit folder. • Select "No" for "Did the participant exit/terminate the study at this visit?" on the Follow-up Visit Summary form in the visit folder.

Dynamic Search Lists

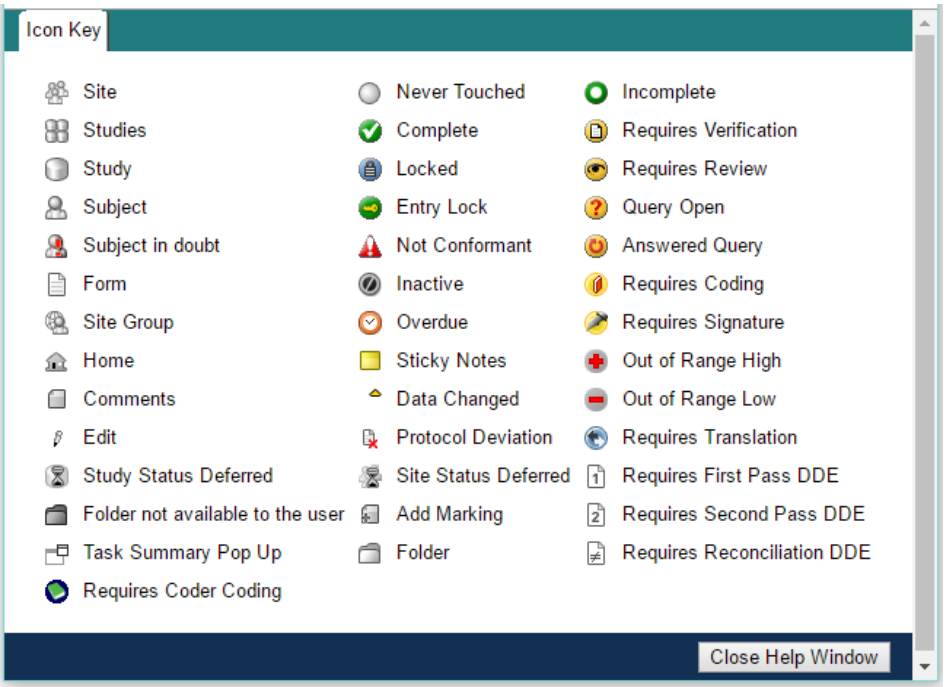
- Some forms have data fields with 'dynamic' drop-down lists of available options. Options are populated by corresponding log form entries.
- Dynamic drop-down lists will be blank until entries are made and saved in the corresponding log form.
- Your selection in the dynamic search list can be deleted if entered in error.
- Changing the original log data or inactivating a log form entry that has been selected for a dynamic search list field, will make that field non-conformant and it will need to be updated.
- For Example:
  - An AE of '*FEVER*' started on 05DEC2017 and is reported on the Adverse Events log form
  - On the Concomitant Medications log form, if a listed medication was used for this AE, a dynamic search list can be used to select the applicable AE record from the dropdown list.

- The start date for AE *'FEVER'* is corrected to 06DEC2017 on the Adverse Events log form.
- The selection on the Concomitant Medication log form becomes non-conformant.
- To resolve the non-conformant data, re-select the AE '*FEVER'* from the dynamic search list with the corrected start date.

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

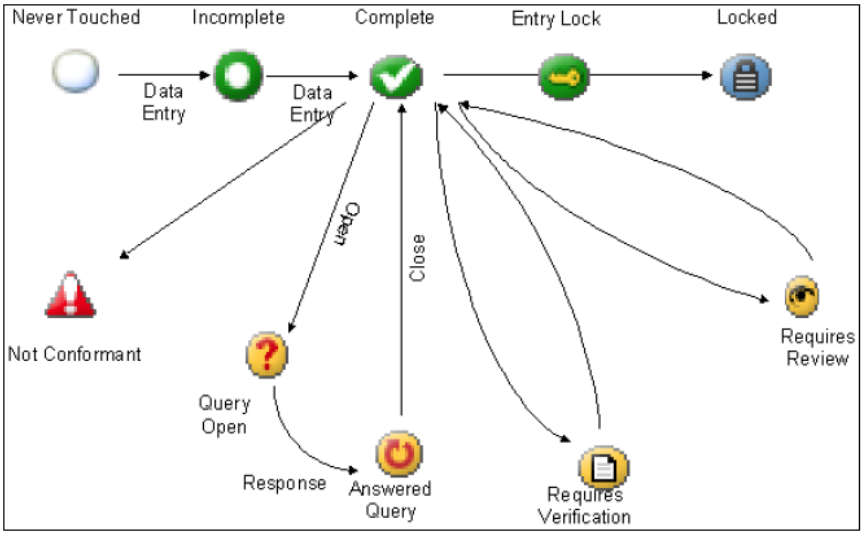


Icon Progression

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. 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

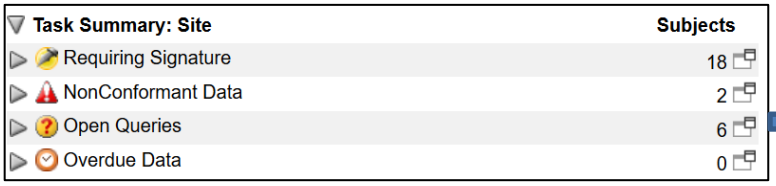
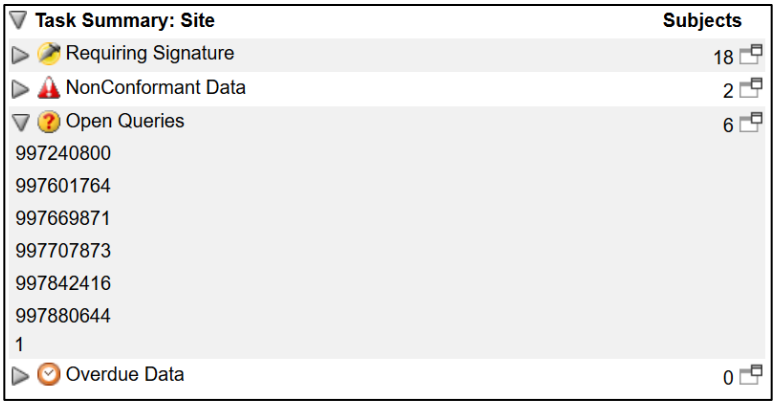
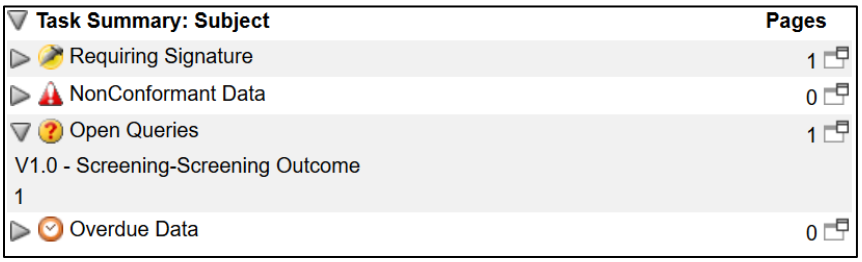


Figure 4. Site-Level Task Summary



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

CRF PDFs are generated from Rave and posted on the protocol webpage. When completing a paper CRF, refer to detailed instructions for data collection pertaining to the specific form and fields on that form in this document.

- Based on Good Clinical Practices (GCPs), refer to the following guidelines to complete paper CRFs:
  - Use a black or dark blue medium ballpoint pen. Do not use any other type of writing tool.
  - Print all data and comments legibly by hand. Do not use cursive/script handwriting.
  - Record data on the front side of the paper only.
  - If the spaces/lines provided for a response are not large enough, continue in another blank area of the paper CRF.
  - Mark only one answer unless instructions state to mark or select all that apply.
  - A response is required for every data field unless skip instructions are provided.
  - Do not use correction fluid (“White-Out”) or correction tape on paper CRFs.

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

For example, record September 20, 2016 as: 

Recording Time - Rave Form and/or Paper CRF

- Use a 24-hour clock (00:00-23:59), where hours are designated from 0–23.
- Midnight is recorded as 00:00, not 24:00.

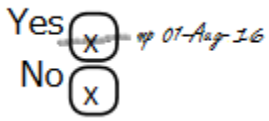
The following chart shows equivalencies between the 12- and 24-hour clocks:

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

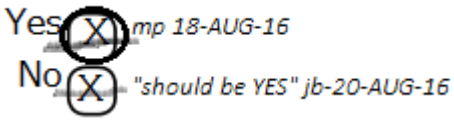
For example, record 2:25 p.m. as:

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:



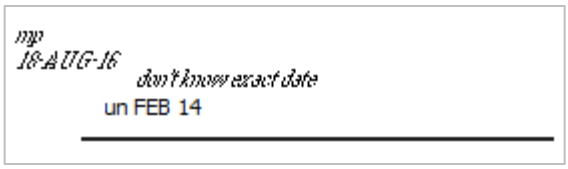
- If the correct answer has previously been crossed out, do the following:
  - circle the correct response,
  - write an explanation in the white space near the response, and
  - initial and date all corrections as shown below:



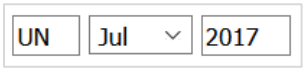
Missing and Unknown Data - Rave Form and/or Paper CRF

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.



- In Rave, where the data are missing or unknown, enter “UN” for the day and/or select ‘UNK’ from the drop-down list for the month.



Form-Specific Instructions

Additional Study Procedures

Purpose:
This form is used to record all additional procedures the participant received at his scheduled study visit (e.g. clinically indicated physical exam). Do *not* record any procedures required and performed per protocol on this form. Such procedures should be entered on the relevant CRF within the scheduled visit folder.

General Instructions:
This form appears dynamically when "Were any additional study procedures or forms completed at this visit?" is selected 'Yes' on the applicable Date of Visit CRF.

Select the applicable CRFs that will be submitted for the visit. For example, if a physical exam was performed (clinically indicated), select the checkbox corresponding to **Physical Exam**. Selecting a CRF will dynamically add the applicable form(s) within the associated visit folder.

Adverse Event Y/N

Purpose:
This form is used to trigger the Adverse Event log.

General Instructions:
This form is in the "Ongoing Logs" folder and is only completed once, at the time the first adverse event is reported or at the end of the study if no adverse events are reported.

Field-specific Instructions:

Field	Instructions
Has the participant experienced an adverse event during the study?	• If "Yes" is selected, the **Adverse Event** log loads in the Ongoing Logs folder. • At the end of study participation, mark "No" if no adverse events have occurred.

Adverse Event

Purpose:
This form documents Adverse Events (AEs) reported by the participant or clinically observed as defined by the protocol.

General Instructions:
- Complete one log line for each adverse event (AE).
- Add additional log lines by clicking "Add a new Log line".
- Only list conditions that start on or after enrollment date, otherwise record as medical history.
- Record increases in severity/frequency as new events with corresponding start/stop dates. The original AE should be recorded as "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.

Field-specific Instructions:

Field	Instructions
Adverse event (AE)	• Describe the AE using medical terminology. • Record a diagnosis/anatomical location if available. • For lab abnormalities, format is (increased/decreased [test name]).
Onset date	At minimum, month and year are required. Record one of the following, as appropriate: • The date on which the participant reports first experiencing the AE. • If the AE is discovered during a study visit, record the date of the study visit. • If the AE is an abnormal lab result, record the date on which the specimen was collected.
Visit AE was reported	Select the appropriate visit from the dropdown menu. If interim visit, enter the interim visit code.
Is the AE ongoing?	Select "Yes" or "No". If "No", enter the outcome date. At minimum, month and year are required. Record one of the following as appropriate: • The date on which the participant no longer experienced the AE. • The date of the study visit or specimen collection at which the change in status/outcome is first noted.
Severity grade	Record the severity grade using the most current version of the *Division of AIDS (DAIDS) Table for Grading the Severity of Adult and Pediatric Adverse Events* (including relevant appendices/addendums) • Grade 1 (Mild) • Grade 2 (Moderate) • Grade 3 (Severe) • Grade 4 (Potentially life-threatening) • Grade 5 (Death)
Relationship to study product	Mark the assessment of the relationship between the AE and the study product. • "Related" - reasonable possibility that the AE may be related to the study product. • "Not related" - not a reasonable possibility that the AE is related to the study product. Record pertinent details for relationship assessment in comments. For more information, refer to the *Manual for Expedited Reporting of Adverse Events to DAIDS,* most current version.

Field	Instructions

Action taken with study product	• ***Dose not changed:***
	  ○ Mark if the participant is expected to continue to use study product and the AE does NOT result in a study product hold or permanent discontinuation.
	• ***Dose reduced:***
	  ○ Not applicable
	• ***Dose increased:***
	  ○ Not applicable
	• ***Drug withdrawn:***
	  ○ Mark if the AE results in permanent study product discontinuation.
	  ○ If multiple AEs are reported at the same visit, mark "withdrawn" for the AE(s) that contributed to the permanent discontinuation.
	  ○ *Complete a Discontinuation of Study Product form*
	• ***Drug interrupted:***
	  ○ Mark if the AE results in a study product hold.
	  ○ If multiple AEs are reported at the same visit, mark "interrupted" for the AE(s) that contributed to the hold. Ensure the Product Hold Y/N and Product Hold Log forms are completed.
	• ***Not applicable:***
	  ○ Mark if the AE occurred after the participant had completed all administration of the study product.
	  ○ Mark if the study product is held or permanently discontinued for a different reason.
	  ○ Mark if the AE is grade 5-death.

Field	Instructions

Status/Outcome	• ***Recovered/Resolved:*** AE is no longer present or returned to the pre-enrollment severity/frequency. If a participant is taking a medication to control an AE that arose during study participation, it is not considered resolved.
	• ***Recovering/resolving:*** AE is continuing and has not yet resolved or returned to baseline severity/frequency.
	• ***Recovered/resolved with sequelae:*** Participant has recovered from the AE, but with remaining effects or impairment.
	• ***Not recovered/not resolved***: Whenever an AE is continuing at the time of participant termination from the study.
	• ***Fatal:*** Severity of this AE is grade 5. Update any other AEs continuing at the time of death to "Not Recovered/Not Resolved."
	• ***Severity/frequency increased:*** AE increases in severity or frequency after it has been reported on the AE Log:
	  ○ On the original AE log line, update the "Status/outcome" field to "severity/frequency increased." Record the date of increase in the outcome field data.
	  ○ Report the increase in severity or frequency of the AE on a new log line. For this new AE, the "onset date" will be the date that the severity or frequency increased. Update SAE form if applicable.
	  ○ Note that decreases in severity should not be recorded as new AEs.

Is this a serious adverse event according to ICH/GCP or protocol guidelines?	If the AE is a Serious Adverse Event (SAE), complete the subsequent SAE criteria questions. Mark all of the SAE criteria that apply. If the AE is not an SAE, skip to "Has or will this AE be reported as an EAE?". For questions about ICH/GCP guidelines and EAE reporting, refer to current *Manual for Expedited Reporting of Adverse Events to DAIDS.*
SAE/EAE onset date	A complete date is required.
Has or will this AE be reported as an EAE? EAE number	If reported as an EAE (indicated as "Yes"), provide the EAE number and complete any subsequent updates to this form on the applicable EAE form. Refer to form instructions for EAE format.
Was this AE a worsening of a baseline medical condition?	Select "Yes" or "No"
Comments	Comments are required for every AE. • Record pertinent details for relationship assessments. • When an AE is assessed as "not related", an alternative etiology, or explanation should be provided here. • Record pertinent clinical information.

Behavioral Assessment

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

General Instructions:
This prompt is present at all visits that require a CASI survey (please refer to the protocol for the complete listing).

Field-specific Instructions:

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

CASI Tracking

Purpose:
This form is used to document information about the Computer-Assisted Self Interview (CASI) at Enrollment and during follow-up.

General Instructions:
Selecting 'Yes' in the Behavioral Assessment prompt will open up the CASI Tracking CRF. Complete this form at all visits that require a CASI survey (please refer to the protocol for the complete listing).

Field-specific Instructions:

Field	Instructions
CASI collection date	A complete date is required.
CASI ID	Enter the corresponding 6-digit CASI ID.
Which questionnaire was completed?	Select the applicable questionnaire from the drop down list that was completed for the participant.
Were there any problems or issues related to the administration or completion of the questionnaire?	Select 'Yes' or 'No'.

Field	Instructions
If yes, please describe:	Use the text field space to describe when and why multiple CASI questionnaires are completed for a participant at a visit or if the incorrect CASI questionnaire is completed at a visit. Use this text field to indicate any technical errors that took place in the administration, storing, or uploading of a CASI questionnaire. If there are any unusual details related to the CASI questionnaire administration or completion, describe them in this field.

CD4 Test Results/Viral Load

Purpose:
To document CD4 and HIV viral load results for HIV infected participants.

General Instructions:
Complete this form when a participant is HIV positive per Protocol Appendix IV. To add this form to a participant's visit folder, select "CD4/Viral Load Results" on the Additional Procedures CRF Once the Additional Procedures form is saved, the CD4/Viral Load Results form appears in the visit folder. *Note: To populate the Additional Procedures CRF, the Date of Visit CRF must be answered as "Yes" to "Did the participant have any additional procedures at this visit?"*

Item-specific Instructions

Field	Instructions
Were Absolute CD4+ collected for testing?	• If "No" is selected, leave the rest of the Absolute CD4+ items blank and move on to the first question in the HIV RNA section.
Specimen collection date:	• If CD4 was done enter the date the sample was collected. • A complete date is required.
Absolute CD4+	• Enter the absolute CD4 in units of "cells/mm^3". • If sample was unable to be analyzed, mark "CD4 unable to analyze".
CD4 unable to analyze	• Mark this box if the sample was unable to be analyzed.
Was HIV RNA PCR testing completed?	• If "No" is selected, do not complete the remaining items on the form.

Field	Instructions
Specimen collection date:	• If viral load was done, enter the date sample was collected. • A complete date is required.
Operator	• If a number for the viral load is provided on the lab report, “>”, “<”, or “=” must be selected.
HIV RNA PCR	• Enter the HIV RNA PCR value in “viral copies/mL”. • A maximum of nine digits is allowed.
Detected, less than LLQ or LLD	• If a lab result says “Detected, less than lower limit of quantification”, mark this box. Otherwise, leave blank.
Detected, greater than the upper limit of quantification	• If a lab result says “Detected, greater than the upper limit of quantification”, mark this box. Otherwise, leave blank.
HIV RNA PCR target not detected	If a lab result says “HIV RNA target not detected”, mark this box. Otherwise, leave blank.
Additional CD4 Test Results or Viral Load data collected	Mark this field if another CD4 Test Results/Viral Load CRF is needed to capture additional testing data.

Chemistry Panel

Purpose: This form is used to provide data on the participant’s baseline and follow-up laboratory test results. To generate this form at a follow-up visit where tests are not normally required, select “Chemistry Panel” on the Additional Study Procedures form.

General Instructions:

- The lab that collected the specimens used for these tests will automatically be selected from the Lab dropdown list at the top of the form. The units and lab ranges for each result will be populated at the bottom of the form.
  Note: The Demographics eCRF needs to be entered prior to entering data on the Chemistry Panel eCRF because the derived age from the Date of Birth on the Demographics eCRF 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), 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 (if applicable).

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 will need to be converted using the Lab Conversion Tool on Atlas before entry into the eCRF.

- Note that the following units are equivalent:

  IU/L = U/L I/l x 100 = % 10^9/L = 10^3/mm3 = 10^3/µL

All analytes should be recorded using the same level of precision according to the source laboratory results document.

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 (Corrected Version 2.1), select the 'Not gradable' option.
- Enter the severity grade for each specific result:
  - Alkaline Phosphatase
  - AST (SGOT)
  - ALT (SGPT)
  - Total Bilirubin
  - Creatinine
  - Creatinine Clearance
  - Phosphate
  - Calcium
  - CPK (CK)
  - Glucose (serum)
  - Amylase
  - Lipase

- 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 "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.

Field-specific Instructions:

Field	Instructions
Specimen collection date	Record the date that the specimen was *collected*, not the date results were reported or recorded on the form.
Severity grade	• 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. • Select 'Not gradable' for a value that does not meet grading criteria.
Adverse event	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.
Not reportable as adverse event	Select this field if the participant has enrolled in the study, but has an acceptable lab value that is outside the normal range and will continue with a sustained lab value that is out of normal range. In this case, an Adverse Event log entry is not expected. Note: This field is not expected to be selected if the severity grade is "Not gradable" because "Not gradable" values are not entered on the AE Log.

Concomitant Medications Y/N

Purpose:
This form is used to trigger the Concomitant Medication log in Rave.

General Instructions:
This form is present in the "Ongoing Logs" folder in Rave and is only completed once, at the time the first concomitant medication is reported.

Field-specific Instructions:

Field	Instructions
Is the participant taking any concomitant medications?	• If "Yes" is selected, then the **Concomitant Medications** log appears dynamically in the "Ongoing Logs" folder. • At the end of study participation, mark "No" if no concomitant medications were reported.

Concomitant Medications

Purpose:
This form documents all medication(s) that are used by the participant during the study (including the protocol-defined screening period), other than study product, [study specific] must be documented on this form. This includes, but is not limited to, prescription and non-prescription drugs, vitamins, topical products, alternative/complimentary medicines (e.g., herbal and health food supplements), recreational drugs, vaccinations, and allergy shots.

General Instructions:
- Complete one log line for each reported concomitant medication.
- Add additional log lines by clicking "Add a new Log line".

Field-specific Instructions:

Field	Instructions
Medication name	Record the medication name as reported by the participant. For example, if the participant reports taking a trade name medication report the trade name. If a trade name is not available or not reportable per national guidelines, record the generic name of the medication.
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"). • For recreational drugs, record "recreation".

Date started	• If the participant is unable to recall the exact date, obtain participant's best estimate. At a minimum, the year is required.
	  ○ If the exact day is unknown, enter 'UN' for the day field.
	  ○ If the exact month is unknown, then select 'UNK' for the month field.
	  ○ For example, a partial date may be recorded as: UN-Jan-2010 or UN-UNK-2010
	• For injections
	  ○ If it is a one-time injection (including contraception), record each injection as a separate entry, with the same date used for date started and stopped.
	  ○ If it is a series of injections, record the date of the first injection as date started and the date of the last injection as the date stopped.

Date stopped *Or* Ongoing	At the participant's Termination visit, the "Date Stopped" must be recorded for each medication OR the "Ongoing" must be checked. At a minimum, the month and year are required.

Frequency	Select the frequency from options provided in the drop-down list. Below is a list of common frequency abbreviations: PRN: as needed QD: every day BID: twice daily TID: three times daily QID: four times daily QHS: at bedtime ONCE: one time Other: alternative dosing schedule or unknown If 'Other' is selected, specify in the corresponding "If other frequency, specify" text field provided. For injections, frequency should be 'Once', with same date used for start and stop dates.
Route	Select the route from options provided in the drop-down list. If 'Other' is selected, specify in the corresponding "If other route, specify" text field provided.
Dose	Record the dose. If the participant does not know the exact dose units (e.g., "250 mg"), record an estimate (e.g., "1 tablet"). For multivitamin tablets or liquids, record the number of tablets or liquid measurement (e.g. "1" pill or "1" tablespoon") if the exact dosage is unknown. If the dose is unknown, check "Unknown" and leave the dose field blank. When documenting medical devices with no active medication, such as an IUCD, enter the dose as "1". For topical applications, if exact quantity is not known, record the number of applications instead (e.g. 'one application').

Dose Units	Select/record the applicable dose units provided in the drop-down list. If the participant does not know the exact dose units (e.g., “250 mg”), record an estimate (e.g., “1 tablet”). If no information on units is known, select the ‘Unknown’ option. When documenting medical devices with no active medication, such as an IUCD, mark the Dose Unit as ‘Other’ and specify “device” in the “If other dose units, specify” text field provided. For topical applications, if exact quantity is not known, record the number of applications instead (e.g. ‘one application’). If ‘Other’ is selected, specify in the corresponding “If other dose units, specify” text field provided.
Taken for Reported AE If "Yes", select adverse event.	If “Yes”, choose the applicable AE log entry from the drop-down list. Note: The applicable AE must first be entered on the AE form in order to be visible in the drop-down list.
Taken for Reported ISR If "Yes", select ISR event.	If “Yes”, choose the applicable ISR log entry from the drop-down list. Note: The applicable ISR must first be entered on the ISR form in order to be visible in the drop-down list.

Counseling

Purpose: This form documents any counseling that may have occurred at each of the participants’ visits.

Field	Instructions
Did a counseling session occur at this visit?	• Select “Yes” or “No” • If “Yes”, check each type of counseling that occurred. If “No”, end form.

Date of Visit - Step 1

Purpose:
This form is used to document information about each visit during Step 1.

General Instructions
Complete this form in order to generate the forms required at the current visit as well as to create the next visit folder with its respective Date of Visit – Step 1 CRF. See item level instructions for the data requirements to populate additional visits and forms.

Item-specific Instructions

Field	Instructions
Did the participant complete this visit?	• "Yes" must be answered if at least one assessment within the visit has been completed. This will also populate additional forms required within each visit. • "No" populates the Missed Visit CRF in the current folder.
Visit Date	• A complete date is required.
Did the participant exit/terminate the study at this visit?	• If "Yes" is selected, complete the Study Termination CRF located in the Discontinuations folder.
Were any new adverse events (AEs) reported at this visit?	• Select "Yes" or "No". • If "Yes", complete the Adverse Event Log
Is the participant taking any concomitant medications that have not been previously reported?	• Select "Yes" or "No". • If "Yes", complete the Concomitant Medications Log
Have any protocol deviations been reported at this visit?	• Select "Yes" or "No". • If "Yes", complete the Protocol Deviations Log
Was the participant observed taking the study product?	• Select "Yes" or "No".
If the participant was NOT observed taking the study product, was it already taken before this visit?	• Select "Yes" or "No". • Only answer if the participant was not observed taking the study product
Did the participant have any additional procedures at this visit?	• If "Yes" is selected, the Additional Procedures CRF will be populated in the current folder.
Is the participant moving to Step 2	• Complete only at Step 1 - Week 4 visit (V104.0) • Select "Yes" or "No"

Field	Instructions
If the participant is not moving to Step 2, please specify	• Enter the reason the participant is not moving to Step 2

Date of Visit - Step 2

Purpose:
This form is used to document information about each visit during Step 2.

General Instructions
Complete this form in order to generate the forms required at the current visit as well as to create the next visit folder with its respective Date of Visit – Step 2 CRF. See item level instructions for the data requirements to populate additional visits and forms.

Item-specific Instructions

Field	Instructions
Did the participant complete this visit?	• "Yes" must be answered if at least one assessment within the visit has been completed. This will also populate additional forms required within each visit. • "No" populates the Missed Visit CRF in the current folder.
Visit Date	• A complete date is required.
Did the participant exit/terminate the study at this visit?	• If "Yes" is selected, complete the Study Termination CRF located in the Discontinuations folder.
Were any new adverse events (AEs) reported at this visit?	• Select "Yes" or "No". • If "Yes", complete the Adverse Event Log
Is the participant taking any concomitant medications that have not been previously reported?	• Select "Yes" or "No". • If "Yes", complete the Concomitant Medications Log
Have any protocol deviations been reported at this visit?	• Select "Yes" or "No". • If "Yes", complete the Protocol Deviations Log

Field	Instructions
Did the participant have any additional procedures at this visit?	• If "Yes" is selected, the Additional Procedures CRF will be populated in the current folder.
Is the participant moving to a different step or visit schedule?	• Select "Yes" or "No" • If "Yes", indicate which step or visit schedule by selecting one of the options in the dropdown menu.
Date of participant's last dose of oral study product **And** **Time of participant's last dose of oral study product**	• Enter a complete date of the participant's last dose of oral study product. • Enter a time for the last dose of oral study product.
Date of participant's last injection	• Complete this only at the Step 2 – Week 33 visit (V209.0) or an early study product discontinuation visit. • Enter the date of the last injection
Was Truvada dispensed at week 34	• Complete only at the Step 2 – Week 34 visit (V210.0) • Select "Yes" or "No".

Date of Visit - Step 3

Purpose:
This form is used to document information about each visit during Step 3.

General Instructions
Complete this form in order to generate the forms required at the current visit as well as to create the next visit folder with its respective Date of Visit – Step 3 CRF. See item level instructions for the data requirements to populate additional visits and forms.

Item-specific Instructions

Field	Instructions
Did the participant complete this visit?	• "Yes" must be answered if at least one assessment within the visit has been completed. This will also populate additional forms required within each visit. • "No" populates the Missed Visit CRF in the current folder.

Field	Instructions
Visit Date	• A complete date is required.
Did the participant exit/terminate the study at this visit?	• If "Yes" is selected, complete the Study Termination CRF located in the Discontinuations folder.
Were any new adverse events (AEs) reported at this visit?	• Select "Yes" or "No". • If "Yes", complete the Adverse Event Log
Is the participant taking any concomitant medications that have not been previously reported?	• Select "Yes" or "No". • If "Yes", complete the Concomitant Medications Log
Have any protocol deviations been reported at this visit?	• Select "Yes" or "No". • If "Yes", complete the Protocol Deviations Log
Did the participant have any additional procedures at this visit?	• If "Yes" is selected, the Additional Procedures CRF will be populated in the current folder.
Is the participant moving to a Seroconverter schedule?	• Select "Yes" or "No"

Date of Visit – Seroconverter Schedule

Purpose:
This form is used to document information about each visit during Seroconverter Schedule.

General Instructions
Complete this form in order to generate the forms required at the current visit as well as to create the next visit folder with its respective Date of Visit – Seroconverter Schedule CRF. See item level instructions for the data requirements to populate additional visits and forms.

Item-specific Instructions

Field	Instructions
	• "Yes" must be answered if at least one assessment within the visit has been completed. This will also populate additional forms required within each visit.

Field	Instructions
Did the participant complete this visit?	• "No" populates the Missed Visit CRF in the current folder.
Visit Date	• A complete date is required.
Did the participant exit/terminate the study at this visit?	• If "Yes" is selected, complete the Study Termination CRF located in the Discontinuations folder.
Were any new adverse events (AEs) reported at this visit?	• Select "Yes" or "No". • If "Yes", complete the Adverse Event Log
Is the participant taking any concomitant medications that have not been previously reported?	• Select "Yes" or "No". • If "Yes", complete the Concomitant Medications Log
Have any protocol deviations been reported at this visit?	• Select "Yes" or "No". • If "Yes", complete the Protocol Deviations Log
Did the participant have any additional procedures at this visit?	• If "Yes" is selected, the Additional Procedures CRF will be populated in the current folder.

Demographics

Purpose:
This form documents a participant's demographic and socioeconomic information.

General Instructions:
Complete and submit this form for participants who have signed a study-specific consent form, regardless of if they enroll in the study or not. This form is completed at the [insert relevant visits]. If the participant does not understand the question, read the categories to the participant. Responses should reflect the participant's status at screening and should not be changed after screening unless correction is needed. If the participant is found to be ineligible prior to the collection of all demographic data, enter all available data and respond to system queries with "Not Collected".

Field-specific Instructions:

Field	Instructions
Date of birth	If the entire date of birth is unknown, record participant's best estimate. At a minimum year is required.
Age	The age field is calculated automatically based on the "Date of birth" field and the "Informed consent date" field on the Inclusion/Exclusion Criteria form. No data entry is required.
Sex assigned at birth	This is the sex that the participant was assigned at birth.
Ethnicity Race	Record the participant's ethnicity and race based on self-definition.

Gender	• This response must be self-reported by the participant.
	• Site staff are encouraged to document in chart notes if the participant, during study participation, prefers to be referred to by a specific pronoun or gender.
	• Gender is the social part of being male or female and related to self-identity. Below are descriptions of each gender category:
	  ○ Male: Any person who identifies their gender as male.
	  ○ Female: Any person who identifies their gender as female.
	  ○ Transgender male (also known as trans male) refers to a person assigned female at birth, but whose gender identity is male or trans-male.
	  ○ Transgender female (also known as trans female) refers to a person assigned male at birth, but whose gender identity is female or trans-female.
	  ○ Gender nonconforming/Gender variant: A person whose gender expression is different than gender norms and does "fit" the male/female categories, regardless of their gender identity or sexual orientation.
	  ○ Self-identify: Any other gender reported by the participant. Record what the participant reports in the "If 'Self-identify', specify:" field.

How do you define your sexual orientation?	Below are descriptions of each sexual orientation: • Gay/Lesbian/Homosexual: Attracted to the same sex as yourself • Bisexual: Attracted to both the same and different sex than yourself • Queer • Two spirit • Straight/Heterosexual: Attracted to a different sex than yourself • Additional category: Any other sexual orientation reported by the participant. Record what the participant reports in the "If 'Additional category', specify:" field. • Not sure • Prefer not to answer

Discontinuation of Study Product

Purpose:
This form documents permanent discontinuation of study product.

General Instructions:
Complete this form at the time of **permanent** study product discontinuation, including a scheduled end of product use. We only expect this form to be completed once per participant. This form is located in the "Discontinuations" folder.

Field-specific Instructions:

Field	Instructions
Date that study product use ended	A complete date is required. Record the date when the participant completed or was permanently discontinued from study product.
Visit that study product use ended	Select the appropriate visit from the dropdown menu. If "interim visit", please provide the interim visit code. Please use 2 digits after the decimal (e.g. 3.01, 3.02, 3.03, etc).
Primary reason for ending study product use	If more than one reason applies, mark only the primary reason for discontinuing study product. If 'Scheduled study product use period completed', then end the form If 'Adverse Event' is selected, choose the AE from the AE dynamic drop-down list. If "Use of prohibited concomitant medications" is selected, choose the concomitant medication from the concomitant medication dynamic drop-down list. If 'Injection site reaction' is selected, choose the ISR from the ISR dynamic drop-down list. Note: If study product is permanently discontinued due to an AE/ISR, the AE/ISR log page must be entered into Rave prior to linking the AE/ISR on the Discontinuation of Study Product eCRF in order for the AE/ISR to be available to select with the drop down field. If the primary reason is "Other", provide additional details in the "If other, specify" text field provided.

Enrollment

Purpose:
This form documents the enrollment status of the participant. This CRF must be completed for every participant that has screened for the study regardless if they enroll or not.

General Instructions:
Complete this form at the time of enrollment or if the participant is a screen failure.

Field-specific Instructions:

Field	Instructions
Was the participant enrolled in the study?	Select "Yes" or "No".
Date of Enrollment	A complete date is required.
Was the participant observed taking the first dose?	If the participant enrolled, select "Yes" or "No".
Date of participant's first dose of oral product	A complete date is required
Time of participant's first dose of oral product	Use a 24-hour clock (00:00-23:59), where hours are designated from 0–23.

Fasting Lipids Test Results

Purpose: This form is used to provide data on the participant's fasting lipid profile.

General Instructions:

- To generate this form at a follow-up visit where tests are not normally required, select 'Fasting Lipids Test Results' on the Additional Study Procedures form.
- The lab that collected the specimens used for these tests will automatically be selected from the Lab dropdown list at the top of the form. The units and lab ranges for each result will be populated at the bottom of the form.
  Note: The Demographics eCRF needs to be entered prior to entering data on the Fasting Lipid Test Results eCRF because the derived age from the Date of Birth on the Demographics eCRF is used to populate the reference ranges.
- For each lab test, enter the specimen collection date at the top of the form for that specific test each time this form is completed unless it was not collected.
- For each individual lab result (e.g. Total Cholesterol, HDL), 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 (if applicable).

  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 will need to be converted using the Lab Conversion Tool on Atlas before entry into the eCRF.

- Note that the following units are equivalent:

IU/L = U/L I/l x 100 = % 10^9/L = 10^3/mm3 = 10^3/µL

All analytes should be recorded using the same level of precision according to the source laboratory results document.

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 (Corrected Version 2.1), select the 'Not gradable' option.
- Enter the severity grade for each specific result:
    - Total Cholesterol
    - Triglycerides
    - LDL Cholesterol

- 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 "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.

Field-specific Instructions:

Field	Instructions
Specimen collection date	Record the date that the specimen was *collected*, not the date results were reported or recorded on the form.

Field	Instructions
Severity grade	• 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. • Select 'Not gradable' for a value that does not meet grading criteria.
Adverse event	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.
Not reportable as adverse event	Select this field if the participant has enrolled in the study, but has an acceptable lab value that is outside the normal range and will continue with a sustained lab value that is out of normal range. In this case, an Adverse Event log entry is not expected. Note: This field is not expected to be selected if the severity grade is "Not gradable" because "Not gradable" values are not entered on the AE Log.

Hematology

Purpose: This form is used to provide data on the participant's laboratory test results, specifically CBC with differential and platelets.

General Instructions:
Use this form to report the hematology and differential test results obtained from specimens collected. To generate this form at a follow-up visit where tests are not normally required, select 'Hematology' on the Additional Study Procedures form.

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 on the 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 will automatically be selected from the Lab dropdown list at the top of the form. The units and lab ranges for each result will be populated at the bottom of the form.
  Note: The Demographics eCRF needs to be entered prior to entering data on the Hematology eCRF because the derived age from the Date of Birth on the Demographics eCRF is used to populate the reference ranges.

- For each lab test (e.g. 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 (e.g. Hemoglobin, Hematocrit, MCV Platelets, WBC, Neutrophils, Lymphocytes, Monocytes, Eosinophils, Basophils, Atypical lymphocytes), 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 l/l x 100 = % 10^9/L = 10^3/mm3 = 10^3/µL

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 (Corrected 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 "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.

NOTE: The fields for lab analyte values (for example: WBC) are located at the bottom of form.

Field-specific Instructions:

Field	Instructions
Collection date	Record the date that the specimen was *collected*, not the date results were reported or recorded on the form.
Severity grade	• 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. • Select 'Not gradable' for a value that does not meet grading criteria.
Adverse event	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.
Not reportable as adverse event	Select this field if the participant has enrolled in the study, but has an acceptable lab value that is outside the normal range and will continue with a sustained lab value that is out of normal range. In this case, an Adverse Event log entry is not expected. Note: This field is not expected to be selected if the severity grade is "Not gradable" because "Not gradable" values are not entered on the AE Log.

Hepatitis Test Results

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

General Instructions:
Complete this form at the Screening and Enrollment Visits 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 Hepatitis Test Results form. If the participant enrolls, the updated results should be submitted into the study database.

Field-specific Instructions:

Field	Instructions
Was a sample collected for Hepatitis B Surface Antigen (HBsAG) testing?	Select 'Yes' or 'No'. If 'No', then the remaining items for HBsAG testing do not need to be completed.
Collection Date	Record the date that the specimen was collected, NOT the date the result was reported or recorded on the form for this visit. A complete date is required.
Hepatitis B Surface Antigen (HBsAG)	Select "Positive" or "Negative".
Was a sample collected for Hepatitis B Surface Antibody (HBsAb) testing?	Select 'Yes' or 'No'. If 'No', then the remaining items for HBsAb testing do not need to be completed.
Collection Date	Record the date that the specimen was collected, NOT the date the result was reported or recorded on the form for this visit. A complete date is required.
Hepatitis B Surface Antibody (HBsAb)	Select "Positive" or "Negative".
Was a sample collected for Hepatitis B Core Antibody (HBcAb) testing?	Select 'Yes' or 'No'. If 'No', then the remaining items for HBcAb testing do not need to be completed.
Collection Date	Record the date that the specimen was collected, NOT the date the result was reported or recorded on the form for this visit. A complete date is required.
Hepatitis B Core Antibody (HBcAb)	Select "Positive" or "Negative".
Was a sample collected for Hepatitis C Antibody (HCAb) testing?	Select 'Yes' or 'No'. If 'No', then the remaining items for HCAb testing do not need to be completed.
Collection Date	Record the date that the specimen was collected, NOT the date the result was reported or recorded on the form for this visit. A complete date is required.
Hepatitis C Antibody (HCAb)	Select "Positive" or "Negative".

HIV Test Results

Purpose:

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

General Instructions

- Complete this form at protocol-specified visits and if clinically indicated at any other visit.
- Only one specimen collection date can be recorded on the HIV test results CRF, any re-testing with a new sample requires an additional new log line. Please do not remove previous test results.
- Every HIV Test result should have a corresponding plasma storage form with matching dates.
- Record HIV specimen test results on this form as they become available from the local lab.
- If test results are discordant or discrepant at a time point, refer to the HIV algorithm for next steps regarding additional HIV testing.
- **If a sample is positive, all confirmatory testing for that sample will be put on the same HIV Test Results Log form in the same visit folder (new log lines will be added for each specimen collected).**

Item-specific Instructions

Field	Instructions
Specimen Collection Date	• Enter the date the specimen was collected. • A complete date is required.
Was this sample collected for additional testing?	• Select “Yes”, if this is a re-draw for confirmation of a previous reactive or positive result. • Select “No” if this blood draw is not to confirm prior test results.
HIV Rapid test result	• Select “Non-reactive/Negative”, “Reactive/Positive”, “Invalid”, or “Not Done”, as appropriate. [Note: Per the HIV Testing Algorithm, this is always required at Screening]
HIV Laboratory based immunoassay test result	• Record the results of the laboratory-based HIV immunoassay here. • Select “Non-reactive/Negative”, “Reactive/Positive”, “Invalid”, or “Not Done”. [Note: Per the HIV Testing Algorithm, this is always required at Screening]

Field	Instructions
HIV-1 RNA Qualitative test result	• If an HIV RNA Qualitative test is done, record the results here. • Select “Non-reactive/Negative”, “Reactive/Positive”, “Invalid”, or “Not Done”. • If an HIV RNA Qualitative test is not done, select “Not Done”.
Was a viral load done?	• If “Yes” is selected, complete the HIV RNA section on the CD4 Test Results/Viral Load CRF
Final HIV Status	• This is a required field. • Select final HIV Status based on local testing. • If final HIV status is “Negative”, proceed with the visit. • If final HIV status is “Positive”, refer to the protocol and SSP for next steps. • If final status is “Additional testing required”, add a new log line to the current HIV Test Results form and record additional test results.

Inclusion/Exclusion Criteria

Purpose:
This form documents a participant’s eligibility status at the enrollment Visit.

General Instructions:
Complete this form for each participant screened in HPTN083-01. Complete this form when it is determined whether the participant will enroll in the study. If the participant has a second screening attempt, update this form with data from the second screening attempt (do not complete a new form).

Field-specific Instructions:

Field	Instructions
Has the participant screened for the study before?	Select 'Yes' or "No' to indicate if the participant has attempted screening previously. If "Yes", record the previous PTID.
Inclusion criteria	Select "Yes" or "No" for each inclusion criteria. When applicable, mark the checkboxes underneath certain inclusion criteria. (Eligible participants should have all criteria marked as "Yes")
Exclusion criteria	Select "Yes" or "No" for each exclusion criteria. (Eligible participants should have all criteria marked as "No")
Did the participant meet all eligibility criteria?	Select 'Yes' or "No' to indicate if the participant met all eligibility criteria.
Eligibility Status	Record the applicable eligibility status by selecting from the drop down menu. If participant met all eligibility criteria, and Eligibility Status is 'Eligible and enrolled', then end of form.
If investigator decision, specify	If "Medical, social, or other condition that, in the opinion of the site investigator, would interfere with the conduct of the study…" was selected, record reason in the specify text box. If any other response was selected, leave this field blank.
If eligible but participant declined enrollment, specify reason.	Record the reason an eligible participant did not enroll. This text field should only be completed if "Eligibility status" is 'Eligible, but participant did not enroll'.

Informed Consent

Purpose:
This form is used to document the administrative details of the participant's informed consent.

General Information/Instructions
Complete this form when the participants completes a consent form (or re-consent form). Add additional log lines as appropriate. This form is located in the Screening folder.

Field-specific instructions:

Field	Instructions
Date the participant or guardian marked or signed the study screening and enrollment consent form	Record the date that the participant or guardian signed the informed consent form. A complete date is required.
Did the participant or guardian consent to long-term specimen storage?	Select “Yes” or “No”.
Did the participant or guardian consent to future testing?	Select “Yes” or “No”.
Did the participant or guardian consent to genetic testing?	Select “Yes” or “No”.

Injection Administration

Purpose:
This form is used to summarize information regarding the injection administration at a given visit.

General Information/Instructions
Complete this form at protocol-specified visits after HIV and pregnancy testing has been completed.

Item-specific Instructions

Field	Instructions
Was an injection given at this visit?	• If “Yes” is selected, complete items underneath the heading “If injection was given”. • If “No” is selected, only complete items underneath the heading “If injection was not given”.
If injection was given:	
Injection date	• Enter the date the injection was received. • A complete date is required.

Field	Instructions
Needle gauge	• Select the appropriate needle gauge from the list provided.
If other needle gauge, specify:	• If “Needle gauge” is “Other”, record the other needle gauge used here.
Needle length	• Select the appropriate needle length in inches. • If the needle length provided with the needle is not in inches, convert the unit of measurement to inches and select the needle length that best fits.
If other needle length, specify:	• If “Needle length” is “Other”, record the other needle length used here.
Was complete dose given?	• Select “Yes” when the full dose is given per protocol. • If “No” is selected, enter the volume of study drug administered below.
If no, what volume was given?	• If full dose was given, this field should be blank. • Enter volume of study drug administered in mL. • Format allows up to one decimal value.
Location of injection	• Select either “Right buttock” or “Left buttock”. • If another location was used, contact the CDM.

Field	Instructions
Time of preparation for injection	• Enter a time using a 24-hour clock. • Time of preparation must precede the time of injection. • The time of preparation for injection is the time when the pharmacist first enters the needle into the CAB injectable vial or when the pharmacist enters the needle into the port of the intralipid IV bag to withdraw the applicable study product into the syringe to prepare participant's injectable study product.
Time of injection	• Enter a time using a 24-hour clock.
If injection was not given:	
Indicate if injection was missed, refused, temporarily held, permanently discontinued or other reason why injection was not provided.	• If the injection was not given at a visit, record the reason here. • Select "Injection missed", "Injection refused", "Injection schedule on hold or permanently discontinued", or "Other, specify" from dropdown list
If Other, specify	• If "Indicate if injection was missed, refused, temporarily held, permanently discontinued or other reason why injection was not provided." is "Other, specify", record the reason here.

Injection Site Reaction Log

Purpose:
This form is used to document any injection site reaction reported by the participant or observed during the clinic visit.

General Instructions:

Injection Site Reactions (ISRs) should only be reported on the ISR Log and not on the AE Log. Complete one log line for each ISR. Add additional log lines by clicking "Add a new log line", located at the bottom of the form. The ISR Log is only used for ISR's related to study product; do not record ISRs for routine vaccinations on this form.

Item-specific Instructions

Field	Instructions
Date reported to site	• Enter the date the site first became aware of the ISR. • A complete date is required.
Event diagnosis	• Select the type of injection site reaction that occurred from the dropdown menu.
Injection site side	• Select “Left” or “Right” for the side of the buttocks on which the injection was given.
Onset date	• Record the date the participant first experienced the reaction. • At minimum, a month and year are required. If day is unknown, enter “UN” for the day. • The onset date must be on or after the date of study drug injection.
At which visit was this reaction first reported?	• Select visit the site first became aware of the ISR. • If an interim visit, select “Interim Visit”.
Interim visit code	• If “Interim Visit” is selected for “At which visit was this reaction first reported”, enter interim visit code in space provided. Otherwise leave this item blank.
Is the reaction still ongoing?	• Select “Yes” if the ISR is continuing at the time it is first reported. • Select “No” if the ISR is no longer present. • If a participant is taking a medication to control the ISR that arose during study participation, it is not considered resolved. • If “Yes”, leave Outcome Date blank.
If no, provide an outcome date	• Record the outcome date for the ISR only if “Is the reaction still ongoing?” is “No”. • At a minimum, a month and year are required. If day is unknown, enter “UN” for the day. • Enter the date in which the participant no longer experienced the reaction.

Field	Instructions
Severity Grade	• Record the severity grade using the *Division of AIDS (DAIDS) Table for Grading the Severity of Adult and Pediatric Adverse Events* (including relevant appendices/addendums). ○ Grade 1 (Mild) ○ Grade 2 (Moderate) ○ Grade 3 (Severe) ○ Grade 4 (Potentially life-threatening) ○ Grade 5 (Death)
Action Taken with Study Product	• Select “dose not changed” if there is no change to the participant’s planned use (dose, frequency, or schedule) of study product as a result of the ISR. • “Dose reduced” and “dose increased” do not apply and should not be selected in HPTN083-01. • Select “drug withdrawn” if the ISR results in permanent discontinuation of study product. • Select “drug interrupted” if ISR results in a product hold. • For multiple ISRs, mark “drug withdrawn” or “drug interrupted” for each ISR contributing to the permanent or temporary discontinuation. Ensure the Product Hold Y/N and Product Hold or Discontinuation of Study Product forms are completed as applicable. • Select “not applicable” if 1) the ISR’s onset date is on or after the date the participant permanently discontinues study product use; 2) study product is held or permanently discontinued for a different reason; or 3) the ISR is Grade 5 – death.
Other action(s) taken:	• Select “None” or check all that apply. • Select “Medication” only if participant reports taking medication for the reported ISR. Report medication(s) on the Concomitant Medications Log. • If “Other”, specify relevant details in the “Other, specify” text field provided.

Field	Instructions

Status/Outcome	• ***Recovered/Resolved:*** ISR is no longer present or returned to the pre-enrollment severity/frequency. If a participant is taking a medication to control an ISR that arose during study participation, it is not considered resolved.
	• ***Recovering/resolving:*** ISR is continuing and has not yet resolved or returned to baseline severity/frequency.
	• ***Recovered/resolved with sequelae:*** Participant has recovered from the ISR, but with remaining effects or impairment.
	• ***Fatal:*** Severity of this ISR is grade 5. Update any other ISRs continuing at the time of death to "Not Recovered/Not Resolved."
	• ***Severity/frequency increased:*** ISR increases in severity or frequency after it has been reported on the ISR Log:
	  ○ On the original ISR log line, update the "Status/outcome" field to "severity/frequency increased." Record the date of increase in the outcome field data.
	  ○ Report the increase in severity or frequency of the ISR on a new log line. For this new ISR, the "onset date" will be the date that the severity or frequency increased. Update SAE form if applicable.
	  ○ Note that decreases in severity should not be recorded as new ISRs,
	• ***Not recovered/not resolved***: Whenever an ISR is continuing at the time of participant termination from the study.

Is this a Serious Adverse Event?	• Select "Yes" or "No". • If "Yes", mark the following, as applicable: "Results in death", "Is life-threatening", "Requires inpatient hospitalization or prolongation of existing hospitalization", and/or "Is another serious important medical event that may jeopardize the patient or require intervention to prevent one of the other outcomes listed above"
SAE/EAE onset date	• Record the date the participant first experienced the reaction. • At minimum, a month and year are required. If day is unknown, enter "UN" for the day. • The onset date must be on or after the date of study drug injection.
Has or will this reaction be reported as an EAE?	• Select "Yes" or "No". • For questions about ICH guidelines and EAE reporting, refer to current *Manual for Expedited Reporting of Adverse Events to DAIDS.* • If reported as an EAE (indicated as "yes"), provide the EAE number and complete any subsequent updates to this form on the applicable EAE form.

Field	Instructions
If yes, EAE number	• Enter EAE number in field provided.

Injection Site Reaction Y/N

Purpose:
This form documents whether any injection site reactions (ISRs) were experienced by the participant during the study.

General Instructions
This form is located within the "Ongoing Logs" folder. It is used to trigger the Injection Site Reaction Log. Once it has been saved, it does not need to be completed again throughout the duration of the study.

Item-specific Instructions

Field	Instructions
Has the participant experienced any injection site reactions?	• If "Yes" is selected, the Injection Site Reaction log form appears in the Ongoing Logs folder and can then be completed.

Interim Visit Summary

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

General Instructions:
This form is required for each interim visit completed for a participant. Use the "Add Event" feature to dynamically create the Interim Visit folder, which will add an Interim Visit Summary eCRF to the participant's casebook within the applicable Interim Visit folder.

Field-specific Instructions:

Field	Instructions
Interim 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'. If 'Yes', then complete a Discontinuation of Study Product eCRF within the Discontinuations folder.
Did the participant exit/terminate the study at this visit?	Select 'Yes' or 'No'. If 'Yes', then complete a Study Termination eCRF within the Discontinuations folder.
Were any new adverse events (AEs) reported at this visit? If yes, complete the AE Log.	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? If yes, complete the Concomitant Medications Log.	Select 'Yes' or 'No'. Select 'Yes' if at least one concomitant medication was newly completed for this visit. Navigate to the Ongoing Logs folder to complete an entry for the applicable CM(s).
Have any protocol deviations been reported at this visit? If yes, complete the Protocol Deviations Log.	Select 'Yes' or 'No'. Select 'Yes' if at least one protocol deviation was newly completed for this visit. Navigate to the Ongoing Logs folder to complete an entry for the applicable PD(s).
Reason for interim visit	Select all that apply.
If other, specify	If "Other" is selected for reason for interim visit, then specify the reason in the text field provided.

Were vital signs (such as weight) taken at this visit?	Select "Yes" or "No". If "Yes", add Vital Signs form. Also note that weight and height are required at all visits.
Is the participant moving to a new visit schedule?	Select "Yes" or "No". If "Yes", select the appropriate schedule from the dropdown menu.
What study procedures were completed at this visit:	Select the applicable procedures that were completed at the study visit. The applicable eCRF(s) will then be added to the participant's visit folder. For example, if a physical exam was performed, select the checkbox corresponding to **Physical Exam**.

Medical History Y/N

Purpose:
This form is used to trigger the Medical History log.

General Instructions:
This form is in the "Ongoing Logs" folder and is only completed once, at the time the first medical history condition/event is reported or at the end of the study if no medical history condition/events are reported.

Field-specific Instructions:

Field	Instructions
Does the participant have any medical history to report?	• If "Yes" is selected, then the **Medical History** log loads in the "Ongoing Logs" folder. • Select "No" at the end of the study if the participant has not reported a medical history condition/event.

Medical History

Purpose:
This form documents a snapshot of the participant's medical history at enrollment.

General Instructions:
- Record only medical conditions/events experienced up to study product initiation unless otherwise specified in the protocol or Study Specific Procedures (SSPs).
- Include current medical conditions/events and any ongoing conditions such as mental illness, alcoholism, drug abuse, and chronic conditions (controlled or not controlled by medication).
- Complete one log line for each medical history condition/event.
- Add additional log lines by clicking "Add a new Log line".
- If a participant recalls additional medical history after enrollment, update the **Medical History** log by adding a new log line.
- Do not update existing log lines after the Enrollment Visit.

Field-specific Instructions:

Field	Instructions
Description of medical history condition/event	Whenever possible, provide a diagnosis instead of listing a cluster of symptoms. If no diagnosis is identified, record each symptom as a separate entry on the **Medical History** log. If an abnormal lab value is reported, record the lab assay with the direction (i.e., increased or decreased) of the abnormality. For example, "decreased hematocrit" or "increased ALT."
Is condition/event gradable?	Mark "No" for a condition/event that does not meet grading criteria per *Division of AIDS (DAIDS) Table for Grading the Severity of Adult and Pediatric Adverse Events*, most current version.
Severity grade	• Grade the severity according to the *Division of AIDS (DAIDS) Table for Grading the Severity of Adult and Pediatric Adverse Events*. • Record the severity grade of the condition/event at the time of enrollment. ○ Example: left ankle sprain that was initially grade 3 (severe) during screening, but grade 1 (mild) upon enrollment, to be reported as grade 1 (mild). • If the severity grade has increased in severity or frequency during the study AE reporting period, then report the change as an AE. The Severity Grade should remain unchanged on the **Medical History** log. • If the severity grade increased or decreased **on or prior to** Enrollment, this should be updated on the **Medical History** log as needed. • If the condition/event improves in severity or resolves during the study, the Severity Grade should remain unchanged on the **Medical History** log.

Start date of medical history condition/event	• If the participant is unable to recall the date, obtain participant's best estimate.
	• At a minimum, the year is required. If the date is within the same year as study enrollment, the month and year are both required.
	  ○ If the exact day is unknown, enter 'UN' for the day field.
	  ○ If the exact month is unknown, then select 'UNK' for the month field.
	  ○ Example: UN-Jan-2010 or UN-UNK-2010.
	• If the condition is diagnosed due to an abnormal lab result, record the date on which the specimen was collected. If a diagnosis is not available, record the date of onset of condition.

Is the condition ongoing?	Review and update conditions marked "ongoing" only prior to and including the Enrollment Visit.
Date medical condition/event ended/resolved	A date is required if 'Is the condition ongoing?' is 'No'. If the exact day is unknown, enter 'UN' for the day field. If the exact month is unknown, then select 'UNK' for the month field. At a minimum, a year is required. Record the date the medical condition was considered resolved. For surgeries/procedures, record the date the surgery/procedure was completed.

Missed Visit

General Instructions:
Complete whenever an enrolled participant misses a required visit according to the Study-specific Procedures (SSP). A Missed Visit form will be added to the visit folder if the response to "Did the participant complete this visit?" is "No" on the Date of Visit form.

Field-specific Instructions:

Field	Instructions
Target visit date	Record the target date of the visit that was missed.
Reason visit was missed	Select the reason for the missed visit from the dropdown menu. If "Other" is selected, please specify the reason.

Participant Identifier

Purpose:
This form generates a PTID for the participant. Complete this form first for each participant.

Field-specific Instructions:

Field	Instructions
Participant ID	• To add a participant to the study database, select the 'Add Subject' link on the study home page. The Participant Identifier form will load. • No data are required from 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. The participant's home page will appear. • The link for the Participant Identifier form is at the top of each participant's home page. PTID will appear on each form in participant's casebook. • The PTID must be written at the top of each CRF PDF completed for a participant. • The first three digits of each PTID is the Rave site ID number.

Participant Receipt

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

General Instructions
This form is completed by the receiving site only when the participant being transferred has provided informed consent at the receiving study clinic/site. Marking "Participant Receipt" under the Additional Forms section on any Date of Visit or Interim Visit form will add the Participant Receipt form to the current visit folder.

Item-specific Instructions

Field	Instructions
Name of receiving study site:	• Select the applicable site from the dropdown list. • Site should match the name of receiving site on the Participant Transfer form.

Name of transferring study site:	• Select the applicable site from the dropdown list. • Site should match the name of transferring site on the Participant Transfer form.
Date informed consent signed at receiving site	• A complete date is required.

Participant Transfer

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

General Instructions
This form is completed by the transferring site (the site the participant is leaving). Marking "Participant Transfer" under the Additional Forms section on the Date of Visit or Interim Visit form will add the Transfer form to the visit folder.

To complete a participant transfer, contact the SCHARP Clinical Data Manager (CDM) to confirm all outstanding queries are resolved before the participant is transferred to a new site.

Item-specific Instructions

Field	Instructions
Name of transferring study site	• Select the applicable site from the dropdown list.
Name of receiving study site	• Select the applicable site from the dropdown list.
Visit code of last completed contact with participant	• Select the applicable visit code from the dropdown list. • If "Interim Visit" is selected, record interim visit code in the text box provided.
Date participant records were sent to receiving study site	• A complete date is required.

Patient Health Questionnaire

Purpose:
This form documents the baseline mental health of the participant. The score is auto-calculated from the participant's answers to the questionnaire. The following chart will be used as a guide to interpret the depression scale.

Score	Severity
0-4	None-minimal
5-9	Mild
10-14	Moderate
15-19	Moderately Severe
20-27	Severe

General Instructions
Complete all fields at enrollment and based on their experiences over the last 2 weeks.

Field-specific Instructions

Field	Instructions
For the first 9 questions	• Select “Not at all”, “Several days”, “More than half the days”, or “Nearly every day”

PHQ Calculated Total	• Auto-calculated after the form is saved
	• If the score is indicative of depressive symptoms (severity of mild and above) according to the table above, enter it into the Medical History Log
	  ○ In the description of medical event, enter “Depressive symptoms” and include the PHQ score
	  ○ For the question “Is the condition/event gradable”, select “No” since this is a self-reported value and do not enter a grading.

If you mentioned any problems, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?	• Select “Not difficult at all”, “Somewhat difficult”, “Very difficult”, or “Extremely difficult”
Last 3 questions	• Select “Yes” or “No”

Physical Exam

Purpose:
This form documents physical exam findings.

General Instructions
Complete at all required study visits as specified in the protocol and schedule of forms.

Field-specific Instructions

Field	Instructions
Was a physical exam performed? Body System Exam Date	If a physical exam is performed: • For each organ or body system, mark “Normal”, “Abnormal” or “Not done”. • If “Abnormal” describe findings in corresponding “If "Abnormal", specify:” box. • Enter the date the physical exam was performed. A complete date is required.
Other system finding	• If no additional body system is evaluated, select “Not done”. • If a body system is evaluated that is not listed on the form, enter body system in the “If "Other system finding", specify:” box. • If “Abnormal” enter findings in the “If "Abnormal", specify:” box.

Pill Count – Enrollment

Purpose:
This form is used to document the participant’s pill dispensation at the Enrollment Visit.

General Instructions:
Complete this form at Visit 2.0 – Day 0/Enrollment.

Item-specific Instructions

Field	Instructions
Number of pills dispensed	• Enter the number of pills that were dispensed at the Enrollment Visit in the field provided.
Comments	• This field is not required. • Provide comments to explain an unexpected amount of pills dispensed or any other unusual circumstances with pill dispensation at Enrollment. • Maximum allowed characters: 400.

Pill Count – Step 1

Purpose:
This form is used to document the participant’s pill counts (i.e. returns and dispensations) during Step 1.

General Instructions
Complete this form for all follow-up visits in Step 1 after enrollment.

Item-specific Instructions

Field	Instructions
Date of pill count	• Record the date the pill count was performed. • A complete date is required.
Number of pills at this visit	• Enter the number of pills the participant has in his possession (remaining number of pills)
Did the participant return any pills at this visit?	• If "Yes", record the number of pills returned. • If "No" is selected, move to "Was the participant dispensed any additional pills at this visit?"
Was the participant dispensed any additional pills at this visit?	• If "Yes", record the number of additional pills dispensed.
Comments	• This field is not required. • Provide comments to explain an unexpected amount of pills dispensed or returned or any other unusual circumstances regarding the pill count. • Maximum allowed characters: 400.

Product Hold Log

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

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

Complete this form for any clinical reason that warrants a product hold.

Item-specific Instructions:

Field	Instructions
Date when study product hold was initiated:	Record the date when the product hold was initiated. A complete date is required.

Why is study product being held?	Record the reason that study product is being held. If study product is held for any reason not specified, mark “Other, specify” and specify the reason in the space provided. Note that participant decline or refusal of study product is not documented as a product hold. Do not record this as a reason in ‘other, specify”.
If product hold was associated with an adverse event, select the applicable AE	If study product is being held due to “Adverse Event”, select the applicable AE from the drop-down field provided. **Note**: If study product is being held due to an AE, the AE log page must be entered into Rave prior to completion of the Product Hold log form in order for the AE to be available to select with the drop down field.
If product hold was associated with an injection site reaction, select the applicable ISR	If study product is being held due to “Injection Site Reaction”, select the applicable ISR from the drop-down field provided. **Note**: If study product is being held due to an ISR, the ISR log page must be entered into Rave prior to completion of the Product Hold log form in order for the ISR to be available to select with the drop down field.
If product hold was associated with a new or updated concomitant medication, select applicable medication(s)	If study product is being held due to “Reported use of PEP”, specify the corresponding concomitant medications log form on which the medication was reported in from the drop down field provided with Rave. At least one medication must be specified and up to four medications can be recorded. **Note**: If the product hold is due to report of medication use, the corresponding concomitant medications log page must be entered into Rave prior to completion of the Product Hold log form in order the medication be to be available within the drop down field.

Will the participant resume study product?	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. Mark, “No – early termination” if the product hold was ongoing at the visit at which the participant terminated early from the study. Mark, “No – permanently discontinued” if the participant was permanently discontinued from study product due the reason indicated on this form. If ‘Yes’, enter the date that the participant was instructed to resume study product. If “No - permanently discontinued' or “No - early termination” complete the Discontinuation of Study Product form.
Date participant resumed study product	Record the date the study product was resumed. Use a best estimate if the actual date cannot be determined.

Product Hold Y/N

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’ in the “Does the participant have any clinical product holds to be applied?” prompt will add the “Product Hold Log” to the “Ongoing Logs” folder.

Protocol Deviation Log

Purpose
This form documents reportable protocol deviations identified for study participants during the implementation of HPTN083-01.

General Information/Instructions
Complete this form each time a reportable protocol deviation is identified. Complete one page per protocol deviation when entering in the study database. If a deviation applies to more than one PTID complete a Protocol Deviation Log for each PTID that is affected; each PTID needs to have a record of the Protocol Deviation on their own Deviation Log. To add an additional deviation within Medidata Rave, click “Add a new Log line” to add an additional log line.

Reportable protocol deviations are defined by the HPTN (HPTN MOP Section 12) as individual incidents, trends or omissions that result in:

- Significant added risk to the participant
- Non-adherence to significant protocol requirements

- Significant non-adherence to GCP

Item-specific Instructions

Field	Instructions
Site awareness date	• Record the date the site became aware of the deviation. • A complete date is required.
Deviation date	• Record the date the deviation occurred (start date). • A complete date is required.
Has or will this deviation be reported to local IRB/EC?	• Select “Yes” or “No”.
Has or will this deviation be reported to DAIDS as a critical event?	• Select “Yes” or “No”.
Type of deviation	• Select the applicable deviation from the search list. *See table below for the types of deviations.* • The first few letters of the description can be typed in the dynamic search list to find the applicable deviation to be entered. You can also use the dropdown arrow to review a listing of the deviation types. To move between pages of deviation types click on the “<<Back” and “Next>>” buttons at the top of the list.
Description of deviation	• Use text field to briefly describe specific details of deviation.
Plans and/or action taken to address the deviation	• Use text field to provide a brief description of plans to address deviation.
Plans and/or action taken to prevent future occurrences of the deviation	• Use text field to provide a brief description of plans to prevent similar deviations in the future.
Deviation reported by (staff name):	• Enter name of staff member that reported the deviation.

PROTOCOL DEVIATION CODE LIST
Description
Inappropriate enrollment: The participant enrolled and not all eligibility requirements were met.
Study product management deviation: The site staff did not instruct the participant to hold, permanently discontinue, or resume study product use per protocol requirements.
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.
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.
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 or in an email to protocol leadership.
Physical assessment deviation: Examples include a protocol-specified exam or assessment consistently not being performed (a single missed exam during one participant visit would not be considered a reportable protocol deviation).
Lab assessment deviation: Examples include a protocol-specified laboratory assay consistently not being performed (a single missed assay during one participant visit would not be considered a reportable protocol deviation).
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.
Informed assent/consent process deviation: Examples include failure to accurately execute and/or document any part of the informed consent process.
Other

Protocol Deviation Y/N

Purpose:
This form is used to document if a protocol deviation has occurred.

Generation Instructions
This form is present within the "Ongoing Logs" folder and needs to be marked only once.

Item-specific Instructions

Field	Instructions
Have any protocol deviations occurred?	If "Yes" is selected, the Protocol Deviation Log will appear in the Ongoing Logs folder and can then be completed.

Screening Date of Visit

Purpose:
This form is used to document the date of the first screening procedure(s).

Generation Instructions
This form is present within the screening folder and needs to be entered once.

Item-specific Instructions

Field	Instructions
Screening visit date	Enter date of the first screening procedure(s)

Social Impact Log

Purpose:
This form is used to document information about reported social impacts.

General Instructions:
Complete this form when a participant reports a social impact. A social impact is defined as a participant reported non-medical adverse consequence or benefit as a result of participation in the study. Refer to the SSP, section 10, for more information on reporting Social Impacts.

Item-specific Instructions

Field	Instructions
Date social impact reported	• A complete date is required.
Concisely describe social impact	• A maximum of 200 characters is allowed in this text field.

Field	Instructions
Onset date	• Enter the date on which the impact began/occurred. • A complete date is required.
Reported at visit code	• Select the visit from the dropdown menu • If "Interim visit", enter the interim visit code.
Social impact type	• Select appropriate social impact type from the dropdown list. • If "Other – Had other problems not covered in the codes above" is selected, specify social impact type in the "If other, specify" text field provided.

Social Impact Y/N

Purpose:
This form is used to document if a social impact has occurred.

Generation Instructions
This form is present within the "Ongoing Logs" folder and needs to be marked only once.

Item-specific Instructions

Field	Instructions
Has the participant experienced any social impacts related to study participation?	• If "Yes" is selected, the Social Impact Log will appear in the Ongoing Logs folder and can then be completed.

Specimen Collection and Storage

General Instructions:
Refer to the SSP for the number and type of tube(s) or slide(s) required at each visit.

The Specimen Collection and Storage CRF will auto-populate at each required visit, but it can also be added through the Additional Study Procedures CRF. On each form, the specimen type fields are auto-populated according to the schedule of procedures per visit.

Do not use this form to document any local lab specimens. Use this form only to document the collection of research blood specimens that will be sent to the site processing lab.

Field-specific Instructions:

Field	Instructions
Was specimen collected?	Select “Yes” or “No” If “No”, record the reason why the sample was not collected.
Specimen collection date	A complete date is required
Specimen collection time	Use a 24-hour clock (00:00-23:59)
Was sample stored? If “No”, record why sample was not stored	Select “Yes” or “No” If a sample was not stored, record the reason.

STI Tests

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

General Instructions:
Complete this form at required protocol visits and as clinically 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 Test Results form. If the participant enrolls, the updated results should be submitted into the study database.

At Screening, record STI diagnoses on the Medical History Log form when applicable. 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 eCRF as applicable.

Field-specific Instructions:

Field	Instructions
Was a pharyngeal sample collected for N. gonorrhea and C. trachomatis testing?	Select ‘Yes’ or ‘No’. If ‘No’, then the remaining items for pharyngeal N. gonorrhea and C trachomatis testing do not need to be completed. Proceed to “Was a pelvic sample collected for N. gonorrhea and C. trachomatis testing?”
Collection Date	Record the date that the specimen was collected, NOT the date the result was reported or recorded on the form for this visit. A complete date is required.
N. gonorrhea – Pharyngeal test result	Select “Detected”, “Non-detected”, “Equivocal”, or “Invalid”
C. trachomatis – Pharyngeal test result	Select “Detected”, “Non-detected”, “Equivocal”, or “Invalid”

Field	Instructions
Was a urine sample collected for N. gonorrhea and C. trachomatis testing?	Select 'Yes' or 'No'. If 'No', then the remaining items for urine N. gonorrhea and C trachomatis testing do not need to be completed. Proceed to the next question
Collection Date	Record the date that the specimen was collected, NOT the date the result was reported or recorded on the form for this visit. A complete date is required.
N. gonorrhea – urine test result	Select "Detected", "Non-detected", "Equivocal", or "Invalid"
C. trachomatis – urine test result	Select "Detected", "Non-detected", "Equivocal", or "Invalid"
Was a rectal swab sample collected for N. gonorrhea or C. trachomatis testing?	Select 'Yes' or 'No'. If 'No', then the remaining items for rectal swab N. gonorrhea and C trachomatis testing do not need to be completed. Proceed to "Was a sample collected for Syphilis testing?"
Collection Date	Record the date that the specimen was collected, NOT the date the result was reported or recorded on the form for this visit. A complete date is required.
N. gonorrhea – rectal swab test result	Select "Detected", "Non-detected", "Equivocal", or "Invalid"
C. trachomatis – rectal swab test result	Select "Detected", "Non-detected", "Equivocal", or "Invalid"
Was a sample collected for Syphilis testing?	Select 'Yes' or 'No'. If 'No', then the remaining items for Syphilis testing do not need to be completed.
Collection date	Record the date that the specimen was collected, NOT the date the result was reported or recorded on the form for this visit. A complete date is required.
Syphilis screening test (Non-Treponemal)	If the result of the Syphilis screening test (Non-Treponemal) is 'Reactive,' complete the Syphilis confirmatory test results (Treponemal). Enter 'Not reported' in the event that a specimen was collected, but the result is not available due to specimen loss or damage.
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 (Treponemal)	If the result of the Syphilis screening test is 'Reactive,' complete the Syphilis confirmatory test results (either 'Negative,' 'Positive,' or 'Indeterminate' or 'Not done').

Study Termination

Purpose:
This form documents participant's termination from the study.

General Instructions:

- Complete once for every participant at the time of early study termination or at visit 11.0.
- This form is in the Discontinuations folder.

Field-specific Instructions:

Field	Instructions
Date of Study Exit	A complete date is required.
Primary reason for completion/termination	Select one reason for study termination from the drop-down menu.
If "Other", specify	If the primary reason is 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	Select the applicable Adverse Event from the list of AE's in the drop down menu. In situations where more than one AE is associated with termination, record the AE that most strongly influenced the decision to terminate.

Supplemental HIV Results

Purpose
This form is used to document additional HIV testing used to evaluate seroconversion.

General Instructions
Use this form as needed following HIV algorithm per the SSP.

Item-specific Instructions

Field	Instructions
HIV 1/2 Discriminatory Assay	
Not Done	• Mark if HIV 1/2 Discriminatory Assay was not done. • Skip to "HIV DNA" Section.
Specimen Collection Date	• If HIV 1/2 Discriminatory Assay was done, enter the date the specimen was collected. • A complete date is required.
Assay Result	• Select assay result from dropdown list.

Field	Instructions
Other assay result:	• If “Other” is selected from the drop-down list, provide other assay results here.
Comments	• Maximum allowed characters: 200.
Laboratory Reported HIV Interpretation	
Not Reported	• Mark if Laboratory Reported HIV interpretation was not reported by lab. • Provide comments at the end of the form.
Interpretation	• Select appropriate interpretation from the dropdown menu • If “Other”, complete “Other interpretation”
HIV DNA	
Not performed/Not reported by Lab	• Mark if HIV DNA test was not performed or not reported by lab. • Provide comments at the end of the form.
Specimen Collection Date	• If HIV DNA test was done, enter the date the specimen was collected. • A complete date is required.
DNA Result	• Select HIV DNA result from dropdown list.
Detectable DNA result:	• If DNA Result is “Detectable DNA result” record the value in copies per million cells. • Value format expected XXX.XX
Comments	• Maximum allowed characters: 200.

Urinalysis

Purpose:
This form is used to document the participant’s urinalysis test results.

General Instructions:

Complete this form at required protocol visits and as clinically indicated during the study.

Item Specific Instructions

Field	Instructions
Was a sample collected for urine tests?	• If "No" is selected, leave the remaining items on the form blank.
Date of collection	• Enter the date the specimen was collected. • A complete date is required.
Protein (Urine)	• Select the applicable result from the dropdown menu.
Protein (Urine) Severity Grade	• Select a severity grade (1-4) or "not gradable" from the dropdown list. • If a severity grade is selected, the test result field must not be blank. • Enter any grade 1 or higher events into the AE log or Medical History log as appropriate.
Protein (Urine) Adverse Event	• If test is linked to a reported AE, select the AE in the dropdown list provided. • An AE form must be completed before it can be selected on the Urinalysis form.
Glucose (Urine)	• Select the applicable result from the dropdown menu.
Glucose (Urine) Severity Grade	• Select a severity grade (1-4) or "not gradable" from the dropdown list. • If a severity grade is selected, the test result field must not be blank.
Glucose (Urine) Adverse Event	• If test is linked to a reported AE, select the AE in the dropdown list provided. • An AE form must be completed before it can be selected on the Urinalysis form.

Vital Signs

Purpose:
These forms document vital signs.

General Instructions:
The form must be completed at screening and enrollment and as needed at all other visits.

Field-specific Instructions:

Field	Instructions
Were vital signs done?	Select 'Yes' or 'No'.
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. The value must be reported in whole numbers (e.g. 180 cm).
Weight	Enter the participant's weight in kilograms. The value can be reported up to one decimal (e.g. 70.1 kg).
BMI calculated	This field is auto-populated after enter the height and weight and saving the form.
Body Temperature	Enter the participant's temperature in Celsius. The value can be reported up to one decimal (e.g. 37.2˚ C).
Systolic BP	Enter the participant's systolic blood pressure in mmHg (e.g., 120 mmHg).
Diastolic BP	Enter the participant's diastolic blood pressure in mmHg (e.g., 60 mmHg).
Pulse	Enter the participant's pulse in beats per minute (e.g., 60 beats/min).
Rate of respiration	Enter the participant's respiratory rate in breaths per minute (e.g., 14 breaths/min).

Change History

Summary of Changes to Study CRF Completion Guidelines

Version		Affected Section(s) or Form(s)	Summary of Revisions
Number	Date		
1.0	23MAR2020	All sections	Original Document
2.0	25AUG2020	Chemistry Panel, Demographics, Fasting Lipids Test Results, Hematology, Patient Health Questionnaire, Pill Count – Step 1,	Updated guidance for "not reportable as an adverse event checkbox on the Chemistry Panel, Fasting Lipids Test Results, and Hematology forms. Fixed typos in Demographics form. Updated guidance on PHQ entry to the Medical History log and added "number of pills" guidance on the Pill Count – Step 1 form. Added instructions for Screening Date of Visit.

		Screening Date of Visit	